LAUNCH & SCALE
SPEEDOMETER

REPORT

Launch and Scale Timelines and Trends of Maternal and Child Health Interventions

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EXECUTIVE SUMMARY

Glaring inequities in global maternal, newborn, and child health persist despite the availability of lifesaving interventions. Many of these interventions are not reaching populations and geographies in need due to bottlenecks in their launch and scale up. We need to break down barriers in deploying effective solutions where they are needed and reduce the time it takes for a proven drug, device, diagnostic, or care delivery model to be introduced in different markets and achieve widespread sustained scale.

The Launch and Scale Speedometer (Speedometer), a multi-pronged initiative led by the Duke Global Health Innovation Center, is building the evidence base on scaling global health technologies and innovations to improve the availability and timeliness of lifesaving interventions where they are most needed. The Speedometer framework emphasizes an intervention's pathway to scale including its development and validation phases, milestones involved in the process of scaling up, actual scale (or coverage) reached by interventions studied, through supply or demand parameters, and institutionalization of interventions through policy. This report describes the Speedometer framework as applied to the analysis of select interventions to address maternal, newborn, and child health. The report also details the interventions studied and our analytical methods to understand patterns and connections in these pathways for the interventions studied, and provides recommendations for the community of innovation funders and policymakers to enable proven innovations to reach more people rapidly.

The team had the following key research questions to guide the data collection and analysis of the launch and scale up of MNCH intervention:

1. How long does it take MNCH interventions to progress through launch and scale milestones globally, across countries?
2. What are the patterns of launch and scale of MNCH interventions nationally?
3. How do countries' contextual factors affect the launch and scale timelines of MNCH intervention?
4. How do milestones at the level of the intervention relate to milestones at the country-level?

Data

Our analysis was based on data from both primary and secondary sources on 14 MNCH interventions. Primary data sources include interviews with key stakeholders for interventions and health focus areas, including from Ministries of Health, global health and international development organizations, and corporations involved in the development and manufacturing of interventions. Priority countries for this phase of research include Ethiopia, India, and Nigeria. We collected milestones and scale data for interventions at the global level priority countries, and 15 additional countries that had valid and reliable measures to facilitate analyses.

Key Findings

We organized findings by the key research questions identified at the outset to understand launch and scale patterns of MNCH interventions. Each section of the results also describe the key findings that relate to a specific question addressed in that section. In summary, our analyses highlight the following key findings:

1. Although no clear pattern emerges in the launch and scale trajectory of interventions, our data show that interventions have progressed through both launch and scale milestones at the global level at a faster pace since 2010.
2. Interventions that were conceptualized and ideated before 1990 took longer to reach critical milestones slowing their overall launch and scale trajectory, highlighting the lack of coordination among developers, implementing organizations, and global and country policymakers. In contrast, interventions launched since 2000s have progressed more quickly. Qualitative analyses show that greater coalition building and multi-stakeholder coordination were instrumental in the faster pace of recent interventions.
3. Preparation for scale (such as developing an implementation plan for an approved intervention or inclusion as a line item in the national budget) as well as scaling within countries take the longest time in the milestones we analyzed. Defining challenges to scale and supporting implementation research that examines diverse solutions are critically needed. Greater engagement with local and national stakeholders to secure their buy-in is therefore essential even in earlier stages of introducing an intervention within a country.
4. Contextual factors such as corruption, quality of healthcare system, and per capita spending on healthcare within countries affect time taken to launch interventions and scale them in countries.
5. Although endorsement from WHO was not a critical factor for earlier interventions, it is increasingly an important enabler for interventions to launch in country. However, WHO approval was not sufficient to reach even 20% scale within countries. Developers and implementers need to work with country-level stakeholders from the early stages of development to ensure sustainable take-up of their interventions.
6. Data on scale are sparse, both due to the lack of data availability and because several interventions have not accomplished scale within countries as highlighted in earlier sections. The global community needs to come together to begin to track key milestones in the growth and scaling trajectory of interventions so that targeted actions can be taken to move lifesaving interventions to people and places where they are most needed.
7. Bundling of interventions such as Vitamin A supplementation with national immunization programs helped to achieve initial scaling success. However, disruption in these campaigns due to lack of funding and poor integration of the delivery of VAS into regular health systems, particularly universal immunization programs have inhibited sustainable scale among populations in need.

Key Recommendations

Based on our quantitative and qualitative analyses, we have distilled key recommendations to the community of intervention developers, funders, and policymakers at the global, national, and subnational levels.

A. **Call to action for data.** Global health and development organizations should prioritize the collection and public sharing of data to inform strategies to address pressing MNCH and other global health challenges. Communities of developers, implementers, private sector, and NGOs must begin to track data on their development, implementation, and distribution efforts to feed into a common, public platform that will enable the creation of a data repository. These data collection activities will be particularly important at the country level due to the limited data available to understand the factors that catalyze or delay launch, adoption, and scale. Furthermore, collecting appropriate data nationally and sub-nationally can also highlight areas and populations still in need that are not equitably receiving the benefits from lifesaving interventions.

B. **Funding programs and policymakers must develop clear, standardized global and country milestones to benchmark the uptake of interventions.** Standardized milestones will allow for targeted action by appropriate stakeholders to speed up phases of proven interventions as in the case of pediatric TB medicines, while maintaining realistic timelines and targets for those that are yet to show promise, such as antenatal corticosteroids. The IDIA scaling framework has taken an important step in this direction in specifying high-level stages of growth for an intervention, as well as key enablers and barriers. The Launch and Scale Speedometer analytical framework has operationalized the conceptual mapping laid out by IDIA and provided useful milestones and indicators of progress to funders, country and global policymakers, developers, and implementers that can be standardized for collective action and greater impact.

C. **Developers must engage and work with country stakeholders early to plan and prepare for scale.** Our research shows that while preparing for scale is often the longest in the launch and scale pathway, activities in this stage are not as clearly defined as other milestones that also take time, such as establishing proof of concept. With several activities needed in preparation for scale for an intervention, such as inclusion in a National Essential Medicines List, development of national policy guidelines and implementation plan, and allocation in national budget, there is a need for strong stakeholder engagement and buy-in and adequate time to complete these activities appropriately. In addition to planning for launch activities, funders, development organizations, and implementers must work with national and sub-national policymakers at earlier stages to better understand local conditions in preparation for scale, secure buy-in for validated interventions, create a conducive environment for scale, and reduce the time lag between validation and scale.

INTRODUCTION

Globally, mortality rates for women and children continue to be unacceptably high. In 2019, 5.1 million children under five were estimated to have died from highly preventable causes in low- and middle-income countries (LMICs), including infectious diseases such as diarrhea, malaria, pneumonia, and preterm births and birth asphyxia.[1] In 2017, 293,000 women were estimated to have died from pregnancy and complications in childbirth in LMICs.[2] A large proportion of these deaths among mothers and children could have been prevented with well-known interventions: quality care in the antenatal, intrapartum, and postnatal period for mother and baby, and care for sick infants.

In comparison, there was an estimated 65,000 deaths among under-five children and 1,526 maternal deaths in Europe, North America, Australia, and New Zealand.[1,2] While the deaths in developed countries are no doubt significant, the stark variation in the mortality between high-income and low- and middle-income countries highlight the inherent inequities in addressing basic healthcare needs of mothers and babies in less developed countries.

A variety of scalable, effective lifesaving interventions to address critical maternal and child health challenges in low-resource settings do exist. However, these interventions are not reaching the women and children who need them most due to bottlenecks in the development, validation, regulatory, and scaling stages of the intervention's lifecycle. Extended timeframes for introducing and scaling maternal, newborn, and child health interventions in different countries are a critical barrier to their reach and impact. Additionally, the pathway from development to scale-up is highly variable among interventions, between and even within countries, which makes it challenging to identify common problems to solve with targeted solutions.

Where data are available, they are highly variable without an architecture to map and synthesize common factors that are crucial to launch an intervention rapidly or are significant bottlenecks in its scale-up by population in need. A number of qualitative, case-based approaches to assessing launch and scale processes exist, including USAID guides such as "Idea to Impact" (USAID, 2015) and "Pathways to Scale" (USAID, 2016), and academic case studies (Spicer et al, 2014; Spicer et al, 2016; Kumar et al, 2019). However, there has been a lack of comprehensive, data-driven frameworks to track and assess launch and scale best practices for global health interventions.

The work of Launch and Scale Speedometer helps fill this gap by systematically tracking key factors for both launch and scale across diverse health interventions to generate insights on the trends and pathways of scale-up in low- and middle-income countries. The research described in this report details the analyses and evidence we generated on select interventions to address maternal, newborn, and child health. Our research seeks to shed light on some of the factors that enable launch and scale as well as the causes of delay of lifesaving MNCH interventions so that the global community can collectively develop strategies that improve the speed of an intervention's reach and impact.

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[1] United Nations Inter-agency Group for Child Mortality Estimation (UN IGME), 'Levels & Trends in Child Mortality: Report 2020, Estimates developed by the United Nations Inter-agency Group for Child Mortality Estimation', United Nations Children's Fund, New York, 2020.

[2] Trends in maternal mortality 2000 to 2017: estimates by WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division. Geneva: World Health Organization; 2019. License: CC BY-NC-SA 3.0 IGO. Accessed from https://www.unfpa.org/sites/default/files/pub-pdf/Maternal_mortality_report.pdf on September 1, 2021.

We uncovered several bottlenecks in conducting this research, chief of which is the lack of availability of data on launch and scale pathways and milestones of interventions. In the absence of data, it is difficult for funders, product developers, implementers, and policymakers to understand how to improve the status quo or what levers to pull to accelerate the progress towards mortality reductions among mothers and children around the world. For lifesaving interventions to make an impact on the lives of populations in need, the global community needs to enable the access, availability, and quality of data on the pathway from ideation to scale and facilitate greater action-oriented collaboration and partnerships informed by data and evidence.

Objectives of this Report

We need to reduce the time it takes for a proven drug, device, diagnostic, or care delivery model to be introduced in different markets and achieve widespread sustained scale so that lives can be saved. This report describes the comprehensive approach we have developed through the Launch and Scale Speedometer project to understand the scaling pathways of a select set of MNCH interventions and generate data-driven recommendations for the global community of product developers, donors, implementers, and LMIC governments who seek to accelerate these pathways to sustained scale.

The report describes the Speedometer framework, which emphasizes an intervention's pathway to scale including its development and validation phases, milestones involved in the process of scaling up, actual scale (or coverage) reached by interventions studied, through supply or demand parameters, and institutionalization of interventions through policy. The report also details the interventions studied and our analytical methods to understand patterns and connections in these pathways for the interventions studied, and provides recommendations for the community of innovation funders and policymakers to enable proven innovations to reach more people rapidly.

The team had the following key research questions to guide the data collection and analysis of the launch and scale up of MNCH interventions:

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We provide a list of key terms and how we define them in this report and our research below (see Appendix I for a detailed data dictionary used in the research):

1. Launch refers to the time taken from proof of concept[3] to first country introduction.
2. Scale refers to the time taken from introduction within a country to scale sustainably.

[3] Proof of concept (POC) refers to the date of successful completion of Phase IIb studies or equivalent. If unavailable, POC refers to date of publishing of RCT or equivalent study.

3. Global milestones refer to milestones that are needed at the level of the intervention to introduce an intervention in any LMIC, and subsequently to help accelerate its pathway to scale starting with ideation, proof of concept, inclusion in WHO guidelines, and eventually achieving global uptake.
4. National or country-level milestones refer to milestones specific to each country to introduce and scale up the intervention within countries, including country pilots, National Regulatory Approval (NRA), inclusion in National Essential Medicines List (NEML), in-country launch, and achieving country uptake.

Data, Methods, and Limitations

Data

This report used data from both primary and secondary sources. Primary data sources include interviews with key stakeholders for interventions and health focus areas, including from Ministries of Health (primarily in Ethiopia and India), and organizations such as Global Drug Facility (GDF), PATH, Philips, and Pfizer. Secondary data sources include publicly available data on websites of international development organizations and large nonprofits such as WHO, UNICEF, World Bank, Jhpiego, and Institute of Health Metrics and Evaluation (IHME).

Priority countries for this phase of research include Ethiopia, India, and Nigeria. We collected milestones and scale data for interventions at the global level as well as for priority countries. The team also collected and compiled milestones and scale data for 15 additional countries that had valid and reliable measures to facilitate analyses. See Table 4 for details on countries included in the analysis.

Data Definitions and Structure

Launch and Scale Speedometer's data framework uses metrics mapped onto the prevailing scaling framework produced by The International Development Innovation Alliance (IDIA) to anchor our data collection within the current understanding about the process of scaling. IDIA is a platform for knowledge exchange and collaboration among development innovation funders to create and facilitate learning about the scaling of innovation across geographies, organizations, and sectors. Based on the experience of a wide range of experts in development innovation, IDIA's "Insights on Scaling Innovation" framework uses standardized terminology to create a shared understanding around the complex process of scaling innovation in LMIC settings, starting from the original idea for an innovation all the way through scaling.[4] Given the intentional parsimony of the IDIA scaling framework, solid empirical grounding and validation from the experiences of several experts, and common language to describe key scaling stages to create a shared understanding, we chose the IDIA framework to expand further and develop the Launch and Scale Speedometer framework.

[4] Insights on Scaling Innovation, June 2017. The International Development Innovation Alliance. Accessed on 25 July 2021 from https://static1.squarespace.com/static/5b156e3bf2e6b10bb0788609/t/5b1717eb8a922da5042cd0bc/1528240110897/Insights+on+Scaling+Innovation.pdf.

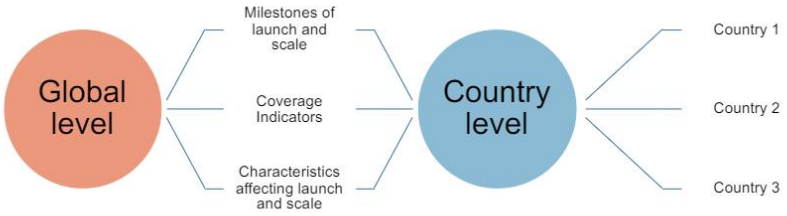
Figure 1. International Development Innovation Alliance's 'Insights on Scaling Innovation Framework'

Source: The International Development Innovation Alliance (IDIA): Insights on Scaling Innovation (2017)[6]

Based on the IDIA typology, the Speedometer framework comprises a data structure that distinguishes key milestones that are common across countries for a given intervention from milestones that are particular to the launch and sustainable scale of the intervention within a particular country. Global milestones include initial ideation of the intervention, proof of concept, regulatory approval from WHO, first introduction within a low and middle income country (LMIC) and aggregate scale across LMICs. Country milestones include pilots and demonstration research projects within specific countries in preparation for subsequent launch and scale, securing national regulatory approval, inclusion in the national essential medicines or procurement lists, and scale up within the country.

The times taken to achieve global and country milestones can also differ widely based on characteristics specific to the intervention (such as type of intervention and health area addressed) or country context (such as corruption index and gender inequality) that the framework incorporates in its data structure. Last, the framework incorporates different ways to measure sustainable scale globally and within countries, given that scale is a complex construct.

Figure 2. Data Structure of Speedometer Framework



Accordingly, in the dataset, we measure sustainable scale globally or nationally in the following ways:

Table 1. Definitions of scale indicators used in research

Type of scale indicator	Global	Country
Demand-side (Use)	Proportion of target global population that has been reached by the intervention through distribution or use of intervention	Proportion of target country population that has been reached by the intervention through distribution or use of intervention
Supply-side (Procurement)	Proportion of units of intervention procured by LMICs	Proportion of units of intervention procured for country
Supply-side (Availability)	Proportion of LMICs with health issue providing the intervention	Proportion of sub-national units with health issue providing the intervention
Supply-side (Sales or Purchase)	Percent of target global sales value of the intervention in LMICs	Percent of target purchase value of the intervention in country
Policy	Proportion of LMICs with policy or implementation plans for roll-out of intervention	Proportion of sub-national units with policy or implementation plans for roll-out of intervention

Figure 3 shows the high-impact milestones in the Speedometer framework mapped to the IDIA framework for scaling innovations. Both global and country-level milestones are displayed in these priority milestones with global milestones reflecting the scaling process mostly from 'ideation' to 'transition to scale', and country-level milestones reflecting the process mostly from 'transition to scale' to 'sustainable scale'.

Figure 3. Speedometer priority milestones mapped onto IDIA Framework

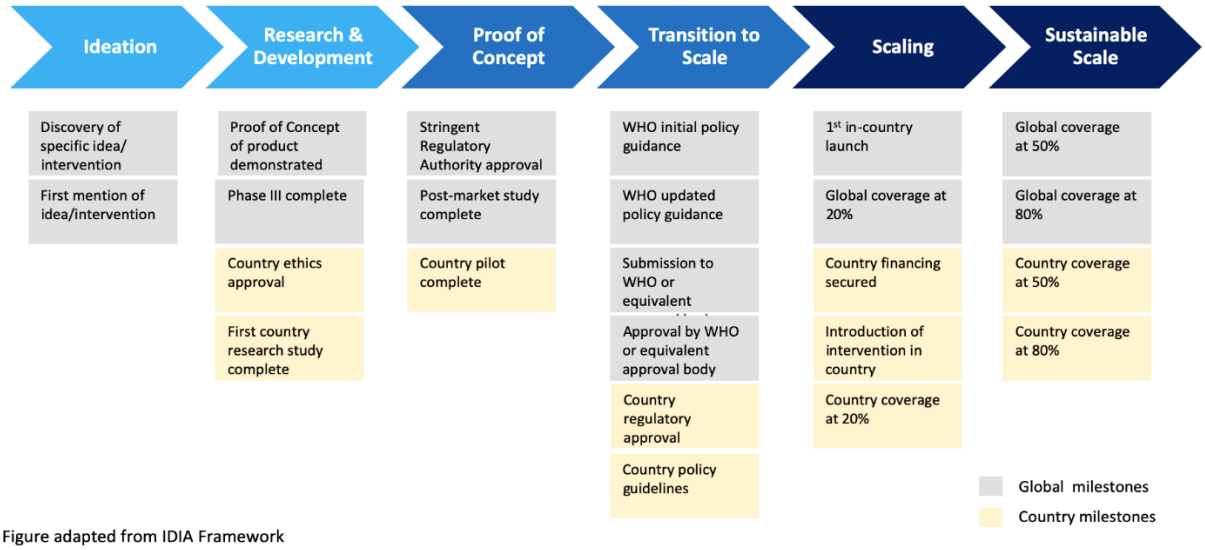


Figure adapted from IDIA Framework

Source: Adapted from International Development Innovation Alliance (IDIA): Insights on Scaling Innovation (2017)[6]

Analytical Strategy

We analyzed data on timelines for MNCH interventions by examining time to reach specific high-impact milestones globally and at the country level (noted in Figure 3), and analyzed the relationships between some of the country characteristics and contextual factors[5] and the time it has taken to launch and scale within countries. We did not examine all country characteristics or contexts in this paper, but have highlighted key factors that could influence the time to launch or scale in different countries. Additionally, we analyzed how milestones at the global level such as inclusion of an intervention in WHO policy guidelines affect the time it has taken the intervention to be introduced and then reach scale-up within specific countries.

For each intervention at global or country level, we identified specific dates of critical milestones from the data collected. Where only the year of a milestone was available, we noted the date as the mid-point of that year (e.g., 01 July YYYY). To compute the time taken for various milestones, we therefore had to restrict our analyses to interventions and countries for which we had complete pairs of milestone dates. For instance, where we had the date for completion of pilot in a particular country for an intervention but no corresponding date for receiving national regulatory approval (NRA), it is not possible to compute the time taken to receive NRA after completing the country pilot for that intervention. Of the interventions studied, ORS and pediatric TB medicines have the most data on matched pairs of milestones.

We describe the key milestones used in this report in Table 2.

Table 2. List and definitions of key milestones used in research

Level	Milestone	Definition
Global	Ideation	Date of discovery or idea for specific intervention addressing health topic
Global/ country	Proof of concept (POC)	Date intervention demonstrated to be safe and effective for intended purpose in humans
Global	Approval from Stringent Regulatory Authority (SRA)	Date of Stringent Regulatory Authority (SRA) approval or clearance
Global	WHO PQ or equivalent	Date the intervention obtained pre-qualification status from WHO or inclusion in other global procurement list
Global	First launch in LMIC	Date the intervention was used in a Low or Middle Income country for the first time outside of a research study

[5] Global characteristics that were analyzed but not featured in this report include: **1) Centralized buying environments**, or where 80% or more of the product is procured by one or several large buyers, including organizations and large governments; **2) Main market type**, which include: a) *Globally Coordinated Market* where technologies such as vaccines are procured and financed through centralized channels, b) *Local Institutional Market*, in which national institutions, such as a ministry of health, purchase technologies such as drugs used for obstetric care, whether through their own resources or from donor grants or loans, c) *Consumer*, in which a large number of disaggregated consumers buy health goods for their own use; **3) Clear champions**, which include interventions whose development and procurement were led/championed by prominent global organizations; **4) Low- and middle-income specific**, or interventions developed specifically for LMIC country use; **5) Significant safety concern**, which refers to whether, after research trials, the intervention or product showed concerns in being implemented safely among all groups, **6) Global pricing agreement**, or if there is a pricing agreement organized by international partners for the intervention.

Limitations

The main limitations of this research are challenges caused by the lack of availability of high-quality, consistent data for milestones and scale globally, nationally, and sub-nationally. Available data are largely sporadic and are not uniformly available across organizations. Our team scoured the internet to collect accurate and valid data, which are diffuse and come from different sources even for the same intervention. Overall, there are significant gaps in how organizations, intervention developers, policymakers, and development organizations report milestones and dates of critical milestones in the field of health innovation. While the IDIA and Speedometer frameworks (and others such as ExpandNet) seek to address these gaps by creating and compiling standard definitions and terminology for the growth trajectories of innovation, the data deficits are large and need substantial collective effort to address them. Additionally, there is no one way to define scale. There is no common language around scale, and scale definition can vary by intervention, type of organization seeking to scale, unmet needs of the target population, or the extent to which the intervention is supported by policy guidelines sub-nationally, nationally, or globally. Although understanding coverage among the most vulnerable and in-need populations is essential, such data do not exist or are not accessible particularly at the sub-national and national levels, where it is important to track who benefits from the intervention.

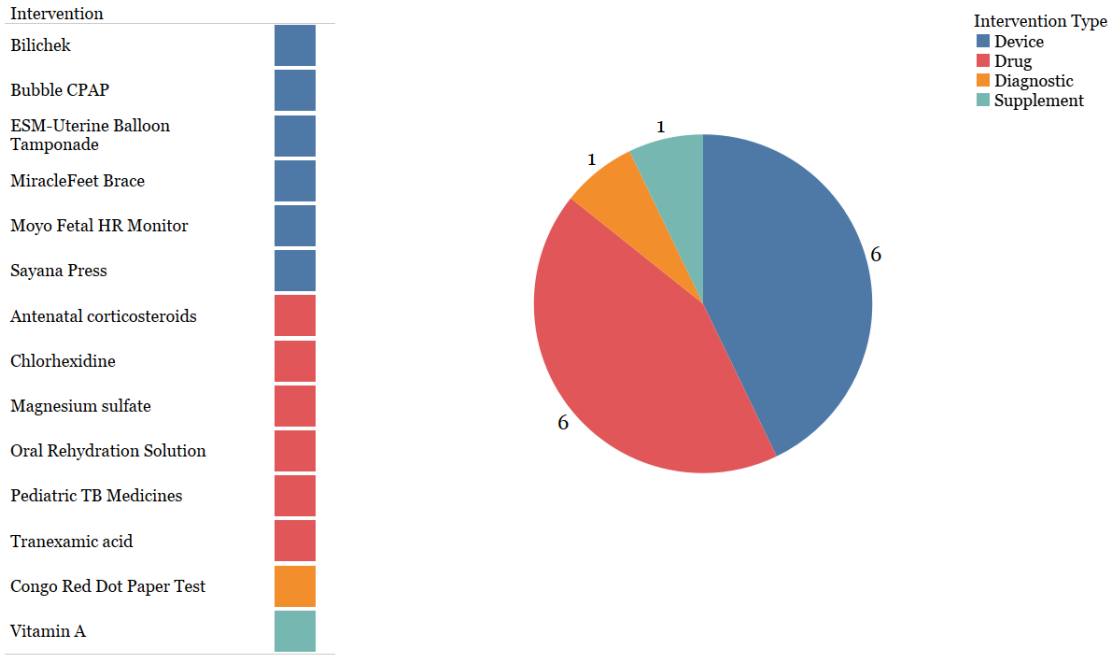
While it is difficult to get milestones data across and within countries, it is particularly challenging to find scale data as many interventions are scaling only recently, and require consolidated efforts from both country governments and international development partners to collect and report data. In addition, there is no standard definition of scale; therefore, with multiple ways of measuring and reporting scale, validated scale data are not available consistently in the formats we need for analysis on a yearly basis (with the right numerator and denominator to enter into our dataset for analysis). Finally, a key limitation of collecting and analyzing aggregate milestones and coverage data is that they do not reveal who receives the intervention within LMICs and if interventions are equitably distributed among vulnerable and marginalized subgroups. While most interventions are developed for LMIC settings, it is not clear if they do reach those most in need even in these settings or if they are able to reach only those that are able to afford and access these interventions.

FINDINGS

1. Characteristics of MNCH interventions studied

We studied 14 MNCH interventions for this research, of which 12 were either devices or drugs (see Figure 6). Interventions were categorized by the following 'types' for the analysis: medical devices, diagnostics, drugs, and nutritional supplements.

Figure 4. MNCH interventions by 'Intervention Type'



Source: Compilation of interventions by Speedometer team

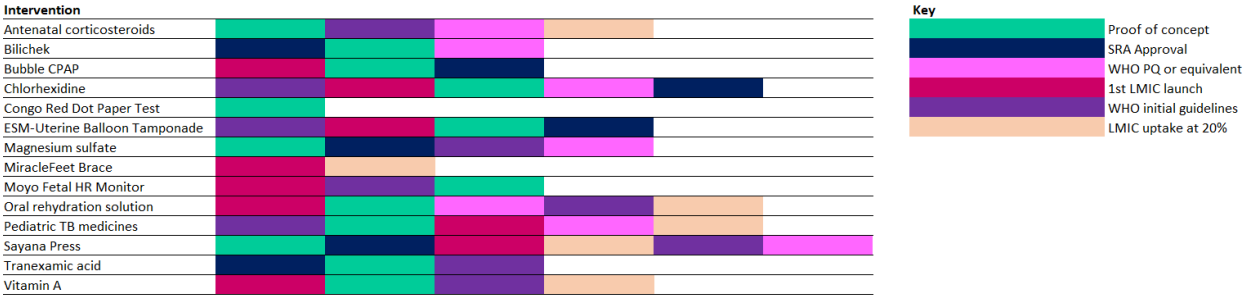
2. How long does it take MNCH interventions to progress through launch and scale milestones across countries?

SUMMARY OF KEY FINDINGS

- *No clear pattern or trajectory emerges in the launch and scale pathway of interventions studied.*
- *Interventions have progressed through both launch and scale milestones at the global level more quickly since 2010.*
- *Older interventions ideated before 1990 have taken longer to reach critical milestones slowing their overall launch and scale trajectory.*

Table 3 shows the scaling pathways for each MNCH intervention included in the Speedometer analysis. Scaling frameworks portray the complex pathways from ideation to launch and then scale in a linear fashion to help funders and innovators orient themselves to sequential progression of milestones, including how to prepare for each step. However, the trajectories of launch and scale of the MNCH interventions studied are highly variable. There is fluidity in the order of milestones, particularly earlier occurring ones, such as proof of concept (POC), stringent regulatory approval (SRA), approval from WHO, and first launch of intervention in an LMIC. Where scale data are available, as in the case of ORS, pediatric TB medicine, antenatal corticosteroids, and vitamin A supplementation (VAS), achieving 20% uptake has followed the occurrence of at least two earlier milestones but in no particular order (POC, SRA, first launch, WHO guidelines).

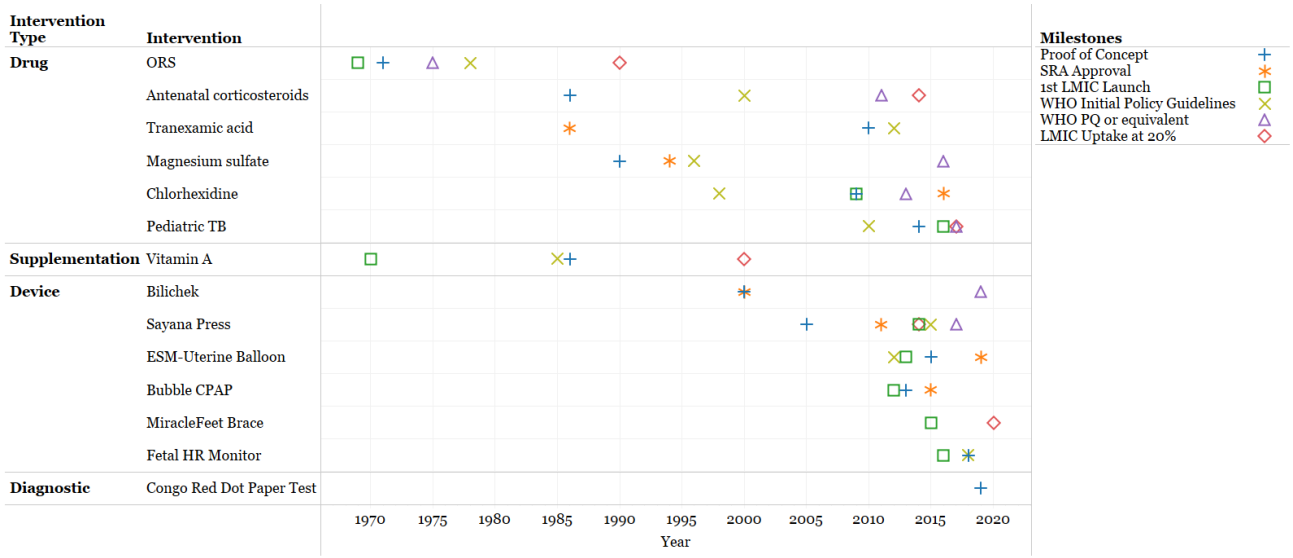
Table 3. Scaling pathways for MNCH interventions



Source: Analysis of publicly available data on interventions by Speedometer team

Figure 5 shows the timeline for key milestones across different intervention types at the global level. Across most interventions, milestones begin to cluster from 2010, indicating faster progression through stages after 2010. Additionally, older interventions such as ORS and VAS took decades to progress through milestones. For example, it took VAS 30 years from first launch in an LMIC to scale to 20% (scale parameter: availability of intervention in LMICs where needed). For a detailed review of how Vitamin A moved from development to scale, please see our case study on VAS. Among recent interventions, pediatric TB medicine took about 9 months and Miracle Feet braces took 5 years to scale after first launch in an LMIC (scale parameter: availability of intervention in LMICs where needed).

Figure 5. Timeline of milestones at global level, by intervention and intervention type



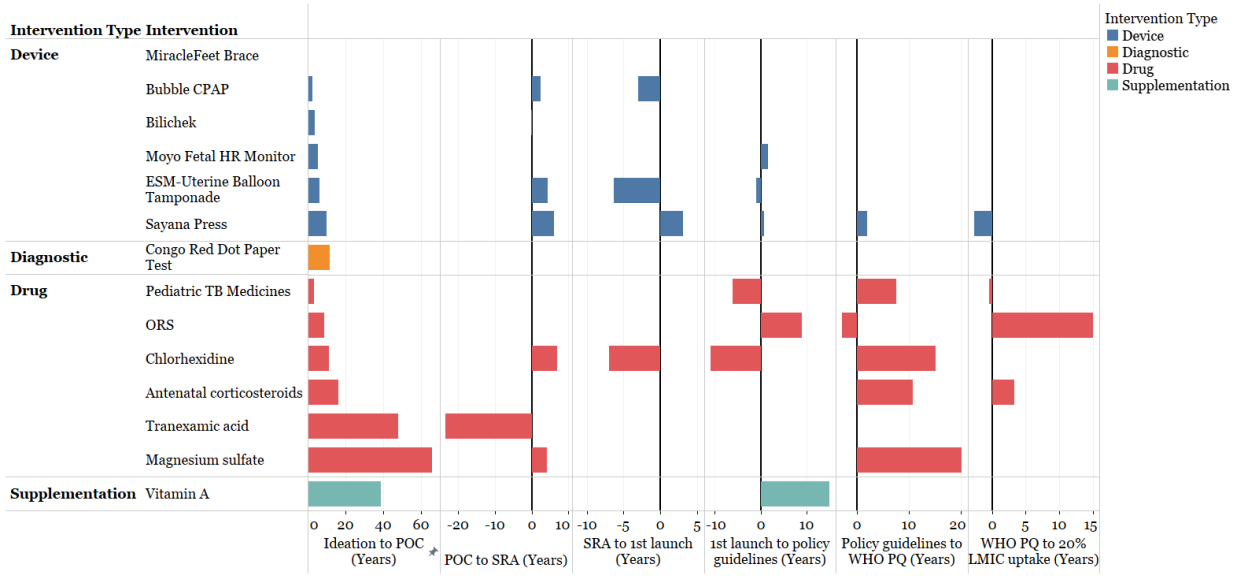
Source: Analysis of publicly available data on interventions by Speedometer team

Global milestones data in Figure 6 from POC to achieving 20% scale show that MNCH interventions take 17.8 years on average to show POC from ideation, which is far longer relative to other key milestones, but also not surprising given the amount of evidence needed to show that an idea could potentially be used to save lives. POC is also the milestone with the most data available. By intervention type, devices progress from ideation to POC within 5.5 years. Drugs, on the other hand, take longer to go from ideation to POC, but there is wide variation among different drugs. Magnesium sulfate and tranexamic acid took the longest to show POC after ideation, 65.9 years and 47.9 years, respectively. Although magnesium sulfate has been in use since 1916, and was a popular treatment of choice for decades, it was not until more than 50 years later that rigorous scientific research was conducted to show POC as a lifesaving intervention to treat eclampsia and pre-eclampsia.[6] Tranexamic acid, originally invented by a Japanese couple for postpartum hemorrhage in 1962, did not gain acceptance as a treatment for this condition as studies on its effectiveness for postpartum hemorrhage were not of high quality, until the WOMAN trials of 2017. [7] Antenatal corticosteroids, chlorhexidine, and ORS average at 12.1 years, while pediatric TB medicines only took 3.3 years to show POC after ideation due to the reformulation of existing TB medicines.

[6] Hunter, L.A. and Gibbins, K.J. (2011), Magnesium Sulfate: Past, Present, and Future. Journal of Midwifery & Women s Health, 56: 566-574. https://doi-org.proxy.lib.duke.edu/10.1111/j.1542-2011.2011.00121.x

[7] Ockerman, A., et al. (2021). Tranexamic acid for the prevention and treatment of bleeding in surgery, trauma and bleeding disorders: a narrative review. *Thrombosis journal*, *19*(1), 54. https://doi.org/10.1186/s12959-021-00303-9

Figure 6. Time taken between key milestones



Source: Analysis of publicly available data on interventions by Speedometer team

Beyond proof of concept, there does not seem to be a clear pattern for the time it has taken for different interventions to reach intermediate milestones prior to being included as recommendations in policy guidelines. Among the seven interventions that have data on the transition from POC to receiving approval from a stringent regulatory authority (SRA), five took an average of 4.7 years to receive SRA after POC. Tranexamic acid, however, received SRA approval in Belgium 40 years[8] before showing POC in the United States through the WOMAN trials to treat various hemorrhagic syndromes including postpartum hemorrhage.

For most interventions with available data (bubble CPAP, ESM uterine balloon tamponade, and chlorhexidine), first launch in an LMIC occurred on average 5.6 years prior to receiving SRA approval. Only Sayana Press launched after receiving SRA approval, taking 3.1 years. Taken together, these data suggest that receiving SRA approval does not influence time taken to launch within LMICs.

Inclusion of interventions in the WHO initial policy guidelines has taken between 1 year and 16 years after their first launch in an LMIC. However, some interventions were included in the initial policy guidelines even before launching in any LMIC, as in the case of chlorhexidine, pediatric TB medicines, and the ESM uterine balloon tamponade.

Data on obtaining WHO prequalification or another equivalent approval following inclusion of an intervention into WHO initial policy guidelines are mostly available for drugs among the interventions

[8] Australian Government, Department of Health and Ageing, Australian Public Assessment Report for Tranexamic Acid (2010). Accessed from https://www.tga.gov.au/sites/default/files/auspar-cyklokapron.pdf on 14 July, 2021.

we studied. It takes about 9.1 years for a drug to receive WHO prequalification or equivalent after it has been included in initial policy guidelines. On the other hand, Sayana Press injectables took 2 years after its inclusion in WHO policy guidelines to be included in the WHO Essential Medicines List that our research considers to be equivalent to WHO prequalification.

Less than a handful of interventions have data on the transition from WHO prequalification (or equivalent) to reaching 20% scale at the global level, with no clear pattern emerging from this data.

3. What are the launch and scale patterns of MNCH interventions in specific countries?

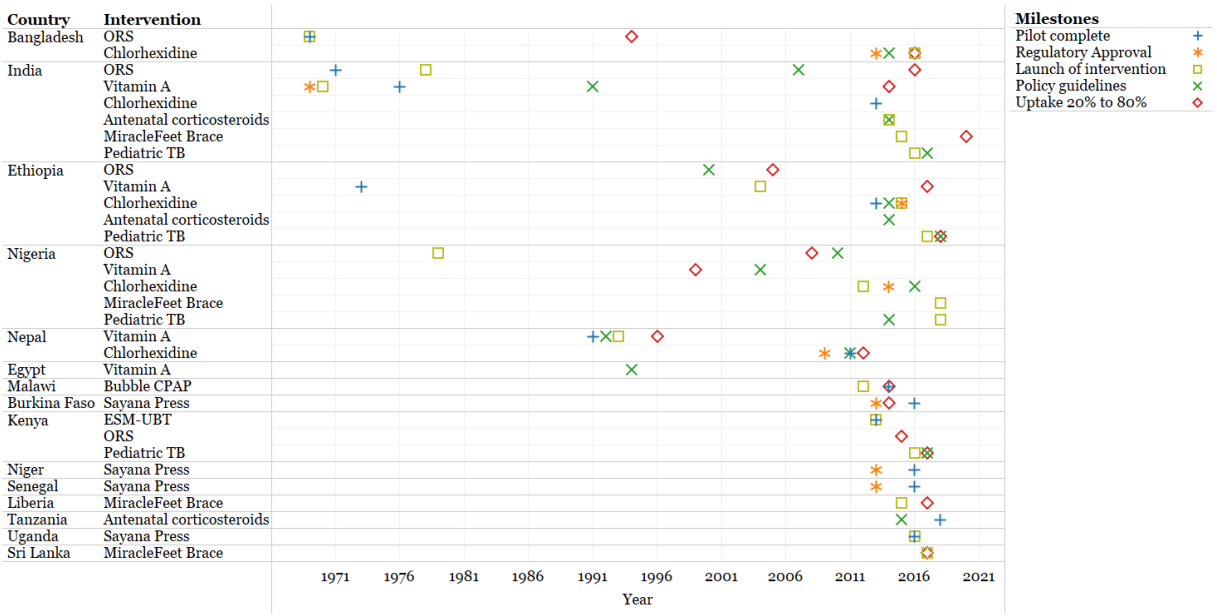
SUMMARY OF KEY FINDINGS

- *Interventions have progressed through both launch and scale milestones more quickly since 2010.*
- *Completion of in-country research studies facilitates national regulatory approval or inclusion of the intervention in country-specific policy guidelines.*
- *However, preparation for scale (such as developing an implementation plan for an approved intervention or inclusion as a line item in the national budget) as well as scaling within countries take much longer for interventions studied. Defining challenges to scale and supporting implementation research that examines diverse solutions are critically needed.*

Like the global launch and scale pathways, country milestones in the pathway to launch and scale are highly variable. Further, not every intervention needs approval from the national regulatory authority to be marketed or sold and not all countries have well-defined regulatory approval processes.

Figure 7 shows the progression of interventions through milestones across countries. Milestones tend to be clustered after 2010, a finding also observed at the global level. Based on available data, ORS is the only intervention which has reached at least 20% scale (in terms of use by population in need) in all countries included in the analysis. Chlorhexidine has reached over 20% scale in Nepal (in terms of use by population in need); Miracle Feet Brace has reached 25% scale in India (in terms of percent of states where it is available), and over 80% in Liberia and Sri Lanka (in terms of use by population in need and units procured in relation to population in need); and Sayana Press injectable has reached over 20% scale in Burkina Faso (in terms of percent of regions where it is available). Antenatal corticosteroids, bubble CPAP, and ESM uterine balloon tamponade have not reached scale within any of the countries we considered for data collection, while pediatric TB medicines have scaled in India, Ethiopia, Nigeria, and Kenya (in terms of use by population in need); and Miracle Feet in Liberia (in terms of use by population in need) among the countries we included for data collection.

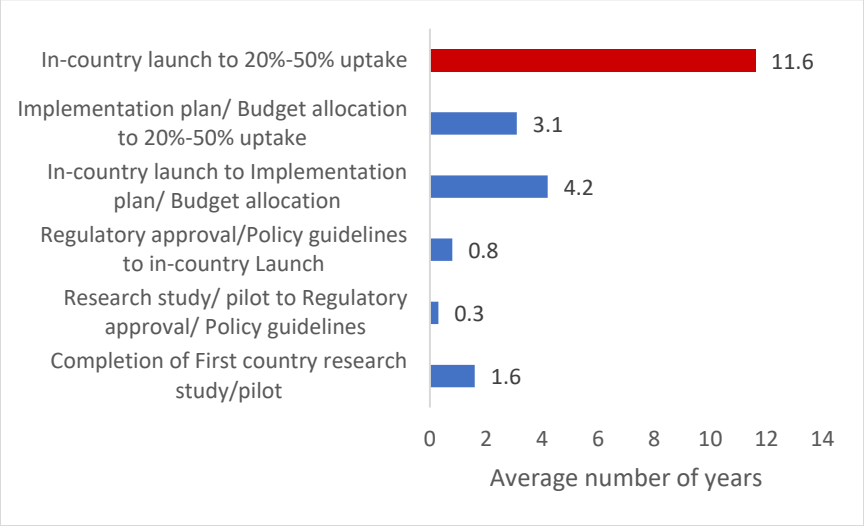
Figure 7. Timeline of milestones, by country and intervention



Source: Analysis of publicly available data on interventions by Speedometer team

Figure 8 shows the average time taken to reach critical milestones within countries based on the available data. Even with limited data, our analyses show that the time taken to initiate and complete country pilots or research studies for interventions is not very long, 1.6 years on average across countries and interventions. These research studies are needed to show evidence on the effectiveness and reliability of the intervention within each country, in addition to demonstrating evidence at the global level in order to secure WHO approval or inclusion in policy guidelines. Regulatory approval within countries usually seems to closely follow the completion of research studies/ pilots, taking about 4 months (0.3 years). After interventions receive regulatory approval, it takes about 9 months (0.8 years) to be launched in a country. So far, these earlier milestones do not seem to be significant bottlenecks that delay the launch of interventions within countries.

Figure 8. Average time taken to reach milestones at country level



Source: Analysis of publicly available data on interventions by Speedometer team

However, it takes much longer to prepare for and reach even 20% scale in countries after their launch. Including an intervention as a budget line item or developing an implementation plan for rollout of the intervention, both essential steps for scale and sustainability, take an average of 4.2 years, after which it could take another 3.1 years for the intervention to reach at least 20% scale. On the other hand, it takes over 11 years for an intervention to reach 20% scale after it has been launched in country, highlighting the significant lag in getting an intervention to reach large numbers of populations in need even after it has received regulatory approval and recommendations in policy guidelines.

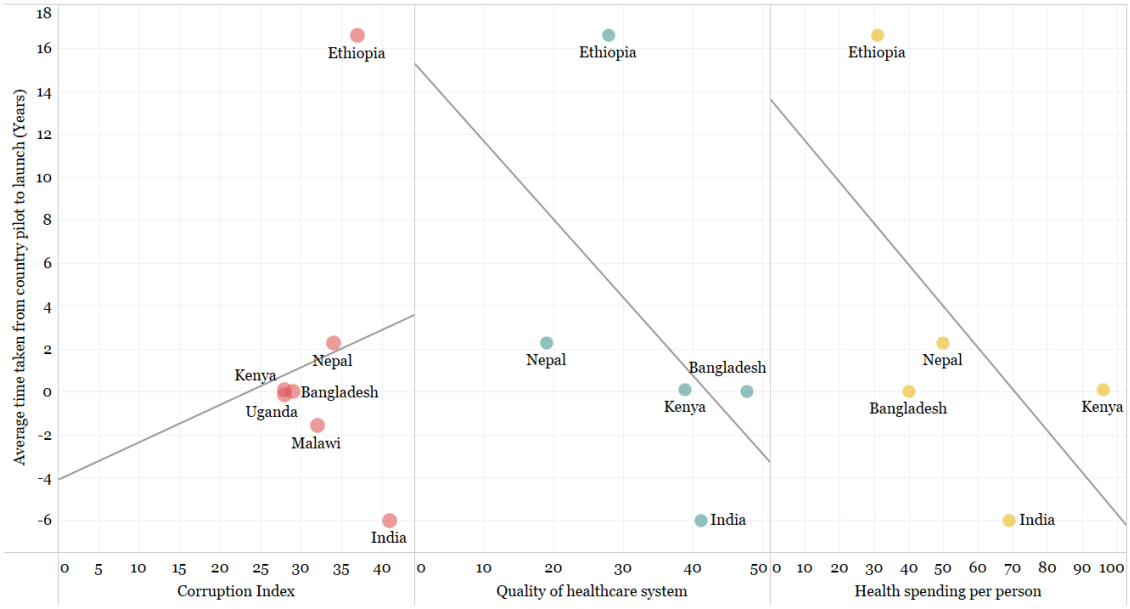
4. How is country context related to launch and scale within countries?

SUMMARY OF KEY FINDINGS

- *Contextual characteristics within countries affect both launch and scale of interventions.*
- *Extent of corruption, quality of healthcare system, and per capita spending on healthcare in country affect time taken to launch interventions within countries.*
- *Extent of corruption and per capita spending affect time taken to scale interventions within countries.*

Country characteristics, representative of the health, economic, and social contexts of countries, are associated with the time it takes for interventions in those countries to launch and scale. We examined three main characteristics for the countries in our analyses: corruption index, quality of healthcare system, and per capita healthcare spending, retrieved from Transparency International and Institute for Health Metrics and Evaluation (IHME). In Figure 9, we find a positive association between corruption index and the time taken for an intervention to progress from in-country pilot to launching within country. Corruption index varies from 12 to 45 across countries included in our sample. For countries with corruption index greater than 30, the average time taken from pilot to launch is 2.8 years. On the other hand, where corruption index is less than 30, the average time from pilot to launch is close to zero. Quality of healthcare systems and per capita spending on healthcare are both negatively associated with the time it takes for an intervention to move from pilot to launch within countries.

Figure 9. Average time taken from Country Pilot to Launch by Country Characteristics

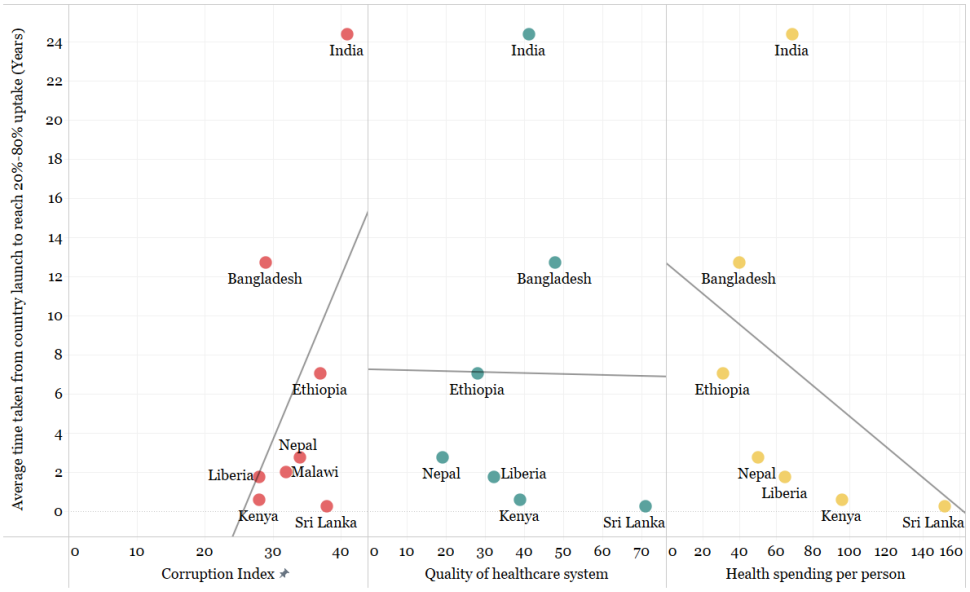


Source: Analysis of publicly available data on interventions by Speedometer team

In examining the association between country context and scale in Figure 10, we again find a positive association between corruption index and the time it takes for an intervention to progress from launch to scale, and a negative association between health spending and time taken from launch to scale. Our data shows no association between quality of healthcare systems and the time taken from launch to scale.

Although these results are not significant, primarily due to the small sample size and availability of data, they are indicative of overarching trends we would expect to see, underscoring the importance of strong health systems and solid governance in creating an enabling environment for interventions to progress through critical milestones.

Figure 10. Average time taken from Country Launch to Scale by Country Characteristics



Source: Analysis of publicly available data on interventions by Speedometer team

5. How are milestones at the global level related to country-level milestones?

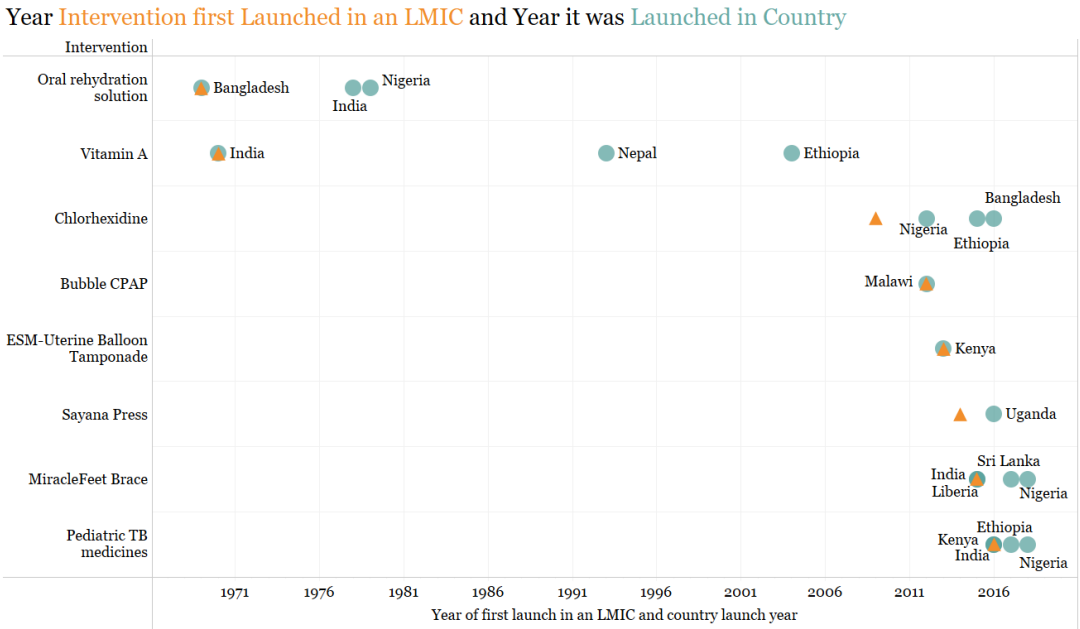
SUMMARY OF KEY FINDINGS

- *Launching a newer intervention in the first LMIC generates momentum for subsequent launches in other countries.*
- *Endorsement from WHO is increasingly important for interventions to launch in country.*
- *However, WHO approval is not sufficient to reach even 20% scale within countries; developers and implementers need to work with country-level stakeholders from the early stages of development to ensure sustainable take-up of their interventions.*

In this set of analyses, we examined how reaching milestones at the global level are related to critical milestones at the country level for different interventions. Figure 11 shows the time to launch an intervention in different high-priority countries selected for our analyses after being introduced for the first time in any LMIC. For some of the newer interventions (chlorhexidine, Miracle Feet braces, and pediatric TB medicines), first launch of the intervention has generated momentum for successive and rapid launches in other countries. The average time lag between the first launch and subsequent

launches in other LMICs was 2.3 years for chlorhexidine, 1.5 years for Miracle Feet braces, and 1 year for pediatric TB medicines. On the other hand, it took decades for VAS to be introduced in other countries after first launching in India in 1970: VAS was launched in Nepal 23.3 years after launching in India in 1970, and in Ethiopia in another 10.8 years. Our data show that bubble CPAP and ESM uterine balloon tamponade have not launched in any of the countries in our analysis other than Malawi and Kenya respectively.

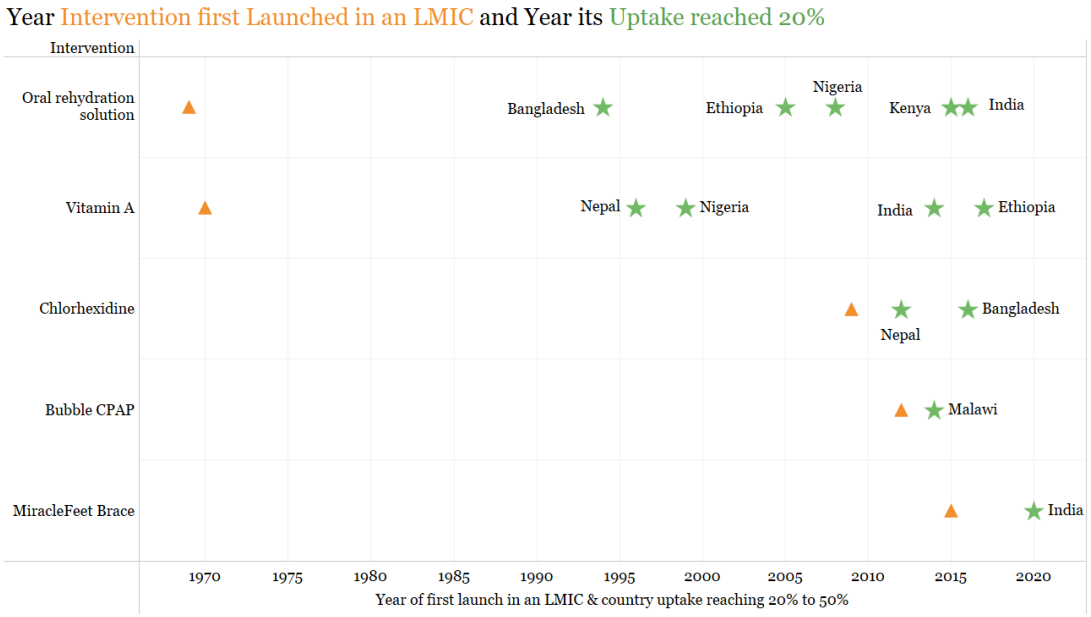
Figure 11. Year Intervention first launched in any LMIC and Year it launched in a specific LMIC country



Source: Analysis of publicly available data on interventions by Speedometer team

Figure 12 shows how long it takes an intervention to scale to at least 20% in other countries after its first launch in any LMIC. We note a distinct pattern for the two notable interventions that were launched in the 1970s relative to newer interventions. ORS and VAS, which launched in the late 1960s and early 1970s reached 50% and 20% scale decades later. On the other hand, the time to scale for interventions launched more recently seems to have shortened, but it should also be noted that few have reached 20% scale in more than one country. For instance, chlorhexidine took 3.0 years to scale to over 20% (in terms of districts with availability and population in need reached) after being introduced in 2009 in Nepal. After its first launch in 2015 in India, Miracle Feet took 2 years to scale to over 80% in Sri Lanka (in terms of use by population in need) as well as in Liberia (in terms of use by population in need).

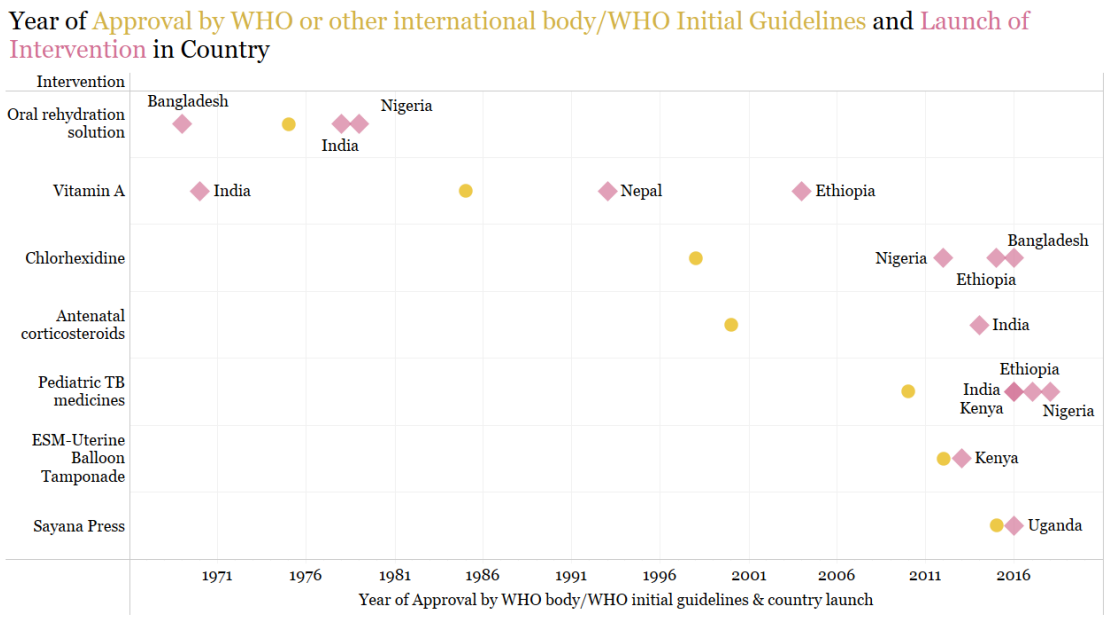
Figure 12. Year Intervention first launched in an LMIC and Year it scaled to at least 20% in different countries



Source: Analysis of publicly available data on interventions by Speedometer team

In Figure 13, we highlight how long it has taken for interventions to launch in different countries after receiving any sort of global endorsement, approval, or policy recommendation from the World Health Organization (referred to as "WHO approval" in this paper). Older Interventions such as ORS and VAS did not go through the WHO approval process prior to launching in different countries. ORS was launched six years prior to receiving WHO approval, and VAS was launched 15 years prior to receiving WHO approval. After receiving WHO approval in 1975, ORS was launched in Nigeria in 1979; VAS was launched in Nepal in 1993 and Ethiopia in 2004 after receiving approval in 1985 among the countries studied. Chlorhexidine received WHO approval in 1998, but it took 14 years to first launch in Nigeria after approval. Antenatal corticosteroids, first approved in 2000, launched in India 14 years after. Taken together, among the interventions studied, securing WHO approval at the global level did not subsequently result in faster launch trajectories in countries of need.

Figure 13. Year of Approval by WHO/other global procurement body or Year WHO initial guidelines were updated and Year of launch of intervention in country



Source: Analysis of publicly available data on interventions by Speedometer team

Newer interventions show a different trajectory, suggesting that endorsement from the WHO is an accelerant in the launch of interventions in recent years. Six years after receiving WHO approval in 2010, pediatric TB medicines were first launched in 2016 in Kenya, and were then launched in quick succession in other countries, including India, Ethiopia, and Nigeria, among the countries that we studied. Devices such as ESM uterine balloon tamponade and Sayana Press moved much faster after WHO approval, taking only around one year to launch in different countries after WHO approval.

Figure 14. Year of Approval by WHO/other global procurement body or Year WHO initial guidelines were updated and Year country uptake reached at least 20%

Source: Analysis of publicly available data on interventions by Speedometer team

Figure 14 shows the time it has taken interventions since receiving WHO approval to reach a minimum of 20% scale in various countries where data is available. Even with WHO approval, ORS took 19 years to first scale to 20% in a country; VAS took 10 years; chlorhexidine 14 years; and pediatric TB medicines nearly 7 years. Taken together, Figures 13 and 14 highlight that while it is increasingly important to receive WHO approval in order to launch an intervention in countries, WHO approval is not enough and has not translated into shorter times to reach scale. These findings underscore the importance of unlocking country-specific factors by developers and implementers to reach scale after launching in countries. Very often, preparation for scale must happen within countries prior to and in tandem with planning for launch of the intervention.

6. Findings from analysis of scale data in countries and at the global level

SUMMARY OF KEY FINDINGS

- *Scale is not uniformly and consistently defined across health priorities. Additionally, what constitutes reasonable scale or coverage varies by intervention.*
- *Data on scale are sparse, both due to the lack of data availability and because several interventions have not accomplished scale within countries as highlighted in earlier sections.*
- *Bundling of interventions such as Vitamin A supplementation with national immunization programs helped to achieve initial scaling success. However, disruption in these campaigns due to lack of funding and poor integration of the delivery of VAS into regular health systems, particularly universal immunization programs have inhibited sustainable scale among populations in need.*

Table 4 provides a list of the countries and interventions for which we analyzed scale data based on three parameters:

1. Demand-side scale measured by the proportion of target population in need using intervention or to whom intervention has been distributed
2. Supply-side scale measured as one of the following:
    a. Proportion of target population in need covered by units of intervention procured
    b. Availability of intervention in LMICs where it is needed (or in subnational units where it is needed)
    c. Purchase (or sales) amount for an intervention out of target amount set aside for the intervention globally or nationally
3. Existence of national or sub-national policy supporting or recommending the intervention in policy guidelines.

Table 4. Countries included in scale analyses, by intervention

Country	Antenatal corticost.	Bubble CPAP	Chlorhexidine	Miracle Feet	ORS	Ped TB medicines	Sayana Press	ESM UBT	VAS	Total
Bangladesh			•		•					2
Burkina Faso							•			1
Egypt									•	1
Ethiopia	•		•		•	•	•		•	6
India	•		•	•	•	•			•	6
Kenya		•			•	•		•		4
Liberia				•						1
Malawi		•								1
Nepal			•						•	2
Niger							•			1
Nigeria		•	•	•	•	•			•	6
Pakistan	•									1
Senegal							•			1
Sierra Leone								•		1
South Sudan								•		1
Sri Lanka				•						1
Tanzania	•	•								2
Uganda							•			1
Total	4	4	5	4	5	4	5	3	5	39

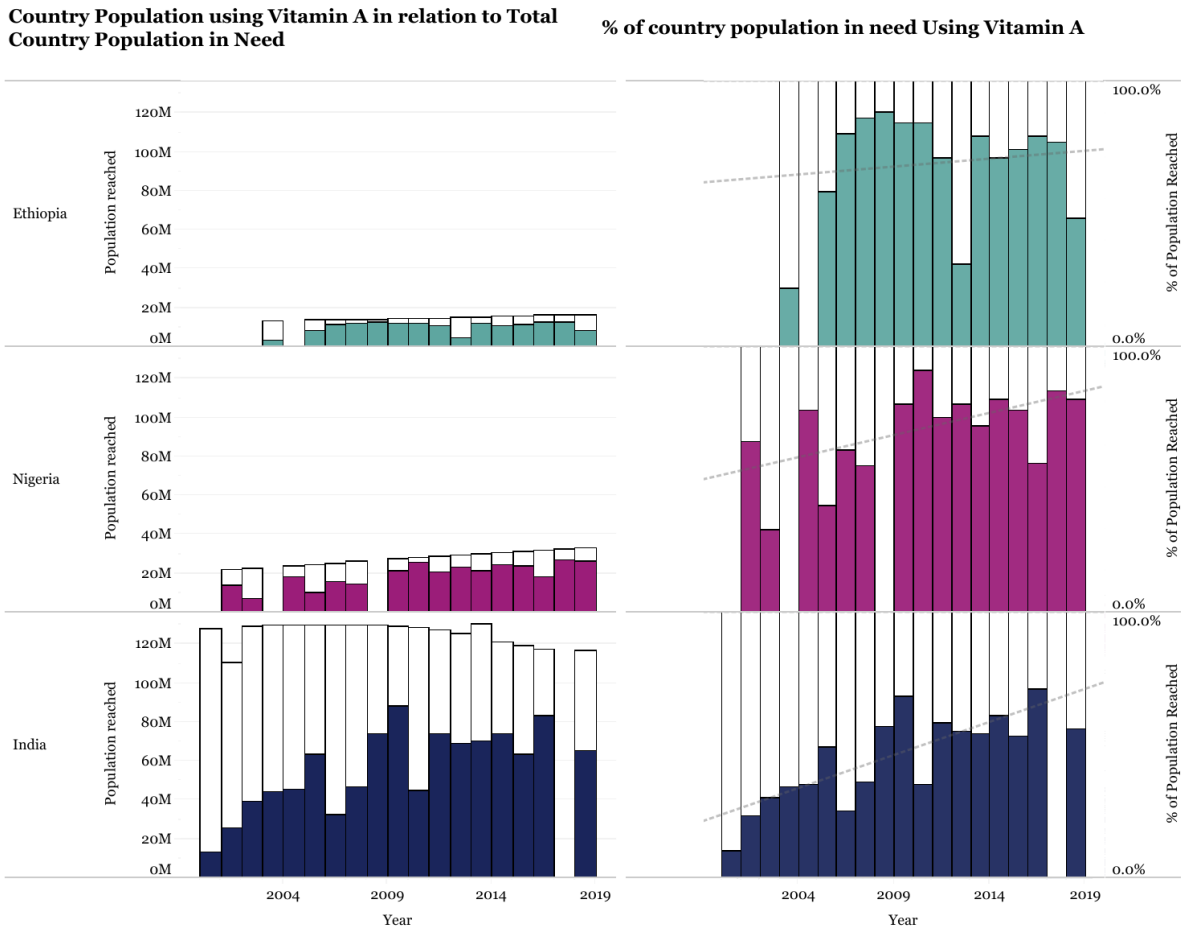
Source: Compilation of countries and interventions with scale data by Speedometer team

We obtained scale data on one or more of the measures described above on 9 interventions from 18 countries. However, even with multiple ways to measure scale, data on scale are sparse, not only due to the lack of data availability but also because several interventions have not accomplished scale within countries as highlighted in earlier sections. Ethiopia, India, and Nigeria, being priority countries, have more scale data as we targeted our efforts to getting high-quality data from both primary and secondary sources.

VAS and ORS, being the oldest interventions, have relatively more scale data than other interventions that have not yet scaled or do not have reliable data. In Figure 15, we examine the demand-side

coverage of VAS across the three priority countries. Specifically, the scale measure used in Figure 15 represents the target population of 6-59 month old children in need of VAS that is receiving the two-dose supplement in Ethiopia, Nigeria, and India. In terms of particular countries, VAS scale up is steadily progressing in Nigeria and Ethiopia, relative to India. However, India has staggeringly higher numbers of at-risk children needing VAS, despite being the first country to launch VAS in 1970. India's large population of young children in need, combined with its weak health infrastructure have largely contributed to its national VAS program becoming unsuccessful in recent years.

Figure 15. Country population (numbers and percent) using VAS in relation to total in-need population



Source: Analysis of publicly available data from UNICEF9 and Our World in Data[10]

[9] UNICEF data on VAS accessed from https://data.unicef.org/resources/data_explorer/unicef_f/?ag=UNICEF&df=GLOBAL_DATAFLOW&ver=1.0&dq=.DM_POP_U5+DM+NUTRITION+NT_VAS_TWODOSE.&startPeriod=2018&endPeriod=2021 on 15 October, 2021.

[10] Data on 6-59 month old children in need accessed from Our World in Data at https://ourworldindata.org/indias-population-growth-will-come-to-an-end#licence on 15 October, 2021.

Two notable champions, Nutrition International and UNICEF lead the advocacy, funding, and procurement of VAS globally and within countries. UNICEF has made its scale data publicly available and accessible, whereas Nutrition International is moving towards making this information public. At the time of this report, data from Nutrition International was not publicly available.

Since 2000, VAS availability increased considerably due to the integration of VAS delivery with national immunization programs. However, disruption in these campaigns due to lack of funding and poor integration of the delivery of VAS into regular health systems, particularly universal immunization programs have inhibited high coverage rates.

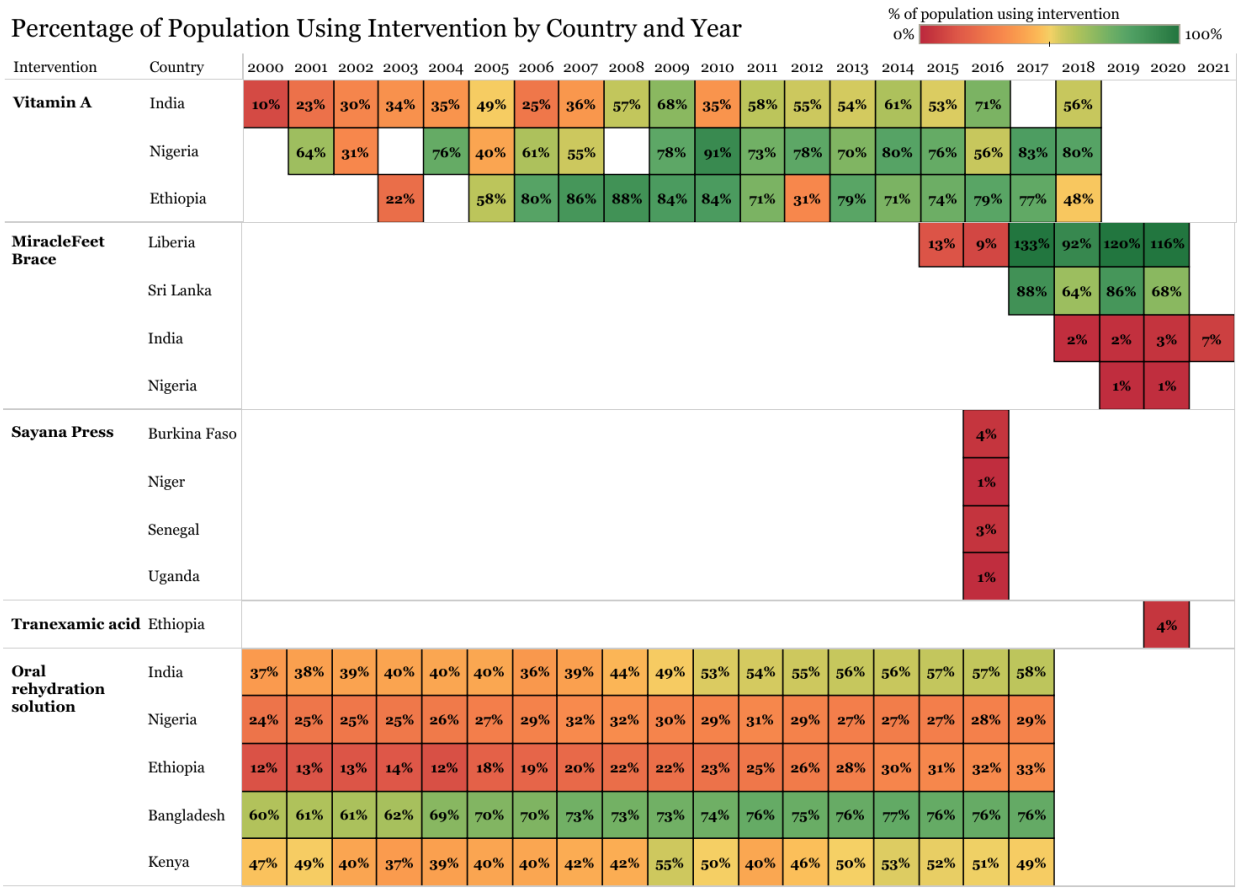
Figure 16 expands the number of interventions with population-level use data for countries where data are available since 2000. Scale data using this measure merely highlights the data we have been able to obtain from reliable public sources (for e.g., VAS and ORS) and/or directly from the developer (Miracle Feet braces). White cells indicate that data were not available for those years in the countries we included for analysis.

Additionally, the numbers for VAS are obtained from publicly available data from UNICEF alone; however, Nutrition International supplies close to 75% of the world's need for VAS. At this time, we do not have complete data from Nutrition International; but Nutrition International will be making their data publicly available, after which we will update our analyses posted on the Launch and Scale Faster website.

Available data for ORS show an overall increase in population-level use among 0-5 year olds for the countries highlighted in Figure 16. Given its long history and strong advocacy by country champions such as ICDDR-B, ORS has achieved over 75% coverage by 2017 measured by use among population in need in Bangladesh, progressing steadily since 2000. ORS has also scaled in India, but reached only 58% coverage in 2017, despite being an early adopter along with Bangladesh. ORS use in Kenya has remained steady under 50% with modest fluctuations between 2000 and 2017. Use in Nigeria and Ethiopia, while generally increasing, is lower than in other countries, reaching 29% coverage in Nigeria and 33% coverage in Ethiopia in 2017.

Other interventions studied do not have data on population-level use other than for certain years. Miracle Feet braces are used widely in Liberia; use of their braces to treat clubfoot among 0-3 year olds is over 100%. Although braces for clubfoot are usually prescribed for children under 3 years, in Liberia, given the high prevalence of clubfoot among children, braces are being ordered and used for children older than 3 years. As a result, use of clubfoot braces is higher than the population of 0-3 year olds in need. Miracle Feet has not yet been able to estimate the population in need in Liberia among older children, resulting in coverage (seemingly) exceeding 100%.

Figure 16. Percentage of population using intervention by country and year

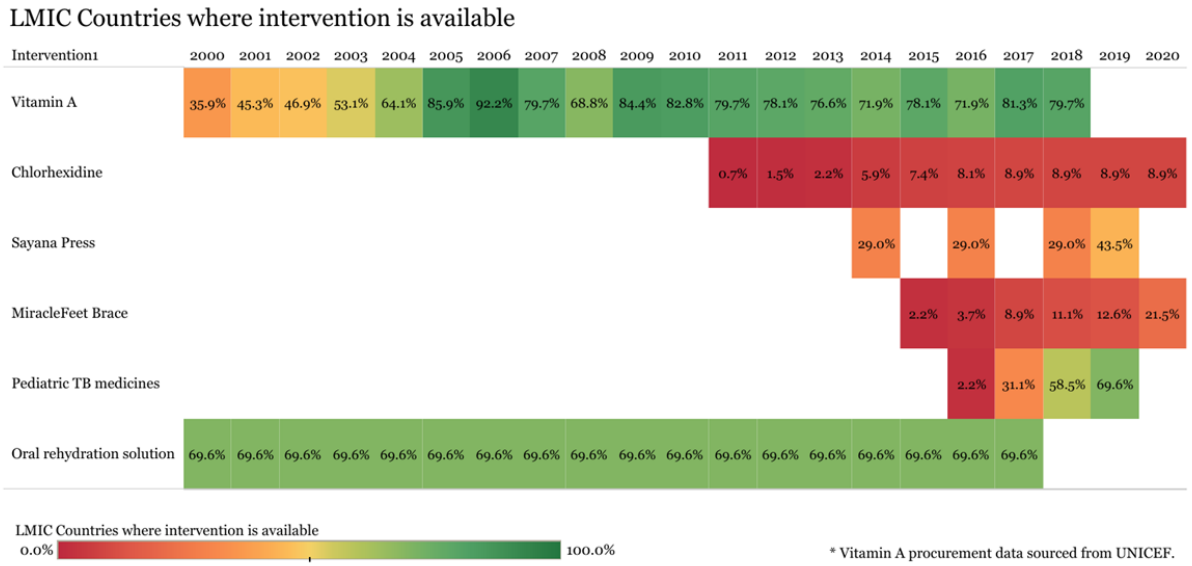


Source: Analysis of publicly available data on Vitamin A (UNICEF), Sayana Press, and ORS by Speedometer team. Miracle Feet braces data from interviews with Miracle Feet team.

Figure 17 displays the proportion of countries in need with data on availability of interventions (supply-side indicator). For VAS, UNICEF and NI have identified 64 countries as priority countries for targeting VAS among 6-59 month olds. Data on availability of VAS from UNICEF globally show fluctuation for the period studied, steadily increasing from 2000 to 2006, decreasing and then fluctuating after that until 2017. Despite these fluctuations, VAS has been available in at least 54 out of the 64 priority countries (70% availability globally) since 2008.

Availability of chlorhexidine across countries also increased initially from 2011 until 2017. Our data show that since 2017, chlorhexidine has been available in 12 countries. For chlorhexidine, Miracle Feet, ORS, and pediatric TB medicines in Figure 19, the denominator refers to all LMICs as per the classification provided by the World Bank.

Figure 17. LMIC Countries where intervention is available

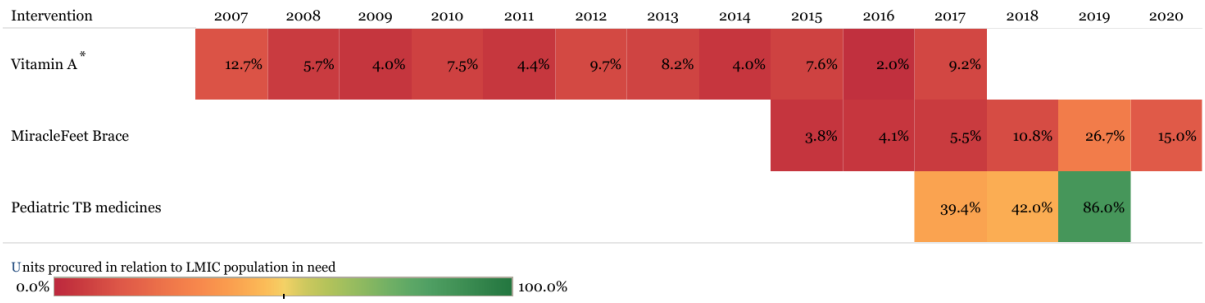


Source: Analysis of publicly available data on Vitamin A, Chlorhexidine, Sayana Press, Pediatric TB medicines, and ORS by Speedometer team. Miracle Feet braces data from interviews with Miracle Feet team.

Priority countries for Sayana Press are those identified for targeting by Family Planning 2020. Data are available for 4 years, showing that the intervention has been available in 20 out of 69 priority countries in 2014, 2016, and 2018, increasing to 30 in 2019. Availability of Miracle Feet braces increased ten-fold from 3 to 29 LMICs between 2014 to 2020. Similarly, availability of pediatric TB medicines globally increased dramatically in a very short time, from 3 to 94 countries between 2016 and 2019. The number of countries in which ORS is available has remained constant throughout the period that we studied, at 94 out of 135 LMICs between 2000 to 2017.

Figure 18 shows the proportion of units procured to address the needs of the target population for different interventions with available data. Procurement of VAS doses by UNICEF alone shown in Figure 20 has addressed between 2% and 12% of the total LMIC population in need. These data need to be supplemented with doses procured by NI and will be updated with new information when they become available on the Launch and Scale Faster website. Miracle Feet braces posted steady increases in addressing its target population needs for braces from 2015 until 2019, but then declined significantly in 2020. Pediatric TB medicines have dramatically increased its coverage of target population needs in just three years, reaching 86% of the pediatric population in need in 2019, starting from 39% only in 2017.

Figure 18. Number of units of intervention procured in relation to LMIC population in-need



Source: Analysis of publicly available data on Vitamin A and Pediatric TB medicines by Speedometer team. Miracle Feet braces data from interviews with Miracle Feet team.

DISCUSSION

We set out to create a common framework to measure and analyze the timelines and key factors that drive launch and scale across different MNCH interventions. We presented findings based on the sample of interventions and countries used in our analysis. Results of this exercise highlight the glaring gaps in the availability and quality of data needed to map and synthesize critical factors including challenges, barriers, and enablers to accelerate the pathway of interventions from development and proof of concept to introduction and scale-up. In this section, we provide a synthesis of key findings from these and other analyses by the Speedometer team to inform future priority-setting and action by stakeholders in this space.

At the global level, older interventions such as ORS and VAS have taken significantly longer to progress through critical milestones. On the other hand, progress among some of the newer interventions, although uneven, has been faster. In general, interventions have progressed more rapidly since 2010, signaling a faster pace of research and regulatory approval processes in the recent decade. Country contextual factors can also serve as important enablers or barriers to both launch and scale of interventions. Not surprisingly, corruption slows the pace of launch or scaling, whereas countries with stronger healthcare systems and greater healthcare expenditures can expedite the introduction and scale-up of interventions.

In reviewing the common characteristics of older and more recent interventions, we note that the lack of coordination and planning among global stakeholders in the early stages of interventions such as ORS, VAS, and magnesium sulfate delayed their introduction and scale-up. Interventions such as pediatric TB medicines also faced significant challenges in gaining traction in the global community during the initial stages when the market size for pediatric TB patients was unclear (see Speedometer case study on pediatric TB medicines). However, having a strong influential champion (TB Alliance) to coordinate and marshal the support of several leading international development organizations (including WHO, USAID, The Global Fund for AIDS, TB, and Malaria, UNITAID) led to the prioritization of pediatric TB and to a

better mapping of the market demand for its treatment. Not only was the medicine launched in Kenya in October 2016, less than a year after the treatment was available for purchase in December 2015, it was subsequently launched in 62 countries in 2017 with strong technical support from the Global Development Fund (GDF).

Our findings indicate that it takes time to prepare for scale and then subsequently reaching sustainable scale-up. Drawing on our quantitative and qualitative analyses, we note that influential champions are needed to engage with global and local stakeholders to minimize bottlenecks and pave the way for a supportive ecosystem for launch as well as scale. Planning for scale requires the advocacy of prominent champions to mobilize resources and facilitate the convening and collaboration of diverse stakeholders around shared priorities.

Finally, we note that in light of the data challenges as well as slow progress of critical interventions to address maternal and child health challenges, the Launch and Scale Speedometer initiative can serve both as an impartial agent for evidence generation and as a platform for data sharing and collaboration. As an extension of the IDIA scaling framework, the Speedometer framework and database can serve to build and aggregate evidence on the launch and scale of important lifesaving interventions and support data-driven decision making to accelerate their scale-up to places and people that need them the most. As a repository for data sharing, the Speedometer initiative can convene leading stakeholders at the intervention, country, or global levels to create action plans, roadmaps for sustainable scale, and advocacy platforms and elevate global and national priorities to reduce the inequities in global maternal and newborn health.

KEY RECOMMENDATIONS AND NEXT STEPS

Based on the findings from our research, we highlight key areas of recommendations for funders, policymakers at national and country levels, and intervention developers and implementers.

A. **Call to action for data.** Global health and development organizations should prioritize the collection and public sharing of data to inform strategies to address pressing MNCH and other global health challenges. Our research has highlighted that data on the launch and scale trajectories of critical MNCH interventions both within and across countries are highly variable in quality, availability, and consistency of definitions. Unless the research and policy communities have credible data to understand how interventions grow and succeed, progress on ensuring that lifesaving interventions reach populations in need faster will continue to be scattershot, unreliable, and inconsistent. Communities of developers, implementers, private sector, and NGOs must begin to track data on their development, implementation, and distribution efforts to feed into a common, public platform that will enable the creation of a data repository. These data collection activities will be particularly important at the country level due to the limited data available to understand the factors that catalyze or delay launch, adoption, and scale. Furthermore, collecting appropriate data nationally and sub-nationally can also highlight areas and populations still in need that are not equitably receiving the benefits from lifesaving interventions.

B. **Funding programs and policymakers must develop clear, standardized global and country milestones to benchmark the uptake of interventions.** Standardized milestones will allow for targeted action by appropriate stakeholders to speed up phases of proven interventions as in the case of pediatric TB medicines, while maintaining realistic timelines and targets for those that are yet to show promise, such as antenatal corticosteroids. The IDIA scaling framework has taken an important step in this direction in specifying high-level stages of growth for an intervention, as well as key enablers and barriers. The Launch and Scale Speedometer analytical framework has operationalized the conceptual mapping laid out by IDIA and provided useful milestones and indicators of progress to funders, country and global policymakers, developers, and implementers that can be standardized for collective action and greater impact. Having a common language around launch and scale pathways with standardized definitions for indicators can help to pave the way towards setting milestone-based targets as well as monitor progress against targets. Together, strong data and a standardized framework would facilitate greater analysis of timelines to critical milestones, provide guidance for course correction for specific interventions, and improve the speed at which interventions are being deployed to save lives.

C. **Developers must engage and work with country stakeholders early to plan and prepare for scale.** Our research shows that while preparing for scale is often the longest in the launch and scale pathway, activities in this stage are not as clearly defined as other milestones that also take time, such as establishing proof of concept. With several activities needed in preparation for scale for an intervention, such as inclusion in a National Essential Medicines List, development of national policy guidelines and implementation plan, and allocation in national budget, there is a need for strong stakeholder engagement and buy-in and adequate time to complete these activities appropriately. Although not part of this analysis, activities at the ground level in preparation for scale also include logistical planning such as supply chain forecasting, distribution channels, and delivery mechanisms, which are instrumental in ensuring that interventions reach populations in need and are administered appropriately. In addition to planning for launch activities, funders, development organizations, and implementers must work with national and sub-national policymakers at earlier stages to better understand local conditions in preparation for scale, secure buy-in for validated interventions, create a conducive environment for scale, and reduce the time lag between validation and scale.

APPENDIX

Appendix 1. Description of MNCH interventions studied

Intervention	Scientific Name	Commercial Name	Description
Tranexamic acid	1-(amino methyl)-cyclohexane-4-carboxylic acid (AMCHA)	Cyklokapron (Pfizer)	TXA is a competitive inhibitor of plasminogen activation and can reduce bleeding by inhibiting breakdown of fibrinogen and fibrin clots
Chlorhexidine	7.1% chlorhexidine digluconate solution	Chlorhexidine	A disinfectant that can be used to treat injuries and wounds to prevent infection. It is used globally to prevent infection and illness in newborns by treating the umbilical stump with chlorhexidine.
Bubble CPAP	Bubble CPAP	Pumani	Low-cost device to manage babies in respiratory distress
ESM™ Uterine Balloon Tamponade		The Every Second Matters for Mothers-Uterine Balloon Tamponade (ESM-UBT)	low-cost device that helps combat post-partum hemorrhage morbidity and mortality by stopping blood loss during hemorrhage
BiliChek	Bilirubin Monitoring BiliChek® Digital Readout	BiliChek System	Device that allows for the detection and assessment of jaundice in newborn babies without a blood draw. It uses light sensors to assess the serum bilirubin levels in the baby in minutes and can be operated by those with little medical training
Congo Red Dot Paper Test		Congo Red Dot (CRD) Paper Test	Simple urine test that shows both the presence and severity of preeclampsia based on the binding of misfolded proteins to Congo Red Dye
Pediatric TB medicines	rifampicin + isoniazid + pyrazinamide		A child-friendly fixed-dose combination treatment course for pediatric TB which quickly dissolves into liquid with a palatable fruit flavor
Vitamin A			Vitamin A supplementation involves treating all children aged approximately 6-months to 5-years in areas at high-risk for vitamin A deficiency with high-dose vitamin A supplements two or three times per year.
Sayana® Press	medroxyprogesterone acetate	DMPA-SC; Sayana Press with Uniject	An easy-to-administer injectable contraceptive that can be administered by an individual without medical training and prevents pregnancy for three months
Oral rehydration solution			A solution made up of water with modest amounts of sugar and salts, specifically sodium and potassium, that is used to prevent

			and treat dehydration, especially due to diarrhea.
MiracleFeet Brace		MiracleFeet Brace	A low-cost, effective brace to treat children with clubfoot using the Ponsetti method
Moyo Fetal HR Monitor	electronic doppler monitor (both continuous and intermittent)	Moyo Fetal Heart Rate Monitor	Innovative and low-cost fetal heart rate (FHR) monitor that can accurately detect FHR within 5 seconds
Antenatal corticosteroids	Dexamethasone, Betamethasone, Betamethasone acetate, Betamethasone sodium phosphate	Bexamethason brand name = Celestone Soluspan	Antenatal corticosteroids are recommended for women who are in the 24 week to 34 week period of gestation are at risk for preterm birth. Antenatal corticosteroids are used to accelerate lung maturation and prevent respiratory distress syndrome on pre-term babies.
Magnesium sulfate	Magnesium sulfate		Anticonvulsant drug to prevent and treat eclampsia in pregnant women