# LAUNCH&SCALE SPEEDOMETER

# A Qualitative Analysis of the Introduction and Uptake Pathways, Enablers, and Barriers of Health Interventions in India and Ethiopia

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# EXECUTIVE SUMMARY

Every day, women and children around the world die from conditions and diseases for which proven and effective health interventions exist but are inaccessible for a multitude of reasons. Maternal, neonatal and child health (MNCH) measures (i.e., infant mortality, under-five mortality, maternal mortality) are some of the most important indicators of a country's development. Even though, globally and regionally, there has been substantial improvement on many of these indicators, the world remains off-track on meeting several of the United Nations Sustainable Development Goals (SDG)-related targets for MNCH. As is the case of SDG target 3.2.1 to reduce under-five mortality (U5M) to at least as low as 25 deaths per 1,000 live births in every country by 2030, in 2019 global U5M rate was at 38 per 1,000 live births.<sup>1</sup> While the SDG target 3.1 which is to reduce global maternal mortality rates (MMR) to less than 70 per 100 000 live births by 2030, in 2017 the global MMR was estimated at 211 per 100 000 live births.<sup>3</sup> In 2019, the Sub-Saharan Africa and Southern Asia regions accounted for more than 80% of under-five mortality and maternal deaths globally.<sup>1</sup>

The health status of women and children is typically a marker of the overall health of a community and lifesaving interventions addressing the MNCH continuum are imperative at all levels of the health system. Barriers in the pathways to the introduction and scaling of these interventions (primarily drugs, devices or diagnostics), such as regulatory, procurement, and supply chain pathways, are part and parcel to the failure to get them to the end-user. Conversely, there may be mechanisms that support the uptake of interventions that should be encouraged and explored further to foster their use to speed their delivery to the end user.

This paper seeks to understand and analyze the reasons behind these intervention pathway bottlenecks and enablers in India and Ethiopia, in order to identify opportunities to improve the local health ecosystem capacity to expeditiously adopt effective approaches to improving health. We selected India and Ethiopia because these two middle-income countries represent contrasting health systems (one primarily driven by the private sector and the latter primarily public or government-run) and approaches to health policy from South Asia and East Africa respectively.

To better characterize and analyze the launch and scale pathways in India and Ethiopia, we analyzed grey and white literature and conducted key informant interviews with public and private sector stakeholders from April to September 2020. We identified and prioritized strategies to increase access to interventions for the MNCH population, noted challenges and opportunities in the ecosystem, and developed recommendations to urgently address these barriers and challenges. We organized our findings by presenting recommendations on key factors that influence launch and scale as well as standalone pathway case studies in each country.

Comparing the findings in India and Ethiopia we found country specific as well as several common barriers and enablers affecting the provision of MNCH interventions in both countries. *Figure 1* describes the main pathway barriers for India and Ethiopia. India's barriers include: 1) a *fragmented health system* 

with 2) *limited access to quality care,* mainly at the last mile, and 3) a *largely unregulated private sector.* Country-specific pathway barriers in Ethiopia include: 1) *resistance to change* from providers and patients, and 2) a lack of *consistency on the updating, dissemination and implementation of Ministry of Health guidelines and recommendations for the use of interventions.* The common barriers for both countries are: 1) *unclear regulatory pathways*, mainly for medical devices, 2) limited *engagement of partners at the sub-national level,* 3) a *bureaucratic* public sector, 4) *underfunding and limited investment* to support introduction, capacity building, scaling up and implementation 5) *mistrust* of new health interventions, and 6) an *over-reliance on development and implementing partners*.



#### Figure 1: Barriers & Bottlenecks

*Figure 2* describes the enablers to drive the uptake of interventions in India and Ethiopia. The enablers of introduction and uptake in India include: 1) *embedding an intervention into a national program*, 2) Ministry of Health support of health interventions through the National Health Mission, and 3) having *strong public-private partnerships (PPPs)*. Country-specific enablers in Ethiopia include: 1) *having prior regulatory approval from a stringent regulatory agency (SRA) and*, 2) *a general openness and willingness to adopt new interventions at the government level.* The common enablers for both countries are: 1) *the collaboration and buy-in from the central government and key development partners*, 2) *having champions and "owners" at every level (i.e.: national, state, regional, and or provincial) and 3) global and local evidence of impact.* 

#### Figure 2: Enablers



Recommendations for more efficient pathways, improvement and/or further inquiry to address critical barriers to launch and scale in India, Ethiopia, and beyond

- 1. Generate stronger qualitative and quantitative evidence in these contexts
  - a) Establish a research team within the MNCH service (or within appropriate health systems research division) that is charged with developing and implementing research protocols focusing on scaling up interventions in MNCH, to establish a national evidence base of effective interventions and share it with the health community.

#### 2. Increase accountability mechanisms

 a) Incorporate monitoring and evaluation of scaling up MNCH interventions within national and subnational service delivery programs, including impact targets. Establish mechanisms for regular reporting to health officials, local government and patient population

#### 3. Strengthen national regulatory approval mechanisms

- a) Build capacity for new medical device regulation and champion more efficient and transparent regulatory processes for introducing new medical devices, with tracking of progress
- 4. Seek and promote more proactive early collaboration and engagement across multiple levels
  - a) Establish a forum for public and private sector MNCH product developers, including health authorities, policy makers and healthcare providers to regularly exchange ideas, review new evidence, address challenges across the trajectory of launch and scaling innovation, and discuss new challenges
- 5. Support an analysis of current status of public and private sector investment in scaling up proven MNCH interventions in these two countries, which can become a template for other countries

*Figure 3* shows identified barriers, enablers and recommendations mapped onto the IDIA Scaling Innovation Framework pathway domains<sup>1</sup>. This figure links our research findings to the pathway framework in an effort to highlight stages/domains that product developers and implementers have challenges or opportunities to launch and scale interventions faster and more efficiently.



Figure 3. Barriers, Enablers and Recommendations Mapped onto Pathway Domains

This research was undertaken as part of the Launch and Scale Speedometer

(<u>https://launchandscalefaster.org</u>), an initiative led by the Duke Global Health Innovation Center aimed at building the evidence base to understand the factors associated with and the speed of introducing and scaling global health interventions in order to accelerate their reach to those who need them the most.

Currently the research team is in conversations with key stakeholders, from the public and private sector, in India and Ethiopia, to develop two country-specific taskforces to work together to action these recommendations.

<sup>&</sup>lt;sup>1</sup> https://static1.squarespace.com/static/5b156e3bf2e6b10bb0788609/t/5b1717eb8a922da5042cd0bc/1528240110897/Insights+on+Scaling+Innovation.pdf

## INTRODUCTION

New and enduring global health challenges need effective, proven solutions and interventions that can be scaled to reach the most vulnerable populations. However, introducing and scaling-up lifesaving interventions (drugs, devices and diagnostics) in low-and middle-income countries (LMICs) is a challenge. The pathways these interventions follow from an innovative idea to sustainable scale-up are outlined in *Figure 4*. Described as an "unpredictable journey", these pathways to scale are not easy to navigate, they include six different stages which do not "always cleanly follow one another in a linear fashion" and are not always clearly standardized and delineated.<sup>2</sup> Moreover, there are several influencing factors (i.e. supporting evidence, funding, policy/regulatory frameworks, demand, politics, partnerships, champions, etc.), that can slow down, impede (barriers) or accelerate (enablers) these pathways.<sup>2</sup> Unnecessarily long timeframes for introducing and scaling health interventions in countries are a critical barrier, but heterogeneity in the pathways to scale (see *Figure 4*), and health topics they address, mean that isolating and mitigating the bottlenecks is difficult.

*Figure 4*: Launch and Scale Speedometer Framework of the Pathway to Scale (adapted from the IDIA Scaling Framework)



Maternal, neonatal and child health (MNCH) measures like maternal mortality, infant mortality and under-five mortality are among the most important indicators of the overall social and economic growth of a country. Globally and regionally there has been a significant improvement of most of these MNCH related indicators, in the case of India there has been a 73% decline on under-five mortality rate in the 1990-2019 period, from 126 to 34 deaths per 1,000 live births; while Ethiopia improved their under-five mortality by 26%, from 200 to 51 deaths per 1,000 live births, in that same period. For maternal mortality, India improved its rates by 61%, from 370 to 145 maternal deaths per 100,000 live births, and Ethiopia improved 61%, from 1030 to 401 maternal deaths per 100, 000 live births between years 2000-2017. However, the world remains off-track on meeting the United Nations Sustainable Development Goals (SDGs), specifically SDG 3, targets 3.1 (reduce global maternal mortality), and 3.2 (reduce underfive mortality). The Sub-Saharan Africa and Southern Asia regions, in 2019, accounted for more than 80% of under-five mortality and in 2017 both regions also accounted for approximately 86% of maternal deaths globally. <sup>3,4</sup>

Our research aims to understand and analyze the launch and scale pathways, and also to identify the causes of delay, barriers, and enablers of launch and scale of MNCH interventions at national and subnational levels in India and Ethiopia. We elected to explore issues in MNCH because it is a marker of

the overall health of a community and also in effort to bring more attention to key SDGs (SDG 3) in which wide variation in quality persist and progress in many countries has been slow.<sup>3</sup> The results of our research will provide actionable insights to improve these pathways within individual country contexts. Selecting India and Ethiopia allows us to compare two different countries which represent contrasting governmental health care policies and systems, and also because of their population size and geographical location these countries serve as representative examples.

India is the second most populated country in the world, with a population of over 1.3 billion. It has a largely fragmented and decentralized health system, where each state (28 states) and territory (8 territories) govern healthcare for its respective population. <sup>5,6</sup> While the central government has implemented various nationwide health programs and policies, the private sector accounts for 70% of healthcare provision.<sup>7</sup> Ethiopia, on the other hand, has a population of around 112 million <sup>8</sup>, and relies on a more cohesive and largely public sector-driven health system (approximately 80% of the total market share).<sup>9</sup> Despite these important differences, there are similarities, Ethiopia, like India, is quite decentralized; while the central government is responsible for policy and the technical support, the regional health bureaus (11 regions) are in charge of managing and operating the health facilities under their jurisdictions.<sup>10</sup>

## METHODS

In an effort to analyze the pathways a health intervention (primarily drugs, devices, and diagnostics) has to follow to be introduced, approved, and scaled in Ethiopia and India, the team reviewed white and grey literature exploring the regulatory, policy, financing, procurement, supply chain, and distribution pathways relevant to these types of interventions. The team also conducted semi-structured, virtual key informant interviews with stakeholders in India and Ethiopia. For the interviews, the team reached out to experts, across stakeholder types and research themes, from existing networks of contacts in these countries. We used a snowball sampling method to identify additional experts. If stakeholders consented, we conducted structured virtual interviews using a deductive approach based on the main launch and scale domains (health systems, regulatory process, policy, financing and supply chain). The team categorized the findings according to the launch and scale domains and then organized them into a set of common themes by consensus. Through our analysis we identified gaps in our learning which we addressed in a second round of focused, structured interviews with new key informants and a subset of prior interviewees. This research is exempt from IRB review by the Duke University Campus IRB.

## STUDY LIMITATIONS

Due to the COVID-19 pandemic, which began in March 2020 at the outset of our research, the team relied solely on virtual meetings with key stakeholders due to travel restrictions. The inability to travel to either country limited our ability to build trusting, collaborative relationships and to make further connections within each country. Therefore, we relied mainly on a snowball approach to identify and recruit key stakeholders, and we recognize that this limited the diversity and number of interviewees. For example, we had minimal access to government and state representatives from India, as well as health care providers and program implementers, all the afore mentioned resulted in a much smaller sample size that we originally expected. In addition, the pandemic made a more formal qualitative research process challenging, leading us to adopt a more streamlined standardized, structured, deductive

approach. Given these limitations, we may not have reached thematic saturation in all of the launch and scale domains nor fully explored the landscape in the countries we studied.

# RESULTS

India and Ethiopia harbor unique health ecosystems that reflect their respective contexts. Our findings from stakeholders in India and Ethiopia confirmed and aligned with assertions from previous studies that the most important factors (enablers or barriers) that influence scale up are the availability of financial and human resources, health systems capacity, supply chain capacity, advocacy, acceptability, partnerships, engagement of local implementers and community participation.<sup>11,12</sup> While there are notable differences between the two countries highlighted in our findings, we identified common push and pull factors that influence the launch and scale up of interventions. Based on the barriers, enablers, and overarching insights we ascertained from our research, we offer recommendations (below) to expedite and streamline pathways for effective interventions to reach intended end-users.

Barriers	Recommendations
<ul> <li>Lack of predictability in regulatory processes. Additionally, for new medical devices or diagnostics, there is limited expertise and not well-defined and consistent guidance on the process to obtain national regulatory approval for these health interventions. This lack of predictability may lead to delays in the launch and scale pathway.</li> </ul>	<ol> <li>Generate stronger qualitative and quantitative evidence in these contexts</li> <li>There is a significant need for publicly accessible, quality data for effective and sustainable scale-up.</li> <li>More than that, it is important to establish a clear research base and protocols to ensure the scale of cost-effective and impactful interventions and to establish a national evidence base of effective innovations.</li> </ol>
<ul> <li>Limited monitoring and evaluation systems could potentially affect the sustainability of an intervention's use and scale up. Many interventions that have successfully been introduced into India and Ethiopia are not being systematically tracked to measure their scale and actual use.</li> </ul>	2. Increase accountability mechanisms Through the development, implementation, and strengthening of data systems and tracking mechanisms in the public and private health sector for lifesaving health interventions. Systematic and transparent data systems, tracking mechanisms and evaluation of impact and cost-effectiveness would increase accountability and transparency and enable an understanding of what to improve and how to improve public health efforts.
<ul> <li>Limited engagement at the subnational level. Across the world, the responsibility for health is</li> </ul>	<ol> <li>Strengthen national regulatory approval mechanisms</li> </ol>

### Key Recommendations to Effectively and Efficiently Launch and Scale Health Interventions in India and Ethiopia

devolving and working with the central government to launch and scale interventions is necessary but not sufficient.	The strengthening of regulatory systems which includes having more predictable pathways and timelines, transparency, and increasing competencies and capacity for regulatory review. Championing efficient and more intuitive regulatory processes is also imperative. Regulatory bodies need not view themselves only as enforcers. Regulatory bodies can support and integrate product developers and innovators in the regulatory process to bring awareness and streamline the regulatory pathway. Additionally, building capacity and expertise in medical device regulation is important.
<ul> <li>Overreliance on the public sector, which is overstretched and limited by bureaucracy.</li> </ul>	<ol> <li>Seek and promote more proactive, early collaboration and engagement across multiple levels from local, subnational to national</li> </ol>
	It is important for product developers and development partners to engage those at the subnational level to accelerate uptake nationwide, recognizing the devolved nature of health policy, financing and delivery. Commitment and advance planning should be sought from all levels in order to ensure the successful uptake of lifesaving interventions. Engaging private sector partners, champions, civil societies, and global development/implementing stakeholders can support introduction and scaling efforts. The role of trusted, non-public actors is important for expanding the reach of the intervention. More attention is needed at the last mile to raise awareness and to sensitize health care providers, the community, and the end users, of the importance of a new intervention.
<ul> <li>Limited health spending and health investment funding.</li> </ul>	<ol> <li>Increase investments in both the public and private sector</li> <li>Support an analysis of current status of public and private sector investment in scaling up proven MNCH innovations (medical devices or other products).</li> <li>Develop the business case for investment in health</li> </ol>
	innovation, and introduce it to public and private leaders and decision-makers

Currently the research team is in conversations with key stakeholders, from the public and private sector to conform a country specific taskforce (one for India and one for Ethiopia), with the intention to work together to improve and make these first high level recommendations operational and actionable in each of those countries.

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## INDIA

India has made significant strides over the past few decades to prioritize and improve health outcomes. With dedicated efforts to improve maternal, newborn, and child health (MNCH) outcomes, India has significantly improved its MNCH indicators, it has decreased the maternal mortality ratio by over 60% - from 370 per 100,000 live births in 2000, to 145 per 100,000 live births in 2017.<sup>1</sup> Similarly, India has reduced under-five mortality rates by over 62% - from 91.8 per 1,000 live births in 2000, to 34.3 per 1,000 live births in 2019.<sup>2</sup> Despite the national progress, these outcomes vary greatly across and within Indian states highlighted in *Figure 5*.<sup>3</sup>This variation underscores the importance of the timely, accessible and equitable scale-up of health interventions and life-saving solutions to improve India's maternal and child health outcomes. One key strategy to ensure continued and accelerated progress in maternal and child health is to strengthen the systems and processes that support faster uptake and broader coverage of lifesaving, essential interventions.



Figure 5. Under-five Mortality Rate in Larger India States<sup>3</sup>

The following sections provide context to India's health system and the critical pathways that interventions must follow to be approved and ultimately used in the country.

#### Context: India's Health System, Governance, and Finance

India's healthcare system is decentralized (*see Figure 6*) and categorized into two major sectors, private and public health care.<sup>4,5</sup> The government is segmented by the central or federal government and the state government. The central government health entity, the Ministry of Health and Family Welfare (MoHFW), controls the majority of policy decisions and holds regulatory power.<sup>4</sup> The Department of Health and Family Welfare designs and implements national-level health programs, and the Department of Health Research focuses on clinical research and the development of health research and ethics guidelines. The MoHFW periodically releases national health policy guidelines to inform, clarify, and define the role of government to support the health and well-being of India's communities.<sup>7</sup> In efforts to support low-income individuals seeking healthcare, the national government launched Ayushman Bharat-

Pradhan Mantri Jan Arogya Yojana, or PM-JAY, which offers free access to primary care in the public sector. The scheme also extends cashless services to the public and access to some private sector secondary and tertiary healthcare facilities.<sup>7,4</sup> Several similar health schemes are dedicated to increasing coverage and quality for MNCH services, such as the Labour Room Quality Improvement Initiative (LaQshya).<sup>4</sup> The National Health Mission (NHM) is India's largest public health program and is categorized in two sub-missions: the National Rural Health Mission and the National Urban Health Mission.<sup>21</sup> Much of a state's public health efforts are executed through this program. Through the NHM, state governments submit their budgeting plans called Project Implementation Plans (PIP) to the MoHFW for approval. Upon approval, funds are then shared with the MoHFW and state governments through a 60:40 ratio.<sup>21</sup>





Indian states are responsible for governing healthcare delivery for their respective population. The Directorates of Health Services and the Department of Health and Family Welfare manage the healthcare workforce, oversee federally funded national programs, collect health information, and supervise local healthcare facilities. Given the largely fragmented system, public sector health services vary across the states, with significant differences in healthcare capacity, service delivery models, insurance coverage, accessibility, and availability.<sup>4,6</sup> While the public sector implements various programs that support little- to no-cost healthcare services, roughly 70% of healthcare utilization is through the private sector.<sup>6</sup>The private health sector is estimated to be four times bigger in overall capacity, with 55% of the total

hospital bed capacity and 90% of the doctors. While state governments allocate more resources to the rural areas, the private sector has a larger presence in urban and peri-urban areas.

The Indian government spends 1.28% of GDP on healthcare (2017-2018), compared to the global average of 9.8% in 2017.<sup>8,9</sup> The healthcare spending per capita varies across states and are not spread proportionally. Densely populated states, such as Bihar and Uttar Pradesh, received among the lowest state GDP per capita (2018) resulting in poor public healthcare infrastructure.<sup>6</sup> With limited capacity, shortages of staff and medical supplies, and public perception of quality of care, roughly 70% percent of Indians rely on the costlier private sector for healthcare (*Figure 7*). A chronically underfunded public health infrastructure has led to high costs for the Indian populations seeking care. Given the limited public sector health capacity, Indians are left to rely on the relatively more expensive private sector. There is a significant reliance on out-of-pocket payments, which accounts for 70% of total health expenditures.



Figure 7. Healthcare Utilization by Type Healthcare Service of Provider (2018).

#### **Context: India's Health Intervention Regulatory System**

India's national regulatory body for drugs, devices, and diagnostics, is the Central Drug Standard Control Organization (CDSCO), which is governed under the Ministry of Health and Family Welfare.<sup>10</sup> The Drugs Controller General of India (DCGI), head of CDSCO, is responsible for examining all clinical trial materials and requirements needed for a new health intervention to be deemed safe, ethical, and appropriate for its intended use in the Indian context, in order to receive regulatory approval to launch in the Indian

market.<sup>12</sup> For drugs developed abroad, the DCGI has 90 days to review the applications, and 30 days for drugs discovered, researched, and manufactured in India.<sup>10</sup> The review and approval processes have been streamlined to a three-tiered process, to eliminate historic bottlenecks, spearheaded by the following reviewing bodies: Subject Experts Committee, Technical Committee, and Apex Committee.<sup>11</sup> Collectively, the entire review and approval process is reported to take up to 180 days.

While the Indian government has devoted efforts to address regulatory bottlenecks, several challenges still remain persistent for developers introducing interventions in India. The medical device industry has been a rapidly advancing and emerging market, shifting the healthcare landscape worldwide.<sup>13</sup> Similarly, this industry is rapidly growing in India, but developers have been facing challenges with regulatory approval restrictions. While the drug regulatory approval pathway is well-defined, the pathways for medical devices are relatively new and still under development.<sup>18</sup> In 2017, CDSCO developed a separate pathway from the drug regulatory approval process and released the first official approval process guidelines for specific medical devices, but these guidelines were limited to a few medical device classes and were not an exhaustive list. Due to its infancy, it has been cited that the rules are constantly and quickly being updated, resulting in an uncertainty for developers over the regulatory process itself.<sup>17,18</sup> In support of advancing medical devices in India, the National Health Systems Resource Centre has recently been recognized as a "WHO Collaborating Centre for Priority Medical Devices and Health Technology Policy" to support the provision, strategic planning, and technical assistance for medical devices and interventions.<sup>16</sup>

#### **Context: India's Health Product Procurement and Supply Chain**

Currently, there is no singular central government procurement office in India.<sup>14</sup> Similar to other governing systems, the procurement mechanisms are largely fragmented and notably complex. Under the Directorate General of Health Services in the Ministry of Health and Family Welfare, the Medical Store Organization is responsible for the procurement of interventions embedded in national eradication programs for public sector health facilities across the country through seven regional stores. Additionally, they support the storage and distribution of drugs, including vaccines, received from WHO, UNICEF, USAID, and other international organizations through bilateral agreements with the Government of India.<sup>14,19</sup> States are largely responsible for public sector health procurement; their procurement mechanisms and efficiency vary, thus presenting a challenge to scale. For example, Tamil Nadu's procurement system, Tamil Nadu Medical Services Corporation, has been recognized by the WHO, the World Bank, and several other leading organizations for its successful approach, though most states have not experienced such success.<sup>20</sup>

There are various pathways an intervention must follow in order to reach the end user (*Figure 8*). A plethora of challenges have been cited when channeling an intervention to the end user, including a fragmented system, lack of coordination and inventory management, infrastructure gaps, limited human resources, and an absence of demand information.<sup>15</sup> These are some of the key challenges to ensuring these lifesaving interventions are reaching the end user through the supply chain systems in India.



#### Figure 8. Supply Chain Flow of Health Products in India<sup>15</sup> (AT Kearney, 2019)

#### Learnings from Key Informant Interviews on Barriers and Enablers to Scale

From March to December 2020, we interviewed 23 local stakeholders in India who are actively working in the MNCH field. Our stakeholders included public sector officials from the Ministry of Health and Family Welfare, IAS, and the National Health Systems Resource Centre; both private and public healthcare administrators and physicians; manufacturers; MNCH experts and consultants; academic institutions; local innovators; NGOs; and leaders from prominent global health organizations such as the Bill & Melinda Gates Foundation and the Clinton Health Access Initiative. In these interviews, we explored the various barriers and enablers to launching and scaling lifesaving MNCH interventions in India. These stakeholders expressed their first-hand experience of the various bottlenecks and barriers found within the health ecosystem in India and highlighted the key areas that can bring success.

Table 1. Summary of Pathways Barriers and Enabler in India		
Barriers	Enablers	
Governance and policy	National health schemes and programs	
Financing	Government champions	
Accountability, logistics, ownership	Public-private partnerships	
Human resources	Consultants and development partners	
Procurement	Power of evidence	
Regulatory process		
Access to quality healthcare		
Early sensitization and health communication		

#### **Barriers:**

#### • Governance and Policy

- The nature of India's fragmented system was defined as a major bottleneck by many 0 stakeholders. "Driving common standards is hard to do" when trying to implement an intervention in the MNCH field in a fragmented system. In order to introduce and scale an intervention in India to the general population, it must travel through multiple levels within the public sector starting from the state-level to national level, going through a very hierarchical and bureaucratic process. Within that process, the developer must present promising evidence of the intervention to an official representing each state health agency/department and consider the local contextual factors, like geography and community demographics. This must be done in each state in order for complete country implementation. Additionally, the logistics of an intervention's implementation must also be presented. Processes are very "person centric" so the introduction of the intervention may depend on the government health official and if it interests them, regardless of the evidence presented. When trying to introduce an intervention through the public sector health system, it can take much longer than anticipated. Even if the intervention is embedded into a national program, it would still require effort to convince state officials to adopt the intervention. Some developers indicated that it could take up to several years to convince state government officials to adopt an intervention. For example, it took one developer roughly three years to convince 11-12 states to embed their intervention into their guidelines.
- Public-private partnerships were noted as both an enabler and barrier. On one hand, there is a large mistrust in the public sector by the private sector. The historical mistrust can be attributed to the lack of clarity in the government's role in these partnerships. On the other hand, the public sector has expressed concern over the private sector's reliability in following the requirements of national programs. Because the private sector does not have to abide by some of the central government's national eradication programs, some interventions embedded in national programs or policies might not reach the majority of Indians seeking care in private sector facilities. In a similar way if a new intervention is implemented in a private hospital and there is interest to generalize it to the public, it will have to follow the long process to ultimately gain access and support from policymakers.
  - The majority of populations seeking care are seen by private sector healthcare facilities. Private sector insurance companies hold valuable data which would be useful for the introduction and scale of health interventions, but rarely make the data public. Our stakeholders emphasized the need for public and transparent health data from the private sector health facilities.

#### • Financing

- Public sector healthcare is underfunded and varies across states, which poses challenges to scaling up new interventions, particularly in states with limited human resource capacity. Public health providers are overburdened with patients and *"can see up to 150 per day"* so they do not have the time to adjust, learn, or even consider newer interventions. Public health providers also lack incentives to use new interventions as part of their practice.
- Budgeting and finance pose critical challenges to scaling interventions on a subnational level in the public sector. The central government drives the budget allocation process to the subnational governing bodies. The budgeting allocated to the states for health interventions and provisions from the National Health Mission is not utilized effectively in

some states due to lack of capacity to support the integration of an intervention and lack of trained personnel to manage the budget. Additionally, the budget is often allocated to support *"politically-driven agendas"* such as building unnecessary infrastructure.

• Across both public and private sectors, there is a lack of investment or funding allocations to up-keep or repair medical devices. There might be capital for the initial purchase, but the *"revenue budget for the consumables getting repaired may not be there"*.

#### • Accountability and Ownership

After an intervention is introduced, the logistics of implementation has been noted as a major challenge. Accountability mechanisms are in place, and it has improved at all levels (central and state) through performance reviews, trainings, orientation workshops happening regularly. What is lacking is that when bringing innovation recommendations and best practices to the national level, there is no support to disseminate and replicate this at the state level. There are no accountability mechanisms in place to take ownership of the intervention. Traditionally, there is an over-reliance on the trusted development partner to handle the logistics and implementation of the intervention, but their efforts are often temporary.

#### Human Resources

 There is a scarcity of human resources in some states. Hence, there may be insufficient stakeholders on the ground to introduce and manage a new intervention. Pay bands are very different across the country, and the hiring process is very complex, so the deployment of health personnel varies across the country. Without proper allocation of human resources, there is often not enough capacity to support and sustain the implementation of new health interventions.

#### • Procurement

Across India, state procurement mechanisms vary significantly. For example, Tamil Nadu and Rajasthan have specific public sector procurement corporations in place that are *"successful in terms of reaching the peripheral levels with medicine."* On the contrary, Uttar Pradesh and Bihar do not have strong procurement mechanisms, and therefore, *"avoid procurement completely leading to stock outs of basic essential medicines."* Similarly, the fragmented private sector health facilities act as an *"isolated island"*, requiring developers of innovations to navigate numerous individual procurement channels.

#### Regulatory Process

- Similar to other governing systems, the regulatory approval process has a bureaucratic structure which sometimes could delay the approval process for new health interventions. Additionally, the lack of defined guidance, specifically for medical devices, has been a challenge when trying to receive national regulatory approval for a novel device or diagnostic. Due to its infancy, there are a limited number of eligible device classes, resulting in local product developers delaying their introduction as they wait for more comprehensive guidance.
- Additionally, some of the stakeholders noted that clinical trials can face delays caused by government approval mechanisms, such as the Indian Council of Medical Research (ICMR). For example, MNCH experts suffered many delays in clinical trials introducing DMPA contraceptive injection. Despite global evidence, the ICMR required India-specific evidence, primarily due to push-back from the activist community claiming damage to bone density from the injection. ICMR held the testing but kept delaying the results. Even though the results were positive, it took many years to officially release the results,

rather than the proscribed 180 days. It required constant pressure and recognition of the need for expanded contraceptive options, to finally push the ICMR to release the results.

#### • Access to Quality Healthcare

Even though India has improved significantly the quality of its healthcare, the last mile continues to be a big challenge. The public health sector lacks incentives, skilled healthcare providers, and the regulation to provide quality healthcare. While government has increased access in rural areas, there is a lack of access to quality care at a low cost. Most of the population cannot afford the quality of private healthcare, so some interventions rarely travel through these pathways to reach the end user. There is also a large mistrust in the public health medical system from the Indian community.

#### • Early Sensitization and Health Communication

 Stakeholders also indicated community members are less likely to use the intervention without the proper health communication strategies to introduce the value of the new intervention as well as to address potential misinformation, or fears. There is a lack of efforts or mechanisms dedicated to sensitization of a new intervention for both providers and community members. Without proper introductions and explanations, there will be limited uptake and use.

#### **Enablers:**

#### • National Health Schemes and Programs

Several stakeholders noted that working with the central government to embed the intervention into a national program is an opportunity to introduce an intervention in the country. While still dependent on a state's governing body to adopt the program, it has been noted as a launch enabler. Furthermore, utilizing enablers such as the National Health Mission Innovation Summit which supports the launch and scale up of innovations through budgeting, training, and most importantly, their summit on health innovations. This is a once-a-year event that showcases novel innovations, both local and globally sourced, to garner interest from the right stakeholders and for relevant players to be informed. The National Health Systems Resource Centre leads the innovation-related technical assistance.

#### • Government Champions

- "There is no singular pathway, but a key champion is critical for the introduction and scale of an intervention." For example, having a Deputy Commissioner (division in charge) within a specific national program, such as Reproductive Maternal Newborn Child +Adolescent Health RMNCH+A), serve as a champion can facilitate scale when approaching states to adopt an intervention. They may serve as a reputable and credible champion due to the bureaucratic nature of the state government. Having strategic champions at diverse levels of the delivery system, and within key organizations can markedly influence the uptake and approval of new health interventions.
- Public and Private Partnerships (PPPs)

 Given the fragmented healthcare system and the largely utilized private health sector, many of our stakeholders indicated that strong PPPs could benefit the uptake of health interventions. In particular, when the role of government and private sector are clearly defined, these partnerships enable low-income communities to receive quality care and greater access to lifesaving interventions. It has been noted that successful partnership involves the government supporting the financing mechanisms for the patients and providing the facilities, and the private sector providing the quality care, healthcare providers, and the medical technology used for care.

#### • Consultants and Development Partners

 Development partners play an influential role when persuading states to adopt or implement a new intervention because they have built trust and are already on the ground. Development partners have also provided funding for procurement to support scaling efforts in some states, such as Bihar and Uttar Pradesh. This was also noted as a barrier because there is too much reliance on development partners. Additionally, consultants were noted as an enabler when navigating the complex regulatory landscape.

#### • Power of Evidence

A major driver of introduction and adoption of a health intervention is presenting a compelling case of the global and local evidence of impact to policymakers. With the majority of the Indian community seeking care in the private sector, private sector health data can be invaluable to support the introduction and scaling of novel, life-saving interventions. For example, presenting global and local evidence was a major driver for the introduction of uterine balloon tamponades (UBT). The UBT trials were led by the Mahatma Gandhi Institute and were implemented across 10 colleges (9 in Maharashtra state and 1 in Madhya Pradesh state). With successful clinical results, The Mahatma Gandhi Institute brought the data to the Government of India and successfully introduced it in Maharashtra. Compelled by the evidence, the Government of India motivated the ICMR to conduct clinical trials to implement it throughout the country. Unfortunately, progress has been stifled due to COVID-19-related disruptions.

#### RECOMMENDATIONS FOR ACCELERATING LAUNCH AND SCALE IN INDIA

- Establish inclusive and early multi-sectoral collaboration including communities, innovators, implementers and governments: Successful introductions have been attributed to periodic collaborative convenings between trusted implementing partners, community health workers, providers, innovators, and state government officials when introducing a novel intervention. By developing a shared vision, these convenings can enable productive engagement from varied perspectives to inform the strategy for introduction across the states.
- Strengthen investments in healthcare: We propose a dedicated and systematic process to alleviate budgeting issues across all the states. Additionally, there is a need for stronger healthcare investments to support capacity issues relating to public healthcare providers, HR staff, and the local intervention market. Workforce and capacity are key components for a country's health system to be able to launch and scale.

- Improve regulatory guidelines for new devices and diagnostics: Due to the infancy of the regulatory guidelines for devices, there is a need for stronger and inclusive categories to be embedded into the CDSCO guidelines.
- **Develop stronger public-private partnerships:** Clearly defined expectations and roles of both public and private sectors in addressing health needs can facilitate cohesive and effective collaboration and may reduce the historic backlash between the two.
- **Promote and incentivize local innovators** (i.e. manufacturers) to produce more local, affordable and accessible health innovations allowing the country to have some control over the supply chain (health security)
- Increase accountability mechanisms: Effective planning efforts should be executed across all levels from the central government down to the district-level. Post-introduction, we propose proper accountability and ownership mechanisms in local government systems to support the planning, sensitization, integration, and monitoring of newly introduced interventions.
- Develop transparent monitoring and evaluation mechanisms to track scale in both public and private healthcare settings: Create transparent mechanisms for monitoring, evaluating the impact, and utilization of health interventions.

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## <u>ETHIOPIA</u>

Ethiopia has made much progress in the last two decades towards a healthier population and future.<sup>1</sup> Since 2000, maternal mortality ratios (MMR) have decreased from 897 to 353 per 100,000 live births and child mortality rates have decreased from a 14.3% to a 6.42% share of newborns who die before age five per 2015 data.<sup>2,3</sup> Nevertheless and despite much effort, maternal mortality rates and child mortality numbers in Ethiopia are very high.<sup>4</sup> Model estimates in 2017 for MMR in Ethiopia showed an increased MMR of 401 per 100,000 live births---compared to 201 for the world--- and the number of children under five years old dying in Ethiopia is still in the top six in the world at 189,000.<sup>5,3</sup> These numbers highlight the need for timely and effective health interventions and solutions. One way to accelerate progress in maternal and child health is to scale-up high impact new interventions in Ethiopia. The following is a summary of our findings on the context, resources and the way forward in getting life-saving innovations to the end-user more efficiently.

#### Context: Ethiopia's Health System, Governance, and Finance

Consistent and coordinated Ethiopian government efforts and global health donor investments in maternal and child health services have been pivotal to Ethiopia's progress and health improvements.<sup>4</sup> With a population of around 112 million, Ethiopia depends on a segmented three-tier health system to manage demand.<sup>6</sup> The health system structure consists of a primary level which includes health posts that funnel into health centers and then primary hospitals, a secondary level (general hospitals), and a tertiary level (specialized hospitals) --- all of which are organized centrally by the Ethiopian Ministry of Health and managed by regional health bureaus.<sup>7,8</sup> While the private sector features at every level of the health system, it is still a developing and somewhat limited sector. Ethiopia has relied on and benefitted from having a centralized and largely public sector driven health system, with 75% of outpatient visits and 80% of inpatient visits taking place in a public facility.<sup>9</sup> Ethiopia's centralized health system structure is one of the reasons that the country is attractive to many global health donors.<sup>10</sup> Ethiopia is considered a "donor darling" and is in the top five of countries receiving development assistance for health in Sub-Saharan Africa.<sup>10</sup> Between 2013 and 2015, around \$1 billion USD in investment aid flowed to the Ethiopian health sector and external health expenditure (as a percentage of current health expenditure) reached 47% in 2008.<sup>10,11</sup> Recent data from 2017, showed that external health expenditures at 22.11%, domestic general government health expenditures at 25%, and out of pocket expenditures at 34.4% as a percentage of current health expenditure.<sup>11</sup> External health expenditure has been decreasing as Ethiopia's economy has been growing, highlighting the need for increased government spending and domestic resourcing. Presently, the government is only meeting about half of the target budget allocation to the health sector at 8.7% (Abuja target: 15%).<sup>12</sup>

#### Context: Ethiopia's Pharmaceutical Regulation, Procurement, and Supply Chain Mechanisms

Investments from both the government and external donors have informed the Ethiopian supply chain landscape (see Figure 9 for an adapted flow chart of the system and Figure 10 for an example of the healthcare supply chain structure in Ethiopia). In Ethiopia, all pharmaceutical and medical products (drugs, devices or diagnostics) are regulated, licensed, registered and inspected for quality through the Ethiopian Food and Drug Administration (EFDA).<sup>13</sup> In recent years, the EFDA has made applications electronic and their website (<u>http://www.fmhaca.gov.et</u>) outlines the process for approval. Despite the EFDA's work, problems in regulating health products still persist with many citing smuggling, poor interagency cooperation, weak enforcement as enduring problems.<sup>14</sup>

There is no singular way for products to get to the end-user; there are many pathways that depend on the sector, procurer, and distributor.<sup>15</sup> The Ethiopian Pharmaceutical Supply Agency (EPSA) handles the procurement of medical supplies in the public sector.<sup>16</sup> Using a procurement list that is updated every two years, EPSA purchases various health products and supplies that are then distributed to 19 EPSA branches, organizations, regional and district stores, health facilities and then to the community.<sup>16,17</sup> EPSA is working to ensure that 100% of the demand for health products is met, despite stock shortages and funding gaps. A study by Shewarega and others in 2014 showed that essential medicines were available most of the time (~90%) up from 70% in 2003.<sup>18,19</sup>

#### Figure 9<sup>9,1</sup>



#### Ethiopian Pharmaceutical Supply Chain Pathways Example

## Figure 10<sup>20</sup> Supply Chain Structure in Ethiopia



#### Learnings from Key Informant Interviews on Barriers and Enablers to Scale

From March to November 2020, we spoke with 22 stakeholders who are working in the MNCH field in Ethiopia. These stakeholders included officials from the Ethiopian Ministry of Health, the Ethiopian Pharmaceutical Supply Agency, Ethiopian Food and Drug Agency, Ethiopian Ministry of Science and Technology, physicians, public health advocates, and leaders from global health organizations, including USAID, CHAI, Jhpiego, John Snow Inc, and Hamlin Fistula. In these interviews we explored the barriers and enablers to launching and scaling MNCH interventions in Ethiopia. Stakeholders reported poor application of evidenced-based practices to launch and scale and reaffirmed some of the keys to success in scaling interventions.

Table 2. Summary of Pathways Barriers and Enablers in Ethiopia		
Barriers	Enablers	
Governance and policy	Collaboration and buy-in from key partners	
Regulatory process	Stringent Regulatory Approval	
Financing	Research and technical assistance	
Socio-cultural environment	Willingness to adopt new innovations	

#### **Barriers:**

#### • Governance and Policy

• The government was described as both a *"major influencer and bottleneck."* Bureaucracy in government made processes longer than they needed to be. The government was said

to have many competing priorities and agendas which make implementation difficult. As such it is imperative that interventions garner political commitment via the backing of a champion.

- Lack of awareness and capacity among decision makers for adoption or implementation. Even when there's a window of scientific evidence about the effectiveness of health interventions, they might not be adopted or implemented in the country because the program officers or decision makers might not know about the evidence or might not have the capacity to implement those recommendations.
- **o** Lack of continuity, there is a frequent turnover of people in critical posts, and within organizations, that negatively affects motivation and sustainability.
- o Some stakeholders discussed the discrepancy between what is written on paper versus what is practiced. Once something has been put into guidelines at the Ministry level, it can take years for the information to get to lower-level facilities, and even more time to actually be implemented
- o Some stakeholders discussed how recommendations and guidelines are revisited every couple of years, variably depending on the team and task force. Thus, this lack of disseminated information made it hard to integrate new, proven interventions at subnational levels, despite references in published literature or textbooks. Without a common evidence base shared with the periphery and across all levels of health care, not surprisingly, there is a wide range of variability in the practice and implementation of government policy.
  - According to one stakeholder, *"the Ministry of Health guidelines not regularly updated; most recent copy was maybe 10 years ago."*

#### Regulatory Process

- o Government stakeholders acknowledged, that even though there is a "clear and transparent regulatory system in place", but because of the complexities of medical devices and diagnostics, they do have a "lack of capacity and shortage of technical expertise in the regulation of medical devices and diagnostics", mainly regarding their validation and assessing their safety and appropriateness.
- For some health-focused innovators, regulatory processes and activities were said to be unclear, time consuming, and difficult to navigate. One stakeholder gave an example of how this lack of well-established policies can lead to *"policy on demand"* which slows down the process.
  - The complexities of medical devices and diagnostics cause delays in approval.
     EFDA has a shortage of expertise in this area. There are health products that do not fit well within the delineated categories which also slows down the process.
  - According to one innovator stakeholder, the regulatory pathway is lengthy, and there are too many offices involved. "It was supposed to take 2 weeks but ended up taking 6 months because you needed a letter from the Ministry of Health, FDA, PFSA, customs office, health bureau."

#### • Financing

- Many of our stakeholders discussed limited funding for various activities (research and development, introduction or implementation) for launching and scaling interventions.
   Some added a special note around even more limited funding for local product developers who usually do not have the backing of external donors and financiers.
  - Examples of limited funding for MNCH interventions slowing their scale (as described by a stakeholder):

- Chlorhexidine introduction took some time because local resources were not able to cover it. "Ethiopia as a developing country does not have much resources to divert to new innovations...especially if they require huge resources." The government had to reach out to and ask global funders to help procure this drug. On top of this, the government wanted to produce it in-country, but global organizations and donors like "USAID and UNICEF, they would like to procure chlorhexidine from globally accredited institutions or manufacturers." Thus, the government had to get permission to procure from local manufacturers which meant the process took longer.
- Bubble CPAP machines are a much-needed intervention in Ethiopia, but financing is hard because *"there are so many initiatives happening, here and there, but you don't see sustainability [which is] a challenge that is heartbreaking."* This lack of staying power is due to various reasons, one of which is funding.

#### • Socio-cultural Environment

- **o** Most stakeholders mentioned some resistance to new interventions from both providers and patients.
  - Providers were said to have a tendency to stick to what they have done in the past, "addicted" to what they are accustomed to.
    - Implementation of new interventions is a real issue, especially when providers get comfortable with certain products and procedures. It is challenging for them to unlearn their previous practice and learn new things.
    - The "mindset" of providers was said to be crucial, as highly trained individuals were said to prefer "challenging" interventions and found simple interventions and procedures beneath them.
  - On the patient side, many stakeholders cited a lack of receptivity to new interventions from the community because of distrust. This was said to highlight the need for more culturally engaging strategies, community awareness, getting participants more information on the evidence base and involving local leaders.
- Many people receive care at the primary level (health posts, centers and primary hospital). This means that interventions that require more skilled providers and higher-level facilities miss a key portion of the population.
  - One stakeholder gave an example using antenatal corticosteroids, which were said to not be reaching those who most needed them because they are only available where C-section delivery is an option (i.e. only in hospitals, not in health centers where most patients deliver). This factor limits the scaling of antenatal corticosteroids in some areas in Ethiopia.

#### **Enablers:**

- Collaboration and buy-in from key partners
  - Collaboration and buy-in from key partners were cited by stakeholders as a key enabler in not only launching interventions but scaling them. Of particular importance was coordinating with the Ministry of Health, healthcare workers, and other trusted community actors to influence uptake.

- According to one stakeholder, "Healthcare workers are a critical mass."
  - Example of opportunity for faster scale of an intervention with buy-in from key stakeholders (as described by a stakeholder): Chlorhexidine introduction has been challenging, utilization and uptake by health workers is low. "In terms of introducing chlorhexidine within the system, it took some challenge. Scaling it up and having it available in facilities was successful, but utilization by the health workers is something that we're currently being challenged [by]..." As such, one option to scale faster and better would be to include chlorhexidine use in on- the- job trainings for midwives. This option would increase "capacity building, demand creation [among] health workers."
- Buy-in from the Ethiopian government helped one small organization that did not have the capacity to reach many Ethiopians, as they were able to utilize the government system and government mechanisms already in place to reach every district.
- Confidence or endorsements from global organizations were said to be enablers. Innovators linked to these organizations could utilize their well-established networks and pathways to scale.
- Stringent Regulatory Authority (SRA) approval from the global North was mentioned as an enabler for launch; with interventions receiving SRA approval having an easier time achieving Ethiopian regulatory approval.

#### • Research and technical assistance for scaling

Ethiopia-specific research and/or evidence generation in the country can accelerate the process for launching and scaling interventions. Along with this, some stakeholders mentioned the need for commitment to push interventions through the entire process to scale, as well as continuing to be responsive and evaluating implementation progress.

- One stakeholder mentioned how there was much *"support during the introductory phase but then organizations leave and don't sustain innovations to scale."* 
  - An example described by a stakeholder: The Every Second Matters for Mothers Uterine Balloon Tamponade was introduced in the country but is still in the testing phase because there is no real implementation support (not enough trainers, imported material). Currently, there is no system to train new healthcare workers to use the intervention, and given that turnover rates at health facilities are high, facility-based processes to train new staff, as well as advocacy to develop such system and trainers of the UBT would be needed to scale this innovative device in Ethiopia.
- Willingness to adopt new interventions. Stakeholders mentioned that there is growing interest among young people to challenge norms and try new things a benefit for new interventions.
  - According to one stakeholder, there is an opportunity to "capitalize on the youth's curiosity, harness this population as capital."

#### RECOMMENDATIONS FOR ACCELERATING LAUNCH AND SCALE IN ETHIOPIA

• Increase private sector engagement in the health sector: As Ethiopia transitions into a new era with less donor assistance, the private sector, which has been in an infantile stage, should increase its engagement with the public sector and be more closely integrated into the health system. By removing barriers that have been limiting the private sector, the private sector may be

able to cover gaps and create an ecosystem for entrepreneurs and new lifesaving health products.

- **Stronger investment in healthcare:** Increase government spending in the health sector and invest in the local intervention system (an opportunity for import substitutions).
- Improve regulatory guidelines for devices and diagnostics: Improve regulatory guidelines, especially for devices and diagnostics. One stakeholder suggested that the EFDA do more than control and regulate but also support, teach, and bring awareness to their policies and activities.
- **Provide technical assistance for scaling:** Product developers need to build capacity and expertise past the introductory phase and commit to seeing interventions through to scale.
- **Strengthen monitoring and evaluation mechanisms:** Improve government capacity to monitor and evaluate the scale up of health interventions.
- Establish inclusive and early multi-sectoral collaboration including community, innovators, implementers and governments: Along with this, we propose utilizing and engaging champions at every stage and the creation of platforms for multi-stakeholder convenings and consortia.

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