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Applying market shaping approaches to increase access to assistive technology in low- and middle-income countries

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ABSTRACT

Development outcomes are inextricably linked to the health of the marketplace that delivers products and services to people in low- and middle-income countries (LMIC). Shortcomings in the market for assistive technology (AT) contribute to low access in LMIC. Market shaping is aimed at improving a market's specific outcomes, such as access to high quality, affordable AT, by targeting the root causes of these shortcomings. The paper summarizes the findings of market analyses conducted under the UK aid funded AT2030 programme in support of ATscale and aims to discuss how market shaping can help more people gain access to the AT that they need and what are the best mechanisms to unlock markets and commercial opportunity in LMICs. The paper also explores how market shaping for AT markets could be part of a mission-oriented approach AT policy. A mission-oriented approach can help accelerate progress toward a common objective among stakeholders, at country or global level. While market-shaping activities direct the outcomes of the market toward a specific end goal, such as access to quality, affordable products and services, missions are more comprehensive and include other policy interventions and stakeholder collaborations in order to create a robust and sustainable structure.

ARTICLE HISTORY

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assistive technology; low-and middle-income countries; market-shaping; missions

Introduction

Development outcomes are inextricably linked to the health of the marketplace that delivers products and services to people in low- and middle- income countries (LMIC). Shortcomings in the market for assistive technology (AT) contribute to low access in LMIC. Market shaping is aimed at improving a market's specific outcomes, such as access to high quality, affordable AT, by targeting the root causes of these shortcomings. The paper summarizes the findings of a market and sector analysis that was conducted under the UK aid funded AT2030 programme and aims to discuss how market shaping can help more people gain access to the AT that they need and what are the best mechanisms to unlock markets and commercial opportunity in LMICs.

Based on an analysis of four AT markets, eyeglasses, hearing aids, prostheses and wheelchairs, and utilizing the principles from USAID's Framework of the Market Shaping Pathway, the following activities appear critical to overcome market shortcomings. These apply across various assistive products and can be addressed when global donors and stakeholders come together under a unified strategy:

- Supporting LMIC governments to develop comprehensive policies, including the development of national priority **Assistive Products Lists (APL)**, **specifications** and **guidelines** for procurement and delivery of AT, and inclusion in national **financing** mechanisms.

- Building and strengthening **procurement mechanisms** that can help facilitate **coordinated ordering** and **value-based negotiations** of assistive products.
- Supporting the **assessment of product quality** and dissemination of results to accelerate uptake of appropriate, quality assistive products.
- Developing **market reports** to enhance information sharing between buyers and suppliers.
- **Build enabling environments for the delivery of AT**, including awareness building and anti-stigma campaigns, training of relevant HR and service delivery infrastructure.

Addressing market shortcomings to increase access to AT will only have an impact on people's lives when it enables them to fully participate in society throughout their lifetime. Inclusive and universal design approaches must be considered, especially for public spaces and buildings. Service delivery systems must be set up to facilitate maintenance and replacement of assistive products. Successful market shaping will be one component of the inclusive ecosystem and will require involvement from a broad and diverse group of stakeholders within a country.

The paper also explores how market shaping for AT markets could be part of a mission-oriented approach AT policy. A mission-oriented approach can help accelerate progress toward a common objective among stakeholders, either at country or global level. While market-shaping activities direct

the outcomes of the market toward a specific end goal, such as access to quality, affordable products and services, missions are more comprehensive and include other policy interventions and stakeholder collaborations in order to create a robust and sustainable structure.

Context

Introduction

Assistive technology (AT) is an umbrella term covering the systems and services related to the delivery of assistive products such as wheelchairs, eyeglasses, hearing aids, prosthetics, canes, club foot braces, fall detectors and digital devices (WHO, 2019). Today, over 1 billion people require AT to achieve their full potential, but 90% do not have access to the AT that they need (WHO, 2019). This unmet need for AT is driven by a lack of awareness of the need, discrimination and stigma, a weak enabling environment that includes limited political prioritization and investment, and market barriers. Many of these barriers involve shortcomings in the marketplace. Therefore, market shaping, rather than market fixing is needed.

Historically, AT has been an under-resourced and fragmented sector and initial analysis indicated that a new approach was required (Holloway et al, 2020). To accelerate access to AT, the global community needs to leverage the capabilities and resources of the public, private and nonprofit sectors to harness innovation and break down market barriers. Two initiatives were launched in 2018 at the Global Disability Summit: 1) the AT2030 programme, a five year, GBP £20 million investment by UK aid, led by the Global Disability Innovation Hub (GDI Hub) to test “what works” to improve access to AT (AT2030, AT2030, 2020); and 2) ATscale, the Global Partnership for AT, a cross-sector partnership with an ambitious goal to provide 500 million people with the AT that they need by 2030. To achieve this goal, ATscale aims to mobilize global stakeholders to develop an enabling environment for access to AT and to shape the markets, in line with a unified strategy (ATscale, 2019).

In support of ATscale’s strategy and under the AT2030 programme to identify and test “what works,” market and sector analysis was conducted for selected assistive products, including wheelchairs, hearing aids, eyeglasses and prostheses, and published as Product Narratives (AT2030 & ATscale, AT2030 & ATscale, 2020a, 2020b, 2020c, 2020d; ATscale, 2019). Utilizing principles from USAID’s Framework of the Market Shaping Pathway, this paper categorizes the observed AT market shortcomings and underlying root causes and then discusses different market shaping interventions that can address these root causes across the selected product areas analyzed (USAID, 2018).

For people to live productive and fulfilling lives, access to AT is only meaningful when it can be used in day-to-day life. The paper will also discuss how achieving impact through increased access from AT differs from other markets. In that

context, UCL Institute for Innovation and Public Purpose (IIPP) proposes to position market shaping for AT markets as part of a mission-oriented approach. Missions provide a target to steer economic growth and policy agendas by providing the means to focus research innovation and investments, must be bold and activate innovation across sectors, actors and disciplines, and enable new possibilities of bringing different actors to spur on collaboration and help redefine what these cross-sector relationships can look like through a shared common purpose (Mazzucato, 2018a).

Role of market shaping in increasing access to AT

Development outcomes are inextricably linked to the health of the marketplace that delivers products and services to low-income populations. A well-functioning market, with public and private sector participation, will lead manufacturers to produce high-quality products and invest into innovative solutions that meet user needs and are cheaper, distributors to deliver the necessary quantities, providers to fit and prescribe them correctly, and patients to be educated and active participants in their own health. However, markets can fall short. Institutions that participate in research and development may not see enough demand to develop a new product, manufacturers may not know how much to produce, and distributors may not see enough profit to justify delivery. The reality is that a single breakdown in this complex system can keep life-saving and life-enabling products and services from those most in need.

Market shaping is designed to improve a market’s specific outcomes, such as availability and access to high quality, affordable AT, by targeting the root causes of market shortcomings. Actors at both ends—for example, producers on the supply side and purchasers on the demand side—can face high transaction costs, critical knowledge gaps, and/or imbalanced risks that hamper participation in the market. At best, market shaping grounded in health ecosystem-level thinking reframes issues, boundaries, and constraints to better align incentives across all stakeholders in the market (MacLachlan et al., 2018). Designed to be transformative, market shaping interventions look to reduce long-term demand and supply imbalances to provide needed products and services to the population.

Market shaping interventions require coordinated engagement on the demand and supply side (see Figure 1). They require participation from country governments, donors, procurers, distributors, service providers, and end users. Successful interventions are tailored to specific markets – after a robust analysis of barriers – and look to coordinate action on both the demand- and supply-side. These interventions are catalytic and time-bound with a focus on sustainability. They are typically implemented by a coalition of aligned partners providing support where each has comparative advantages. Examples of market shaping interventions include: pooled procurement, de-risking demand, bringing lower cost and high-quality manufacturers into global markets, developing demand forecasts and market intelligence reports,

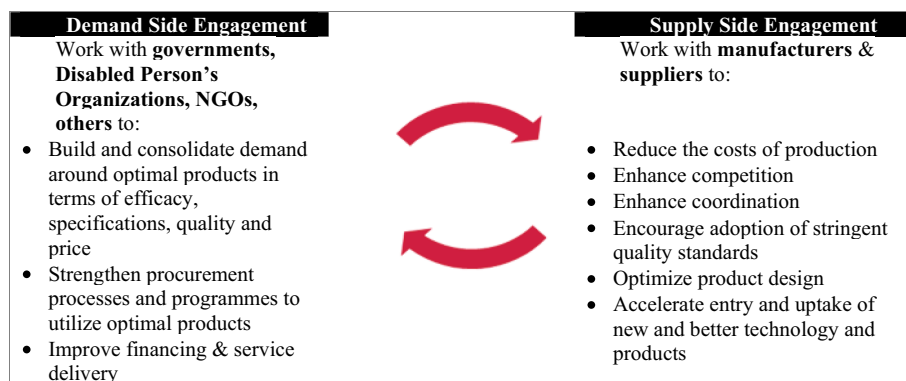


Figure 1. Engaging both demand- and supply-side for market shaping.

standardizing specifications across markets, establishing differential pricing agreements, and improving service delivery and supply chains.

The design of successful market shaping interventions requires analytics to pinpoint the underlying root causes of market shortcomings. For example, unaffordable prices can stem from a variety of causes, including expensive inputs, high margins, high transaction costs, uncertain demand, or a combination of these factors. Only by identifying the relevant root causes can a market shaping intervention target the shortcoming effectively. Market shaping interventions typically use three levers to achieve a socially relevant outcome for the market:

- (1) Reducing transaction costs: reducing transaction costs seeks to lower structural hurdles to interacting in the market, such as simplifying, smoothing, or rationalizing purchase orders in a fragmented market.
- (2) Increasing market information: increasing market information seeks to generate new data, align existing analyses, and/or improve the visibility of existing data to reduce asymmetries of information, such as demand forecasting, pricing information exchange, or market landscape analyses.
- (3) Balancing supplier and buyer risks: balancing supplier and buyer risks seeks to offset financial risks borne by suppliers and shifting them to donors/purchasers in order to make market engagement more attractive, such as advance market commitments, volume guarantees, or guideline inclusion.

Whether by reducing the cost of antiretroviral drugs for HIV by 99% in 10 years, increasing the number of people receiving malaria treatment from 11 million in 2005 to 331 million in 2011 (Unitaid & WHO, 2013), or doubling the number of women receiving contraceptive implants in 4 years while saving donors and governments US\$240 million (Suzman, 2016), market shaping has addressed market barriers at scale. Market shaping successes in other health areas have led experts in the global community to hypothesize that market shaping could also be applied to AT markets (ATscale, 2019; Holloway et al., 2018; MacLachlan et al., 2018).

Market shaping alone does not address product uptake and access challenges in LMIC. While market shaping interventions can enhance market efficiencies, they must be coupled

with ongoing and routine programmatic interventions to effect change. Examples of programmatic interventions include provider training, procurement, infrastructure and supply chain strengthening and information, education, and communication campaigns. Market shaping must also exist within the constraints of national, supranational and international law that may impact the production, supply and delivery of products. For example, many countries have specific laws and regulations regarding standards of quality and procurement under government contracts that can limit market actors. MacLachlan et al. (2018) provides a discussion of these potential legal and regulatory impacts within AT markets.

Method to assess market-shaping in AT: USAID market shaping pathway

This paper aims to answer the question: “How can market shaping help more people gain access to the AT that they need and what are the best mechanism to unlock specific product markets?” It will use the USAID Market Shaping Pathway as a framework to assess the role for market shaping and evaluate different mechanisms. The Market Shaping Pathway was selected for its simplicity as an approach to assess what and how interventions may be appropriate in a given market and that it aggregates years of market shaping work within global health across a variety of commodities and expert opinion into a five-step pathway. Frameworks for market shaping, such as Gavi’s Health Markets Framework and the SMART (Systems-Market for Assistive and Related Technologies) Thinking Matrix, were also reviewed (Gavi & Melinda Gates Foundation & UNICEF, 2015; MacLachlan et al., 2018). Gavi’s framework was not used due to its product specific focus on vaccines, while the SMART Thinking Matrix is more relevant when assessing an individual assistive product or related technology and the interactions at the systems level. Although many findings, particularly the root cause and market analyses, from this work may be relevant within those frameworks. For example, many of the market shortcomings are also reflected in the market characteristics of the SMART Thinking Matrix and recommendations can help move toward the optimally functioning market as defined by the SMART Thinking Matrix.

USAID proposes a five step Framework to organize market shaping questions and key considerations to assess market shaping interventions (Figure 2). The first step is to assess the

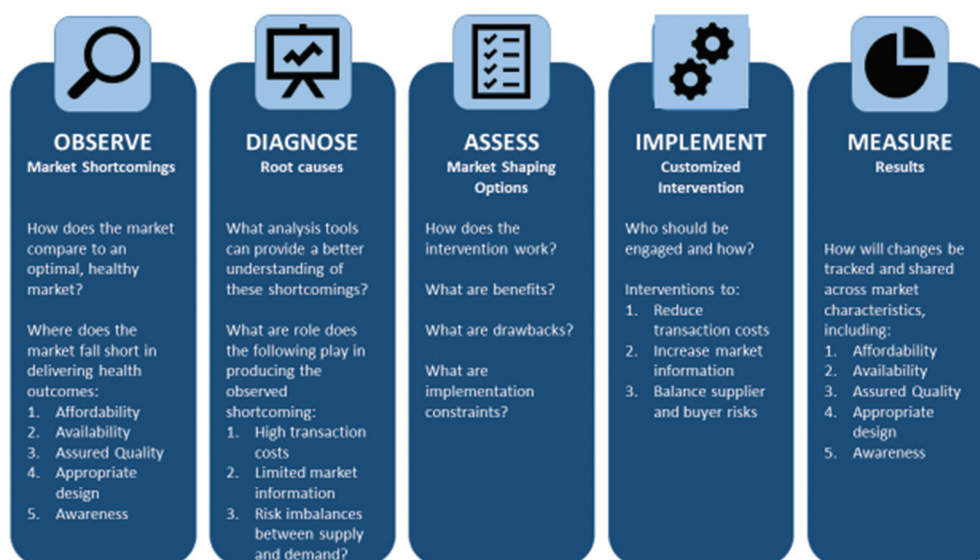


Figure 2. Framework of the market shaping pathway (adapted from USAID, 2018).

health of the market and identify the market shortcomings. The Framework organizes measurable indicators to assess where the market is falling short around the 5As: affordability, availability, assured quality, appropriate design and awareness. The 5As align with the outcomes that a market should deliver in order to work for the most stakeholders. The second step of the pathway is to use analytics to pinpoint the underlying root causes of the shortcomings. The third step is to assess the different market shaping options, which look to utilize one of the three levers described in the previous section to address the root causes identified in step 2. Step 4 is to implement the chosen interventions ensuring that there is collaboration among all stakeholders, trade-offs between desired market characteristics are accounted for, unintended consequences are monitored, and a sustainability plan beyond the intervention is in place. Lastly, the impact of interventions on market outcomes should be monitored and evaluated.

In applying this Framework to the AT sector, a product and sector analysis was conducted for five product areas: hearing aids, wheelchairs, prostheses, eyeglasses and digital AT. The findings for each market are published in product narrative reports (AT2030 & ATscale, 2019, 2020d, 2020c, 2020b, 2020a).

In line with the five Steps, the analysis began with market landscaping to observe market shortcomings and a diagnosis of the root causes. This work was conducted through desk research, market sizing and segmentation, supplier and pricing analysis, informant interviews, and site visits with stakeholders and governments. For each product area, 30–50 interviews were completed with suppliers, users, service providers, academic experts, among others. The list of those interviewed is available as an annex to each product narrative.

Using the findings from the analysis and expert inputs, long-term strategic objectives were identified to shape the market and increase access in LMIC. A series of immediate interventions are proposed. These are a mix of market shaping and programmatic interventions. In line with Step 5 of the Market Shaping Pathway, each objective has measurable

outputs and outcomes. These findings, strategic objectives and interventions were reviewed and refined during a set of calls with experts, including founding partners of ATscale and members of the AT2030 programme. Each product narrative and its objectives were also reviewed by at least one product area expert from the AT2030 programme and an additional product area expert that was identified during the interview process. Feedback was incorporated into the final recommendations.

Results

The below section summarizes key cross-cutting themes that have been observed across four product areas analyses and published in individual product narratives: wheelchairs, hearing aids, eyeglasses, prostheses, and digital AT (AT2030 & ATscale, 2020d, 2020c, 2020b, 2020a; ATscale, 2019).

Step 1 of the market shaping pathway: Identifying market shortcomings across four assistive products

The following market shortcomings apply across the five product areas analyzed:

Affordability

In a healthy market, the price of a product should be low enough to make it accessible and cost-effective to buyers, but also high enough to incentivize suppliers to innovate new products and/or enter and remain in the market. Analysis showed affordability issues across all products investigated. The need for customized products coupled with small volumes, a lack of competition, high shipping costs and high taxes all contribute to high or unaffordable prices of active wheelchairs (up to US\$4,000 per unit) and prostheses (up to US\$3,000) from most leading global manufacturers. Lower cost options (e.g., US\$150 – 350 for

active wheelchairs) exist, but uptake is limited by a reliance on donor-funded programs for distribution, lack of revolving capital by suppliers to enter the market and limited visibility for suppliers and buyers. Supply chain analysis indicated that the cost of a hearing aid from leading global suppliers to the service provider may range from US\$100 – \$150, but the the cost to the user can exceed US\$2,000 whereby the device and high service delivery costs are bundled. Additionally, due to tendering practices in most LMIC, suppliers must rely on local distributors to respond to government tenders or register products, which adds additional margin to the final price.

Availability

A healthy market is characterized as one where the capacity and stability of supply meets demand and there is consistent local access at adequate service delivery points. Most assistive products are available on the global market at sufficient capacity, but there is limited choice and availability in LMIC. Many suppliers are not focused on LMIC markets, which limits availability and choice of products. For example, a lack of capital to procure quality components at service delivery points limits the availability of prosthetic components. Very few local distributors supply prosthetic components, so prosthetists often place individual orders directly with international manufacturers. This result in inconsistent availability and delays in fitting to end-users. Within the wheelchair and hearing aid sector, the majority of products are donor-funded or delivered as part corporate social responsibility program at little or no cost to users and therefore, governments are disincentivized to procure and build delivery systems for products. Furthermore, availability is hindered by a lack of service delivery points. For instance, the provision of assistive products based on existing standards of care require skilled personnel, expensive equipment and significant infrastructure, which are all limited or unavailable in LMIC, particularly outside major urban centers. Lastly, where LMIC markets exist – for example, in eyewear – these focus primarily on high-value market segments, such as wealthier, often urban populations.

Assured quality

Products should meet a level of quality assurance as defined by standards and specifications to ensure appropriateness, which must in turn be informed by users themselves. An appropriate assistive product is one that meets the user's needs and environmental conditions, is safe and durable. Most assistive products found in LMIC markets do not meet quality standards set out by international or national organizations or lack quality markers for use in LMIC context. Purchasers often procure the least expensive option, which may be sub-standard or inappropriate for the end user. For example, prosthetics ISO standards only focus on durability and not on performance of components once fitted on a user or used in an LMIC context. Other quality standards (i.e. CE and FDA) are obtained through self-declaration. Therefore, there is limited guidance for

prosthetists to determine quality beyond anecdotal feedback or ad-hoc field testing. Within hearing aids, the lack of an objective quality certifying mechanism results in procurers unable to differentiate higher quality products and make informed choices.

Appropriate design

Appropriately designed products maximize cultural acceptability, choice and ease of use and are fit for purpose in LMIC context. Many assistive products available on the global market are not appropriately designed for this context. Many wheelchairs and prosthetics are not designed for factors typical for LMIC context, such as rough terrain, high humidity, exposure to water and sand, which can lead to premature failures. NGOs and innovators have looked to develop and bring to market more appropriate products, but uptake is limited. Additionally, assistive products have many variants, which fragments the demand and complicate supply chain. For example, in hearing aids, different functional features (i.e. amplification power, amplification technology, sound processing capabilities), styles (i.e. behind-the-ear, receiver-in-the canal), battery types used, and advance features (i.e. Bluetooth) create wide variety of configurations. Lack of global guidance on a limited set of specifications to serve most users has led to procurers buying a proliferation of products, complicating procurement and provision. Lastly, style and attractiveness are often not considered in the design of assistive products, specifically for wheelchairs, prostheses and eyeglasses, which affects community and users' acceptance.

Awareness

Policy makers lack awareness on the need, importance and impact of assistive products which affects prioritization in policy, financing and the types/quality of products to procure. Teachers, elder care providers, parents and users are often not aware of the sign of hearing and vision loss, existence of devices to correct it, and how to seek care. This prevents access to hearing aids and eyeglasses. Communities stigmatize people who use assistive products hence preventing or limiting use. Additionally, providers are not aware of available assistive products and not trained in the service delivery of assistive products (i.e. assessment, fitting and user-training) to ensure appropriate provision and use by users. For example, wheelchair service provision and training on seating and positioning is often not seen as part of the scope of practice for relevant professionals (i.e. physical therapists, occupational therapists) hence training packages, such as the WHO Wheelchair Services Training Package have not been adopted in training curriculums or by professional associations.

Step 2 of the market shaping pathway: Evaluating root causes of market shortcomings in AT

Across all product areas assessed, the AT markets in LMIC were found to be nascent, with a need to focus on demand creation. On the demand side, a lack of understanding of the unmet need, the role and function of AT in improving health, social, and economic outcomes results in a lack of political will to invest in

AT products and services. On the supply side, the system has perpetuated an economic and value system whereby companies fail to serve user need as demand and economic value assessments focus solely on production costs, manufacturing and distribution channels. This results in overall production levels that are far below what is needed for universal global coverage.

The market shortcomings identified often stem from the same root causes. These root causes are often interlinked and play out in each of the product areas assessed as summarized below:

- (1) **A weak enabling environment whereby political will and investment is limited:** LMIC governments are typically not prioritizing assistive products within a constrained resource envelope. Donors, such as faith-based organizations or private foundations, fill this gap and deliver assistive products at no or limited cost to the end user, often in parallel to nascent government systems. The lack of prioritization inhibits investment in human resources and service capacity and the development of a public sector market. Where governments procure AT or cover them through an insurance scheme, it is often insufficient to meet population needs. Lack of awareness on the need for and the economic benefits of AT, as well as data to quantify this need and benefit, limits government prioritization and investment.
- (2) **Insufficient market information:** The current provision of AT in LMIC is characterized by poor visibility and data on actual demand, high fragmentation with erratic procurement patterns, and a lack of objective quality standards to differentiate higher quality from poor quality products. As a result of the fragmentation in the innovation and delivery chain, the marketplace is one of incomplete information. Without visibility on demand, there is no incentive to participate in the market. A limited consensus on a range of preferred product classes and no commonly accepted objective measure or standard of what is appropriate has led to a proliferation of often inappropriate and low-quality products. Lack of market information leads procurers to make purchasing decisions based on price alone. For some assistive products such as prosthetics, limited transparency on the quality and performance of lower priced components in LMIC contexts inhibits uptake and wide-spread adoption. Lastly, lack of demand information, such as visibility on government tenders and supplier capacity to respond to government tenders, limits market-entry options into LMIC markets.
- (3) **High transaction costs to operating within the market:** Small markets, erratic procurement patterns, and a proliferation of products leads to unfavorable manufacturing economics and inefficient manufacturing schemes. From a logistics point of view, a sustainable LMIC supply of assistive products is hindered by supply chain challenges, such as customs duties or delays, resources required to build and operate local assembly, or last mile delivery. Moreover, many assistive products

require a level of customization to meet a prescription and should be available to providers through a responsive supply chain to support product selection. Such supply chains are not available in LMIC, leading to high costs of shipping directly from overseas and long lead times.

- (4) **Risk imbalances between demand and supply:** Suppliers have faced long sales cycles and late payments which limits their desire to interact with government as a customer base. Erratic procurement patterns and limited information on demand limit the incentive to enter a market. In addition, registration of assistive products in LMIC can be time-consuming, particularly when compared to HIC markets, and suppliers may have to compete with low-priced products that may not be regulated. Innovation within the AT sector is limited as the risks for development of new products are perceived to be high; less than 10 percent of innovative devices will show sufficient enough potential to merit pushing forth from prototype to manufacturing stage (Lane, 1997). Within the innovation ecosystem, most innovative AT is too expensive by the time it reaches the user as cost control is only considered after the innovation process instead of building affordability at inception. On the demand side, cultural biases related to comfort, style, and attractiveness, as well as misperceptions around the benefits of assistive products pose hurdles for compliance.

Step 3 of the market shaping pathway: Discussion of market shaping interventions that can increase access to AT

In line with Step 3 of the Market Shaping Pathway, different interventions were assessed. Market shaping interventions can be categorized by the primary level used: 1) reduce transaction costs; 2) increase market information; and/or 3) balance risk between demand and supply actors. Some interventions utilize only one lever, while some use a combination of levers. Others can be seen as programmatic interventions such as increasing provider training, improving government policy, and supporting the strengthening the health, social and financing systems. The distinction between market shaping and programmatic interventions is more of a continuum than a clear divide and a mix of interventions are required to create long-term sustainable markets. The Supporting Materials for this paper outline the strategic objectives and corresponding activities for each product assessed. The supporting materials classifies each proposed intervention based on its primary lever(s).

Interventions to reduce transaction costs

Intervention that aim to reduce transaction costs look to streamline demand by simplifying, smoothing or rationalizing procurement. A more predictable demand can support lower and less variable prices, allowing suppliers to better plan capacity, and enhancing economies of scale.

Pooled procurement is when – for a set of standard products – the volume to be procured is consolidated by a third party who acts as a procurement agent to obtain better terms. For pooled procurement to be a viable intervention there should be a standardized set of products, enough predictable volume, and the financing, delivery systems and policies in place to support the absorption of product into the system. Pooled procurement may not be feasible for AT markets as these lack standardized product requirements across purchasers, have limited demand and limited financing, procurement and ability to integrate into provision systems.

Coordinated ordering allows for a third-party agent to negotiate price and sales terms on behalf of multiple buyers who then purchase from the supplier individually. Similar to pooled procurement, coordinated ordering reduces transaction costs by streamlining interactions with suppliers, but allows procurers to manage individual timelines and procurements. Coordinated ordering could allow buyers to access volume pricing for high quality assistive products, such as hearing aids.

Product variant optimization through the design of guidelines or specifications helps to rationalize demand that is otherwise fragmented in small orders across multiple, similar products. Fragmentation can prevent suppliers from reaching more favorable manufacturing economics. Product optimization can be facilitated by developing target or preferred product profiles (TPP/PPP). A target product profile is used to guide the development of new products while a preferred product profile provides criteria to classify products already within the market. These documents outline desired characteristic and the required features and standards that the product must meet. Often, they will also indicate a target price. They can guide industry during the development process and serve as a market information or planning tool. The product narratives highlight where a TPP or PPP already exist and where they can be strengthened.

Procurement hubs are a mechanism to facilitate pooled procurement or coordinated ordering. Procurement hubs enable buyers to make large or small orders of mixed products and sizes, delivering devices that best suit users' individual needs faster and more efficiently. For example, the Consolidating Logistics for Assistive Technology Supply and Provision (CLASP) is a wheelchair procurement and distribution hub that stocks adult and pediatric wheelchairs, walking aids, cushions, spare parts kits, and modification kits from suppliers. In addition to reducing transaction costs, procurement hubs can promote appropriate provision and allow for increased market visibility of quality products.

Regulatory policy support to support governments in the development of policy and to suppliers to navigate the policy is needed in AT as regulatory processes are unclear or non-existent at the country level. Registration processes of assistive products should be clarified, simplified and if possible, harmonized. In many LMIC, medical devices are exempt from import duties, but AT is often not classified as a medical device. Processes to obtain classification for exempt status are cumbersome and

challenging and therefore need to be streamlined by the government. Suppliers require support to navigate these processes across countries.

Strengthened quality assurance (QA) systems are needed. This includes developing clear QA objectives and providing publicly available assessments of product quality to increase transparency and guide procurement of quality products. Strengthening, creating or streamlining a QA system lowers the administrative burden of differing systems and requirements for suppliers. CLASP has a Product Advisory Council, who reviews all products that are placed within the procurement hub catalog. For many assistive products, there is a need to strengthen quality standards and testing capabilities, while also publishing results of quality testing for a wider audience, such as procurement and purchasing organizations.

Interventions to increase market information

Interventions that increase market information improve visibility, reduce information asymmetry and strengthen coordination and decision-making across demand and supply-side actors, including programmatic actors

Market landscape reports can provide an up-to-date view of a market. Limited market visibility prevents key stakeholders from making informed decisions and investments. Via market landscape reports, key stakeholders (including private sector buyers, government purchasers and providers) can access information needed to make product comparisons and informed purchasing decisions. Data monitored by landscape reports and dashboards includes intelligence on suppliers, products features, innovation pipeline, pricing at various volume thresholds and access points in supply chain. Pricing information that is aggregated from tenders, purchase orders and self-reporting can empower buyers to negotiate and holds suppliers accountable. Market landscape reports can track procurement cycles and publish upcoming tenders to disseminate such opportunities and promote competitive bidding. Market landscape intelligence should be regularly updated can help inform programmatic actors as well as suppliers on market cycles to improve and ensure efficient use of available resources for assistive products.

Demand forecasting can be used to predict growth in funded demand. Demand forecasting that is supported by commitments from governments and donors acts as a market signal for suppliers. Demand forecasts decrease risk and promote investments in LMIC market-entry, or in research and development of appropriate AT that meet desired standards and specifications. AT are frequently segmented into sub-categories (for example, behind-the-ear (BTE) versus Receiver-in-Canal (RIC) hearing aids) and need to be forecasted accordingly.

Publicly-available assessments of product quality in LMIC is needed across all priority AT to accelerate market uptake of appropriate, high-quality, affordable products. Lack of evidence for use of products in LMIC context slows or inhibits the adoption of innovative technologies that have the potential to improve patient outcomes or service delivery. An example is new socket fabrication technologies in prosthetics delivery. Clear product and testing standards appropriate for LMIC

need to be established, with ongoing support in developing and maintaining capacity for testing, and publication and dissemination of results to empower buyers to make value-based purchase decisions.

Interventions to balance supplier and buyer risk

AT markets are nascent and erratic, which prevents suppliers from entering and participating in the market. Risk sharing interventions aim to transfer part of the financial or execution risks to other parties:

Promotion incentives provide below market and time-limited financing to increase promotion efforts and support broad demand generation campaigns. This could occur through the provision of grants to support consumer campaigns or concessional pricing from suppliers to support low-cost products. The goal is to push the product into the market and increase consumer uptake. Continuous stocking of the product once the intervention ends is key to ensure long-term demand. In the eyeglasses sector, availability of products has been not been sufficient to increase adoption. Demand generation activities are needed to achieve greater user awareness and acceptance.

Channel subsidies allow for the reduction in price of the product to consumers via price subsidy to the supplier. Suppliers have a direct incentive to stock and promote the product, therefore increasing the availability and awareness of the product to the end-user. There is however a risk that suppliers will increase mark-ups instead of lowering prices for end-users, or that lower prices may lead to overuse. Coordinating investment from current donors into subsidies is a recommended intervention to increase procurement of wheelchairs by governments.

Addition of product to **global or national lists of essential commodities** or improvement of **global guidelines** around products and innovations can encourage investment and uptake by leading to an increase in demand from public, and potentially private, providers. The WHO Priority Assistive Products List (APL) serves as a catalyst in promoting access to AT, following in the footsteps of the WHO Essential Medicines List. Countries should be supported to adopt the APL. Across all AT areas investigated, there is a need to improve global guidelines, particularly on the adoption of new innovations that support simplified service delivery and lower cost products.

Innovative financing mechanisms can support innovation and uptake of new products. Capital and technical assistance is made available to decrease financial risks associated with product development. This type of intervention is particularly suited for products in early-stage development with intensive, upfront investment. A recommended intervention in the eyeglasses space is to set up a blended financing vehicle that combines technical assistance, grant and equity funding to support start-up or scaling of high potential innovators.

Steps 4 & 5 of the market shaping pathway: Implementation and measuring results of market shaping interventions

Beyond just a traditional measure in the change of the number of individuals receiving more AT, monitoring and evaluation of market shaping interventions should assess improvements

in the 5As of healthy market as well as how well the intervention addressed the identified root causes. Annex 1 identifies some of the initial outputs expected for interventions proposed within the product narratives.

As interventions are shown to be effective, the investment case outlining the magnitude and types of market shaping investments needed should be further refined and developed. It is expected that a mix of different large-scale investments and financial instruments will be needed to achieve and sustain long-term outcomes. For example, programmatic system strengthening grants may be needed to support the integration of products and services into the public system, while match funding or co-investments may catalyze government procurement and investment and thereby support de-risking market participation by a global supplier.

Discussion

How market shaping can help more people gain access to the AT

Market shaping can help more people in LMIC gain access to the AT that they need. Based on an analysis of four AT markets, eyeglasses, hearing aids, prostheses and wheelchairs, and utilizing the principles from USAID's Framework of the Market Shaping Pathway, the following activities appear critical to overcome market shortcomings. These apply across various assistive products and can be addressed when global donors and stakeholders come together under a unified strategy:

- Supporting LMIC governments to develop comprehensive policies, including the development of national priority **Assistive Products Lists (APL)**, **specifications** and **guidelines** for procurement and delivery of AT, and inclusion in national **financing** mechanisms.
- Building and strengthening **procurement mechanisms** that can help facilitate **coordinated ordering** and **value-based negotiations** of assistive products.
- Supporting the **assessment of product quality** and dissemination of results to accelerate uptake of appropriate, quality assistive products.
- Developing **market reports** to enhance information sharing between buyers and suppliers.
- **Build enabling environments for the delivery of AT**, including awareness building and anti-stigma campaigns, training of relevant HR and service delivery infrastructure.

Market shaping must be coupled with programmatic interventions to ensure that the policy, personnel and service provision environment exists to delivery AT to the user. Additionally, there must be the financing available to support market shaping – implementers will need to work with and target donors, such as multilateral and bilateral donors, to support interventions, and will need to work with governments to assign budget lines or include in insurance packages for product procurement and provision. Market shaping works best for a commoditized set of products that can be purchased from global suppliers. It may therefore not address bespoke AT solutions required for complex needs.

There are successful examples in the global health commodity space that can inform and provide lessons learned for the activities highlighted above. Market shaping for zinc and oral rehydration salts (ORS) for the treatment of diarrhea provides a market example where a variety of market shortcomings were successfully addressed through a number of interventions including: increasing market information between manufacturers, importers and sellers, such as market size, competitive landscape and return on investment; updating regulatory guidelines and facilitating market entry of optimal and quality products; and technical assistance to support marketing and awareness building among providers and caregivers (Brimoh et al., 2021). Lessons from the highly fragmented pediatric ARV market show how coordinating global demand and rationalizing product selection has helped overcome long lead-times, high prices and stockout. Coupling global coordination with country-level technical assistance to optimize the efficiency of supply chains and financing ensures that ARVs reach patients at the local level (Unitaid, 2019).

Healthy marketplaces can play a role in ensuring affordability and availability of products to be delivered to those in need but will only impact on people's lives when it enables them to fully participate in society. To achieve this, inclusive and universal design approaches must be considered, especially for the public spaces and buildings. Service delivery systems must be set up to facilitate maintenance and replacement of assistive products. Successful market shaping will be one component of the inclusive ecosystem and will require involvement from a broad and diverse group of stakeholders within a country.

Exploring a mission-oriented approach to shaping AT markets

In order to embed market shaping approach into AT policy making, UCL Institute for Innovation and Public Purpose (IIPP) proposes a mission-oriented approach to shape AT markets in LMIC whereby coordinated action is needed to accomplish the greater mission of AT access.

The AT market is one of complexity and fragmentation. This system has perpetuated an economic and value system whereby companies fail to understand true user need as demand and economic value assessments are oriented solely on production costs, manufacturing and distribution channels. The ongoing system of AT innovation and delivery is hugely unhelpful as it stifles rather than stimulates innovation. A further challenge is the heterogeneous nature of AT. There are fifty essential priority assistive products (APs) defined by the WHO, which range from wheelchairs to pill organizers, communication software and screen readers, to incontinence pads – each representing a very different marketplace (WHO, 2016). While these products are seen to be priority products, there are many times this number of APs – and in some cases, hundreds of product versions within a single type of (e.g., manual wheelchairs).

In order to lead a comprehensive, sustainable and directed approach to market shaping, AT access has to be redefined and understood as a worthwhile public policy mission (Mazzucato, 2018a). While President Kennedy's moon-shot is the best-

known example of mission-oriented policies, governments across the world in the 1960s seem to have been open to such bold policies. The first-generation mission-oriented policies followed a “big science meets big problems” maxim that worked spectacularly well in some instances (e.g., the space race and the internet), in others created inertia or, worse, long-term problems (e.g., nuclear energy). Importantly, the success of mission-oriented policies relied on innovative institutional solutions (e.g., creating demand for new solutions through procurement, prize schemes, or similar) and mission-oriented agencies (such as DARPA and related procurement programmes in the US).

Applying mission-oriented thinking in our times requires not just adaptation, but also focusing the attention of missions to social-economic challenges rather than simply technological ones (Soete and Arundel, 1993). A report for the European Commission titled *Mission-Oriented Innovation Policy: Challenges and Opportunities* sets out a framework for developing a series of cross-sectoral missions and projects within missions (Mazzucato, 2018b). This framework sets out that missions must satisfy 5 criteria:

- (1) Be bold, inspirational with wide societal relevance
- (2) Set a clear direction: targeted, measurable and time-bound
- (3) Be ambitious but not unrealistic
- (4) Be cross-disciplinary, cross-sectoral and cross-actor innovation
- (5) Involve multiple, bottom-up solutions.

Mission-oriented thinking requires understanding the difference between: (1) broad challenges, (2) missions, (3) sectors and (4) specific solutions. A challenge is a broadly defined area which a nation or regional authorities may identify as a priority (whether through political leadership, or the outcome of a movement in civil society). These may include areas like inequality, climate change, or the challenges of an aging population.

Missions, on the other hand, are concrete problems that different sectors can address to tackle a challenge, such as reducing carbon emissions by a given percentage over a specific year period. Sectors define the boundaries within which firms operate, such as transport, health or energy. Missions require different sectors to come together in new ways: climate change cannot be fought by the energy sector alone. It will also require changes in transport and nutrition, as well as many other areas. Finally, solutions are specific projects undertaken by businesses, governments, universities or the third sector that can help support a mission. Solutions have clear objectives and should involve many different sectors, and can be supported through the use of supportive policy interventions and financial instruments.

We propose that access to AT could be seen as one such national challenge, with specific missions defined in order to tackle the challenge. These missions would be implemented by the market shaping approach described above. A market shaping approach driven by a government that is mission-led drives forward the agenda of AT access whilst incorporating NGOs, industry and the charity sector to work together toward

achieving the agenda through their own essential and complementary roles. Government involvement that is inspirational and forward leading would not only de-risk the AT marketplace, but can also create a market and policy landscape which is tilted toward innovation and equality. In this way it can play a varied and vital role in shaping the AT ecosystem through both its traditional and recognized role to govern, finance, create policy, and legislate along with performing less traditional parts which are beyond defined state craft such as playing a proactive role in market shaping and taking on a leading role in innovating the economy toward a specific direction.

Missions thinking would prioritize and make evident the larger social and economic value of AT and allow for the framing of access to AT as part of larger global missions such as ones involving overarching grand challenges of achieving health, equity, and autonomy. Given this, one may argue that access to AT in and of itself may not meet the definition a true mission, as a mission requires a remit that brings together global action and entails an agenda with a precise target that is of great societal relevance and that which would also stimulate innovation across the system. However, missions thinking reframes the discussion by focusing on AT as a matter of innovation dynamics and would enable innovation in the way AT is procured and invested in, partly by crowding in public sector, third sector and private sector interest. This is important as currently we know governments are not allocating sufficient funds and or/ are providing variable financial resources for even priority APs like wheelchairs and hearing aids.

AT is still well positioned to be thought of through a mission-oriented framework which would link AT access to a larger global vision. This would ensure that AT is not seen as a competing interest but rather a necessary step to reaching an ambitious and societal goal that brings together sectors that may have not traditionally prioritized AT. There are already numerous platforms for which the delivery and access to AT is an essential building block, such as Sen and Nussbaum's capability approach (Nussbaum, 2000; Sen, 1979). The capability approach links together the need for a mission to be driven by larger societal goals and provides the direction of growth that AT innovation and access would bolster.

Missions thinking builds on a systems approach by recognizing the interconnected nature of the economy, public sector and private enterprise. This approach does more than just scale AT, but rather creates and highlights an AT innovation ecosystem which supports economic and social change. Government is a key player in driving forward the economy if it is recognized and seen as such. An example would be that through a mission approach, AT demand could possibly be stimulated through the integration of services via the incorporation of procurement and provision of AT within health and social care systems. The focus of a mission is based in innovation economics. Rather than viewing AT only through the lens of health and social perspectives, it places AT from the vantage point of technological change and innovation. Directed innovation and growth within the AT sector, which would result in successive waves of further AT innovation, would result in cheaper and higher quality products. As was the case with investment and innovation in solar photovoltaics when there was national green economy investment (Mathews, 2019). Missions would help to address current challenges found within the innovation domains of

product, supply and procurement by bringing together stakeholders and enhancing public sector interest and investment (Albala et al., 2021).

The role of actors that help to drive the mission forward is especially relevant and essential in LMIC settings as programmes and interventions deployed do not just require cross sectoral thinking, but must be targeted, societally relevant and incorporate bottom up solutions. Currently, the charity-based model is one of the key existing AT delivery mechanisms within many local as well as global communities. In this model NGOs and faith based organizations are credited with providing materials, engaging in low-cost prototype distribution and development, participating in mass distribution, fundraising and refurbishing existing AT (Adya et al., 2012). NGOs are able to leverage unique expertise in order to advocate and influence activities, operationalize goals, and build institutional and social capacity (Teegen et al., 2004). In order to perform such activities fruitfully, NGOs will be required to work in dynamic cross-sectorial partnerships with the government directing how their resources and expertise can be used most efficiently to achieve the mission.

In essence, a mission-oriented approach would create a new delivery model for AT. Due to the varied landscape of AT, it is important to engage not only the government and the private sector, but to fully embrace the varied and essential roles that social enterprise, local and international civil society, universities, individual AT users, informal markets and innovators play.

Limitations

Limitations in both the approach to defining the role that market shaping can play in AT markets and to the role of market shaping itself need to be acknowledged. The process to identify the market shortcomings, root causes and proposed market shaping interventions for AT took place in 2019. Markets by nature are dynamic and consistently changing and so while a best effort to capture and scope the market was made, there is a risk that any proposed intervention may not be relevant in future years due to innovation, regulatory changes or market entrants or exits. Additionally, the nascent nature of AT markets in LMIC means that market data is scarce and so assumptions from one geography or from high income markets to LMIC markets had to be made based on data availability. Lastly, while a wide variety and number of stakeholders were consulted for the product narrative, the analyses represent a common perspective by stakeholder and do not reflect individual opinions and not all opinions may have been captured.

Conclusion

This paper explored the role and importance of market-shaping on AT. By utilizing the USAID Market Shaping Framework across four different products areas, this paper summarizes how the product narratives inform a sector wide approach to increase access to AT. A combination of market-shaping and programmatic interventions are required to create

sustainable markets. From these findings it was evident that the implementation of interventions is not meant to only be taken on by one actor in the sector, but rather will require active partnership and coordination from multiple stakeholders and experts. The publication of the product narratives is a first step in a consultative process to build broad support and buy in across implementing partners, suppliers, donors, country governments and end user advocacy groups.

To foster an eco-system that supports the adoption and use of assistive products and guides innovation to solutions that are context-appropriate, the paper proposes that a mission-based approach is applied to shape markets for AT. A mission-based approach can provide a direction and help accelerate progress toward a common objective among stakeholders, either at country or global level. A mission-oriented approach would create a new delivery model for AT. Due to the varied landscape of AT, it is important to engage not only the government and the private sector, but to fully embrace the varied and essential roles that social enterprise, local and international civil society, universities, individual AT users, informal markets and innovators play. This collaborative angle will provide the structure to bring multiple actors together in order to accomplish the goal of increasing access to AT.

We conclude that market-shaping can help more people in LMIC gain access to the AT that they need and that a broad coalition of stakeholders needs to come together under a unified strategy to support efforts to create a more enabling environment and shape markets for AT in LMIC.

The further development of a unified strategy for market-shaping of assistive products and the implementation of the strategy may stimulate additional research questions, including:

- What is the relevant mix of stakeholders required to shape a market for assistive technology?
- What are the barriers and facilitators to implementing the recommended market shaping strategies?
- Which market shaping interventions prove most relevant to different assistive products?
- What is the optimal mix of market shaping and programmatic interventions required to increase access to each assistive product category?
- What learnings from research on market shaping in other health areas and product categories are sector-specific or transferable to AT markets?
- What are the best ways of capturing AT value which would inspire a cross-sectoral mission approach?
- What can be further learned from innovation economics that can be cross applied to implementing an AT mission approach in practice?
- How do the strategies and recommendations from this paper relate to other frameworks, such as mapping onto the systems levels and market characteristics of the SMART Thinking Matrix?

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