MEASURING AND ANALYZING THE LAUNCH AND SCALE OF LIFE SAVING HEALTH INTERVENTIONS

A User Guide

LAUNCH&SCALE SPEEDOMETER

Duke GLOBAL HEALTH Innovation Center

Cover image: UNICEF Ethiopia/2022/Mulugeta Ayene

CONTENTS:

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Overview

The Launch and Scale Speedometer aims to accelerate the introduction and uptake of lifesaving health interventions, primarily products such as drugs, devices, diagnostics, and vaccines in low- and middle-income countries (LMICs), by developing evidence-based actionable insights about the timelines, enablers, barriers, and pathways taken by these interventions to reach and sustain reach to intended users.

The Duke Global Health Innovation Center (Duke GHIC) developed the Launch and Scale Speedometer framework to collect and analyze data to facilitate insights to accelerate the scaling of life-saving interventions. To date, the Speedometer program has collected data on over 50 interventions to understand their scaling timelines. This data and analyses are available on the Duke GHIC website (dukeghic.org). The Speedometer program has systematically analyzed the pathways, timespans, and influencing characteristics that accelerate the introduction and scaling of interventions. We intend for Speedometer resources and tools to be a global public good, and will continue to collect and analyze data to address the global need to accelerate scaling of life-saving health interventions. We hope that researchers, innovators, development organizations, and others will contribute to the database over time to increase its collective value.

The Speedometer achieves its goals by:

- Cultivating a community of global stakeholders to provide guidance to the work and build consensus on framework and metrics;
- Collecting launch and scale data and evidence—from proof of concept to global scale-up—on health interventions and developing a data clearinghouse as a public good; and
- Generating and sharing valuable insights and good practices to advocate for the acceleration of launch and scale of lifesaving health interventions and products at global and country levels.

Speedometer Data Collection and Analytical Approach

Through an iterative process of research, development, and validation, a common measurement framework was established to identify and track metrics along the pathway from discovery to sustainable scale for a variety of health interventions. Framework development centered around three guiding questions:

- *How long does it take to introduce and scale up health interventions?*
- *What makes the process of launch and scale faster or slower?*
- *What are the most important factors driving uptake at country and global levels?*

This user guide is intended to **support better measurement and understanding of the pathways and key factors** involved in the launch and scale of health interventions in LMICs. Different audiences may use the framework in various ways, for example:

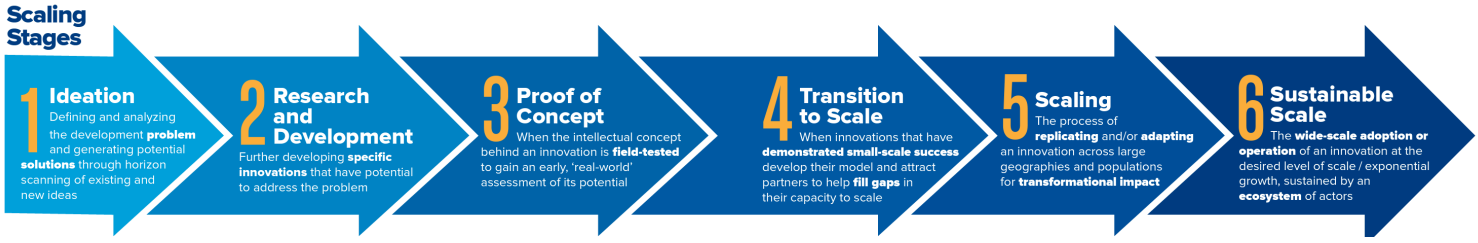
Researchers: data collection and analysis opportunities to facilitate improved understanding of the field of launch and scale of health interventions;

Funders: portfolio management and analysis opportunities to understand the time spans between ideation, research & development, proof of concept, transition to scale, scaling, and sustainable scale; and

Product developers: support for decision making by tracking pathways that interventions are taking, time spans, addressing common barriers and enablers in the design and introduction of new products, and considering diverse influencing factors during the launch and scale of interventions.

A variety of inductive and deductive methods were used in developing this framework, including prior work to benchmark innovation scale-up (Luthra et al., 2021; IVAC, 2016), discussions with experts in the fields of scaling and global health innovation, examining pathways across product categories, and evaluating existing scaling frameworks in relation to our goals (IDIA, 2017; USAID,2016; Barker, 2016). While specific stages described in the scaling framework literature vary in certain details, including where they start on the pathway, frameworks generally describe stages in the same sequential order. Stages include defining the problem, discovery and set-up, research and development, testing and launch planning, introduction and scale-up. In order to measure end-to-end timespans, it was important that the framework focus on the entire pathway to scaling from ideation and research and development through sustainable scaling, with milestones defined for each of the scaling stages. Milestones chosen for inclusion were mapped onto a prevailing scaling framework used in the broader global development sector – the International Development Innovation Alliance (IDIA) Innovation Scaling Framework – to anchor our work within the current industry understanding about the scaling process (Figure 1) (IDIA, 2017). The IDIA framework was best suited and easily adapted for this project because it provides a delineation of the scaling process from the original idea through scaling and uses standardized terminology that can be recognized across the broader development community (see definitions in Figure 1).

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



Applications of the Speedometer Framework

The Speedometer Framework is designed for both retrospective and prospective data collection, to consistently measure and effectively organize data around pathways of scaling health interventions. It offers point-in-time measurement for specific milestones and longitudinal measurement to look at the introduction and scale-up of an intervention over time, thereby facilitating greater awareness of the overall process. By applying the Speedometer Framework, funders, researchers, and product developers will be able to measure and analyze the specific pathways, timelines, and key factors associated with the scale-up of health interventions. Analyzing this information will generate key insights to pinpoint opportunities for maintaining or accelerating the introduction and uptake pathways of interventions.

The Speedometer Framework can be used to:

- Track and facilitate understanding of characteristics of enablers and obstacles to scale
- Benchmark milestones, timespans of activities, and comparisons across products
  - Understanding how fast (the speed at which) activities occur. Note that 'fast' is not necessarily better, but understanding timelines of launch and scale gives an idea of how long it may take an intervention to reach end users.
- Enable investment scoping and selection
- Provide portfolio view and measurement of launch and scale
- Assist planning and monitoring of intervention introduction and uptake
- Measure longitudinal scale-up
- Support retrospective and prospective evaluation of end-to-end scaling journey
- Support product designer and implementing agencies in their design of new innovations that take account of delineated barriers (or enablers) in the design process and implementation plans

This Framework presents an opportunity to donors, product developers, and researchers to understand and track the scaling pathways of health interventions – either individual interventions or comprehensive portfolios. While audiences may be interested in a unique phase of the scaling pathway, this Framework can provide an informational bridge and feedback loop for the complete end-to-end pathway of launch and scale. Prospective data collection approaches can track "growth" of a portfolio of interventions, capturing the launch and scale pathways of both successful and unsuccessful interventions. Retrospective data collection can offer insight to benefit new products, accelerating progress at

Arne Hoel/World Bank

lower cost. Additionally, this Framework offers a unique opportunity to closely connect with key stakeholders at the data collection stage and generate real-time actionable insights to affect the launch and scale process. Reflecting this use, real-time insights were able to be drawn from the aggregation of COVID-19 vaccine purchasing data by countries thus helping identify disparities in purchases, which, given the initial manufacturing constraints showed supply being sent to high-income countries over low-income countries. Based on the results of this analysis, subsequent data collection focused on vaccine donations, leveraging the data to call attention to vaccine purchasing and distribution inequities (Taylor, Biru, & Udayakumar, 2022).

Additional collective value will be developed through contribution and aggregation of additional data over time, enabling more robust analyses to provide key insights to accelerate scaling of life-saving interventions.

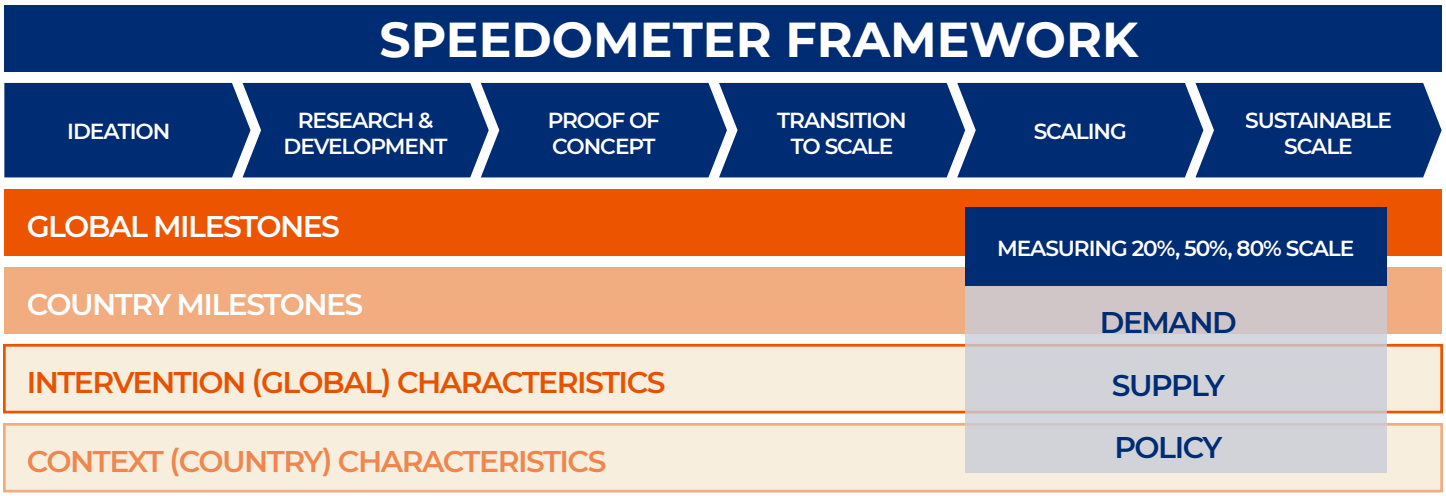
About the Speedometer Framework

Framework Organization

Using the anchoring elements of the IDIA Framework, the Framework is organized according to the six categories of scale starting with ideation, research & development, proof of concept, and moving towards transition to scale, scaling, and ending with sustainable scale (Figure 2).

Within each of these categories, global and country-specific milestones and characteristics have been identified as key metrics representing achievement of that category along the pathway. Additional measures of scale-up are also included to support the understanding of longitudinal uptake at 20%, 50% and 80% from the demand, supply and policy lens.

Figure 2. Launch and Scale Speedometer Framework



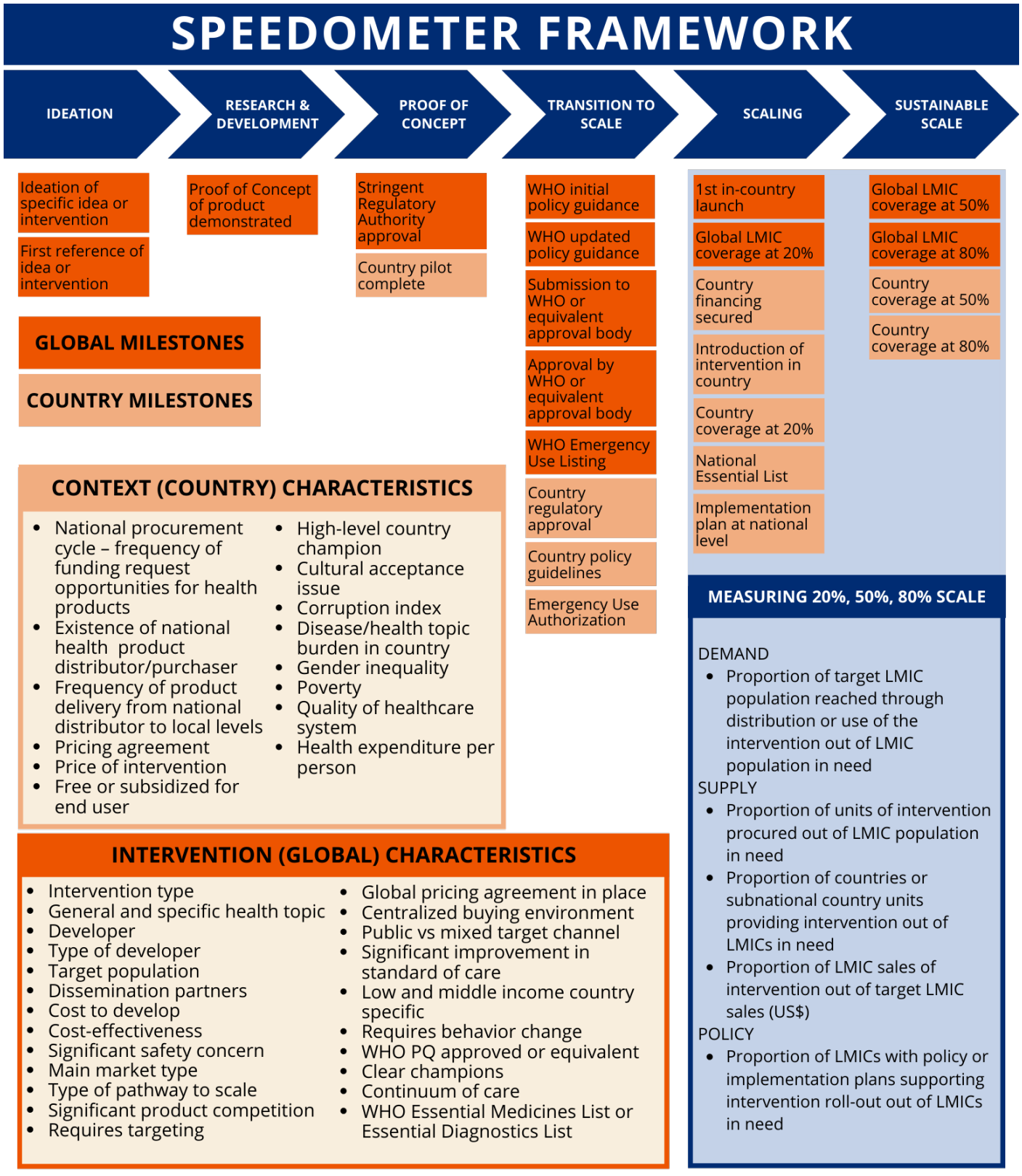
Framework Components

GLOBAL MILESTONES: global-level milestones capture the timing of important steps that interventions take through the scaling pathway. Steps are inclusive of the date of original idea (Ideation), through stringent regulatory approvals, first country launch, and include date that global scale reaches various coverage levels (20%, 50%, and 80%). Not all interventions will have dates for milestones along the pathway, for instance, Stringent Regulatory Authority (SRA) approval is not needed for all products, such as Class I medical devices. Additionally, milestones may not all happen in a linear order—launch, for instance, could come before a policy recommendation. For example, there may be strong evidence for the use of an intervention in improving health, but policy guidelines such as those produced by the World Health Organization (WHO) may only be released every five or ten years. Thus, launch of an intervention may predate a policy recommendation.

CHARACTERISTICS: global and country-level characteristics are defined as the factors that may influence launch and scale timelines and pathways. They may be related to the intervention itself, such as type of intervention (vaccine, drug, etc.) or type of developer (not for profit, for profit, academic, etc.). Characteristics may also be identified at a context level, such as health system quality or disease burden in a specific country or market.

SCALING METRICS: scaling metrics are included to measure longitudinal uptake at 20%, 50% and 80% of the intervention across all LMICs and/or within specific countries. These measures include indicators of demand (e.g., use of the intervention by target populations), supply (availability or procurement of the intervention), and policy inclusion.

Figure 3. The Launch and Scale Speedometer Framework, detailed



Data Collection Process

Having established the structure of the Speedometer Framework, we now have the means to measure launch and scale of health interventions. The data collection process is broken down into steps that define the desired goal of data collection, and provide guidance on collection, management, and analysis of the data. Note that identifying plans for the collection of both quantitative and qualitative data will be important.

SUMMARY OF DATA COLLECTION STEPS

1. Identify the purpose of data collection and define the scope
2. Define the interventions for study
3. Data collection structure
4. Data collection
5. Validation and quality control

step 1 Identify the purpose of data collection and define the scope

The first step is to understand what overarching health topics or interventions will be analyzed: are they products your organization has developed? Products a donor is interested in? Are they specific disease areas of interest? Although this rationale may evolve, it will be helpful to have an understanding of what exactly you want to achieve through this data collection. This initial scoping will help you make decisions about the types of questions you want to answer through this analysis, who the audience is for the insights, on what types of interventions you want to collect data (e.g., vaccines), what countries or regions are important, or health topics you want to focus on (e.g., maternal, newborn, child health).

> **Example**: Scope of the research may focus on vertical program interventions (e.g., malaria), type of audience (e.g., private sector or academia), or you may want to focus on specific health topics or populations such as women and children.

step 2 Define the interventions for study

GiveWell/2011

The Speedometer Framework is designed to study health interventions or products, such as vaccines, medicines, diagnostics, and medical devices. In Step 2, identify the specific interventions for analysis. Depending on the scope outlined in Step 1, the intervention may be a specific formulation of a medicine, or type of product (e.g., a dispersible formulation, the newest generation of a diagnostic, or a series of products addressing the same problem). You may also study a group or portfolio of interventions.

QUESTIONS TO CONSIDER WHEN SELECTING YOUR INTERVENTIONS MAY INCLUDE:

What generation of the intervention do you want to research? There may be multiple generations of the same product. This is where understanding the use of your collected data is important. Are you interested in the first use of a product? The evolution of the product? Only the most recent generation of the product? Or the pathway across all generations, from initial to current, to understand the evolution of scaling of generation of products over time?

***For example**, the tuberculosis diagnostic assay, Xpert MTB/RIF, is the original version of the Xpert MTB/RIF Ultra diagnostic. It is important to define which one is preferred for study, if not studying the overall evolution of this diagnostic. Each version of a product has different milestones, characteristics, and scaling data.*

If you are studying medicines, what formulation do you want to research? The first formulation of a medicine may have been developed with a specific dose and in a specific form, but subsequent formulations may have changed to become dispersible or require different dosages.

***For example**, Artemether/lumefantrine tablets are medications to treat malaria. A dispersible version was made available as a more pediatric friendly treatment option. Understanding the landscape of pediatric friendly formulations for malaria, for example, would be beneficial to understand penetration of current pediatric formulations which may yield insights on potential reach and effectiveness of newer pediatric formulations.*

Does the developer of the intervention matter? If you wish to understand the pathway to the first launch of an intervention, then you may look at a specific intervention from a specific developer. Alternately, you may want to understand how the launch of the same intervention (e.g., a generic medicine of the same dose and formulation, or a product like long-lasting insecticide-treated bed nets) compares across different developers.

Figure 4. Example of intervention classification

Health Topic	Intervention	Drug	Diagnostic	Device	Vector Control
Infectious Disease					
Tuberculosis	TB Molecular DX (Xpert MTB)		•	•	
Malaria	Long Lasting Insecticidal Nets				•
	Tafenoquine	•			
HIV	Pratt Pouch			•	
	PrEP	•			
	HIV Self Test		•		
HPV	Pocket Colposcope		•	•	
Maternal, Newborn, Child Health					
Family Planning	Sayana Press	•			
Neonatal Care	Chlorhexidine	•			
Disability	MiracleFeet Brace			•	
Neglected Tropical Disease					
Human African Trypanosmiasis	Tiny Targets			•	

step 3 Data collection structure

The Speedometer Framework is built around the goal of data collection and analysis. A data entry form offers an effective and efficient method to operationalize the Framework by bringing together all the elements of the Speedometer Framework.

CREATING A DATA ENTRY FORM FOR EACH INTERVENTION:

The data entry form should be organized according to the Framework with global and country milestones, characteristics, and coverage indicators. Not all indicators will be relevant depending on the scope defined in Step 1 and 2. Each intervention is intended to have its own individual template completed, thereby keeping each intervention's data separate from others. A combined form (removing source data to reduce visual clutter) is also possible to view the information collectively across interventions. Each column contains one data point (such as a date or a variable category), and includes a corresponding cell for the citation of the source of the data, link, type of source (quality), and a ranking of the confidence of the quality of the source (high, medium, low).

Data components collected for each milestone, characteristic, or scale measure

Source: the citation for where the data point was found. The full citation helps us track where data was found and is important in case web links stop functioning.

Link: the link for where the data point was found.

Quality: the type of source the data came from as a means to assess quality. Typical classifications include: journal article, report, news article, news release, webpage, interview, database, but also includes an option for free text.

Confidence: a judgement, measured on a high, medium, low scale of data quality. This assessment is tied with the classification made in the "quality" cells. An interview with a direct source may be of high confidence, while a news article with no citations or dates may be of lower confidence. Further details regarding data quality can be found in Step 5, Validation and quality control

Figure 5. Sample data entry form: illustrating both unfilled and filled template cells

Interventions		First discovery	Ideation	Patent approved	First reference of intervention	Application to begin testing submitted to SRA	Proof of Concept	Phase III complete	Application for product approval submitted to SRA
Definition	Milestones	Date of discovery for the original product or intervention from which the current intervention is adapted.	Date of discovery or idea for specific intervention	Date of patent approval	Date that intervention was first found in the literature describing the product and its potential impact	Date that new device, drug, or diagnostic application was submitted to a stringent regulatory authority (SRA) body for initial approval to begin testing. For devices of non-significant risk, date of IRB submission	Date intervention demonstrated to be safe and effective for intended purpose in humans	Date of completion of Phase III clinical trial	Date that application for drug, device, or diagnostic was submitted to stringent regulatory authority (SRA)
Milestone Dates									
Source*									
Link									
Quality*									
Confidence*									

Sample section of a filled data template for country milestones for Sayana Press

Interventions	Country		Ethics committee submission	Ethics approval in-country	Country's first Research Study starts	Country's first research study complete	Country pilot starts	Country pilot complete	Product Dossier Submission to Country Regulatory Body	Country Regulatory Approval (NRA approval)
Definition			Submission date to the country IRB or	Date of approval of research project by	Start date of research studies in country	Date study results of first research	Start date of country implementation pilot	Date implementation	Submission date to the country	Approval date to the country regulatory
Milestone Dates	*Country 1: Ethiopia*				Jul-12	Jul-12				
Source					Keith B, Wood S,	Keith B, Wood S,				
Quality					Journal Article	Journal Article				
Confidence					Medium	Medium				
Milestone Dates	*Country 2: Senegal*	Milestones			Aug-12	Mar-13	Jan-15	Jun-16		2013
Source					Burke HM, Mueller	Burke HM, Mueller	Stout A, Wood S,	Stout A, Wood S,		PATH. (2018). How
Quality					Journal	Journal	Journal	Journal		Report
Confidence					Medium	Medium	Medium	Medium		Medium
Milestone Dates	*Country 3: Uganda*				Jul-12	Feb-13	Sep-14	Jun-16		
Source					Burke HM, Mueller	Burke HM, Mueller	Stout A, Wood S,	Stout A, Wood S,		
Quality					Journal	Journal	Journal	Journal		
Confidence					Medium	Medium	Medium	Medium		
Milestone Dates	*Country 4:Burkina Faso*				Jul-14	Jun-16	Jul-14	Jun-16		2013
Source					Stout A, Wood S, Bari	Stout A, Wood S,	Stout A, Wood S,	Stout A, Wood S,		PATH. (2018). How
Quality					Journal	Journal	Journal	Journal		Report
Confidence					Medium	Medium	Medium	Medium		Medium

DATA COLLECTION PROCESS

When beginning data collection, it may help to conduct an initial search of the intervention you are focused on, through your preferred search engine. This will give you an overall idea of the variety of sources to pursue for that intervention's data. We recommend creating a separate document to track the information you are finding about the intervention, so that you can begin to understand the story or trajectory of the intervention, before inputting information into the Framework data entry form.

Process tip: Once again, as you are searching for data on the intervention, it is key to know the specific intervention you are trying to analyze. Is the information you are finding referring to a generic version of a product as opposed to the original? Is the information you are finding relating to an earlier or later formulation of the one you are looking for (e.g., quadrivalent HPV vaccine versus nanovalent HPV vaccine)? Reports or literature may not specify the exact intervention and you will need to do your best to understand which version they are describing.

Your research techniques will vary based on the intervention(s) you are researching. Some details may be easier to find through a general search engine whereas others may require you to look at a specific source like an academic journal or database. Engaging with the product's developer, development and/or implementation partners, and even countries implementing the intervention can be an important way to collect data for both global and country milestones and coverage indicators, as well as supplementing your qualitative understanding of the intervention's pathways and context. In Table 1 (see next page) we have provided common sources for the Speedometer Framework data points.

Data collection typically takes 20-40 hours of research per intervention. This may take longer at the beginning of your study, and can require as many as 100 hours per intervention initially, but the time required will decrease as you become more familiar with diverse sources of information. Note that some data may never be found or may be unavailable, in particular if searching public records.

Table 1. Illustrative primary and secondary data sources

Source	Tips
Manufacturer/developer or partner websites	Public developers tend to have more data than private developers; partners may write up the process of launching and scaling a product more frequently than manufacturers.
Direct source or interviews	If feasible, reach out to individuals involved in the process. They may have additional information that is not published.
Regulatory agency documents or websites	These sites are helpful to identify regulatory approval dates.
News articles	These may not be the highest quality data source, but may be the only source you have; do your best to validate the information using another source if possible.
Academic papers/ research publications	These are high quality sources typically; clinical trial dates and other milestone dates are often found in these sources.
Implementing organization websites and reports	Organizations implementing the intervention may have published key milestone or characteristics data given their direct involvement in implementation of an intervention.
Grey literature	Additional sources of grey literature may include policy literature, newsletters, government documents, and reports.

RECORDING THE DATA

While the data entry form keeps track of the specific data points you are looking for or have identified, it does not have extensive room for longer details about the data collected. As such, it is important to keep track of such information in a separate document.

Best practices for data collection include:

- Keeping track of the source location (HTML, or in email communication) or downloading it when possible
- Tracking the date of the source
- Tracking the date you found the information

This step is important for both personal record-keeping of your research, but also helps identify information gaps, and contextualizes when data is found so that updates may be made when new information becomes available.

Process tips:

Data collection can be both prospective and retrospective. This will depend on your scope of interest, are you looking at interventions that have already been introduced? Or are you interested in tracking interventions as they progress through the different stages of the framework in real time?

There will be information gaps: many steps of the launch and scale process may not be recorded; privacy concerns may limit the availability of publicly available data; website updates may cause materials to disappear; interventions may change names; and policy changes - all are reasons for data gaps that can impact your overall data clarity and availability.

Make a note if you are not confident of a date or data point, or if there are deviations of the data from the definition of the milestone, so that you can address it during the quality check phase.

Know your framework definitions. Typically, the framework is looking for the first date of a key activity (like the first time an intervention is launched in any low- or middle-income country).

Remember that **data is collected on milestones, characteristics and coverage data**.

The data collection process is not always direct, it may take some **searching and cross-referencing to understand what pathways**, both formal and informal, an intervention took to launch and scale. Some interventions may never have reached a certain scaling stage – or they may have, but the data may not be available that documents the process.

Alternative measurements or proxies can be considered when data is not available or the data quality is concerning. But, keep in mind that such measurements are intervention - specific, time-intensive, and require additional justification.

step 5 Validation and quality control

The next step in the data collection process is to critically assess the quality of the source of the information. For the type of data in the Speedometer Framework, we expect there will be a variety of sources; therefore, we also include a place to rank the source with a low, medium to high confidence level. Common criteria used to assess quality of a source includes: purpose of the source, intended audience, authority of source or author on the topic, peer-review, date of source, objectivity or bias. Using these criteria, a level of confidence can be assigned as described in the box to the right.

LEVELS OF SOURCE CONFIDENCE

High: sources with high confidence include: the manufacturer webpage, a direct source involved in the process of scaling, peer-reviewed journal articles, or public documents from government agencies such as regulatory approval applications

Medium: sources with medium confidence may include press releases from the manufacturer or other trusted sources, grey literature, or direct sources who may not have been fully involved in the launch or scale process

Low: sources with low confidence may include news articles with no source, or publications with conflicting information

The final step in the data collection process is the review of the data points by a team member not involved in the original data collection process. These processes reflect similar quality check processes often conducted in qualitative research to ensure consistency and validity of data and interpretations.

Quality check process:

1. Data collector reviews and discusses all data points with another team member to address any initial questions or unsure data points,
2. Team member independently spot-checks various milestones and sources to verify the validity of the data,
3. Team member notes questions that arise and discusses any additional discrepancies with the data collection lead, and
4. Data collector finalizes the data entry form with accurate information.

Data analysis

Analysis can be done from varying perspectives depending on what is most relevant to your goals. Analysis can be conducted on one intervention or multiple interventions. Using the data collected, analysis should be planned based on the scope of your interests defined in Step 1. Keep in mind that there will likely be data gaps, especially if using primarily public data sources, that will impact what kinds of analysis that can be done, and conclusions that can be drawn. Missing data imputation techniques can be applied, but you will need to include data limitations in your conclusions (Rubin, 1987). Robustness of analysis will also depend on the amount of data you have. Analyses will be stronger the more data is available, but the level and type of analyses which can be conducted may also depend on whether you are assessing data at a portfolio level, individual level, or if the data comparisons are between geographies.

Descriptive analysis

Descriptive analyses, or exploratory data analysis, should be conducted as a first step to understand the data you have. This may include data as basic as frequency, median, inter-quartile range, mode, or dispersion of data. Understanding the descriptive statistics of your data will help with context, but also drive what kinds of additional qualitative data may need to be collected to add nuance that otherwise cannot be measured, or to fill in gaps in the

Descriptive analyses of the Speedometer data may yield (illustrative examples):

Time spans between milestones

- Length of time between proof of concept demonstrated and regulatory approvals
- Length of time between country introduction, launch and 50% coverage

Frequencies or distributions of global, regional or country characteristics

- Understanding the intervention cost, pricing agreements, and procurement of an intervention or interventions
- Understanding the target populations and whether the intervention was developed for low- and middle-income country use specifically

Trends and distributions

- Understanding regional/country trends so that you can facilitate more efficient and effective implementation into each country you are targeting for product launch and scale
- Understanding of a country or intervention that launches or scales faster than others
- Understanding of certain type(s) of interventions that are launching or scaling faster than others (or that proceed faster between any particular milestones)

Association analyses

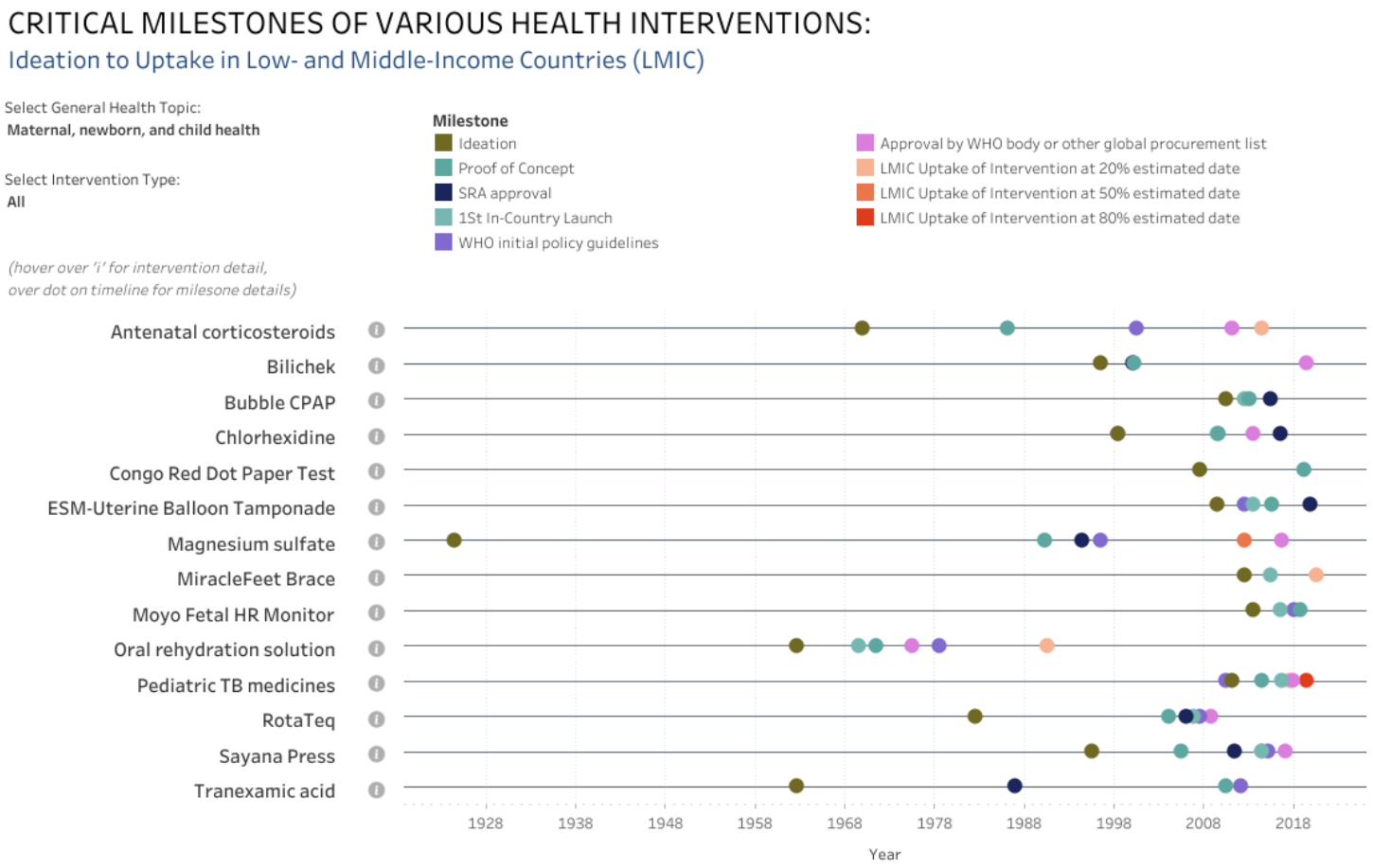
Analysis for association can help us better understand and handle the relationship of averages versus variance across interventions. This is where having a larger sample size is important. Assessing the Speedometer data in this way can help identify factors that are associated with faster or slower launch and scaling. Characteristics, such as those between and among interventions or geographies, can be analyzed for how they influence launch and scale time spans, thus offering a way to identify barriers and enablers to the process.

Association analysis could look at the relationships between milestones and characteristics outlined in the Speedometer Framework to help understand drivers of launch and scale and what factors make a pathway faster or slower. Possible characteristics to compare include types of interventions, influence of WHO prequalification on the launch of an intervention in LMICs, association between health topics and how long an intervention took to scale, or association of country regulatory requirements on country launch.

Visualizations

Visualizations can also be a powerful tool for analysis. Through visualization, trends in the data such as directionality, variance, and averages can be highlighted. Representing the data in a visual way can help with both identification of trends and reaching audiences effectively with key messages about the data.

Figure 6. Sample visualization of descriptive analysis of maternal and child health intervention ideation to uptake timelines



Key Terms
Ideation: Date of discovery or idea for specific intervention
Proof of Concept: Intervention demonstrated to be safe and effective for intended purpose in humans
SRA: Stringent Regulatory Authority (Approval from a stringent regulatory body as defined by ICH)
LMIC Uptake: Refers to demand (use), supply (provision), or policy uptake in LMICs
Source: Duke Global Health Innovation Center http://launchandscalefaster.org

Case studies

Case studies provide another way to showcase the data and analysis. Case studies can draw on both the quantitative and qualitative data to share key findings in a story-like format. Use of the case study format can add in-depth understanding on interventions, global, national, and sub-national factors associated with launch and scale. They can offer an opportunity to triangulate information and to pressure test the evidence drawn from the quantitative data.

Examples of case studies conducted using the Speedometer Framework are summarized below. Additional case studies can be found at dukeghic.org/launch-and-scale-speedometer/.

1

Scaling life-saving interventions faster: case studies that explore pathways and important factors that contribute to the development and uptake of global health interventions from proof of concept to scale-up

- Novel Oral Polio Vaccine Type 2
- Vitamin A Supplementation
- Sayana Press (DMPA-SC)
- Pediatric Tuberculosis Treatment

2

Lessons learned from providing real-time analysis for COVID-19 global response: a case study about the process of collecting real-time data to inform policy and advocacy on critical issues

Pippa Ranger/Department for International Development

Summary

The Speedometer Framework is designed for both retrospective, real-time, and prospective data collection, to consistently measure and effectively organize data around progressing along diverse pathways to scale health interventions. The longitudinal measurement of scaling up an intervention over time helps create a dynamic feedback mechanism on the scaling process in its entirety, but also provides important information about each step along the journey from ideation through sustainable scaling. In a field where demand for new and effective health interventions continues to grow and evolve, the systematic collection of data using this Framework can catalyze the scaling of effective health interventions, and hopefully promote sustainable scale of the most promising, thereby accelerating our ability to reach the most vulnerable to avert premature mortality, and minimize morbidity.

By applying the Speedometer Framework, you will be able to identify, collect, and organize launch and scaling data regarding health interventions in order delineate barriers or enabling factors along the trajectory from ideation to global uptake. Using prospective, or retrospective data collection approaches, users can track portfolio growth, generate real-time actionable insights, or gain insight to streamline future launch and scale endeavors. Analyzing Framework information can illuminate opportunities to accelerate the introduction and/or uptake of life-saving healthcare interventions.

Part of the value of the Speedometer program is its aggregation of over 50 interventions to understand their scaling time lines. We will continue to aggregate and analyze data to address the global need to scale life-saving interventions more quickly.

Some of the key uses of this Framework include:

- Track and facilitate understanding of characteristics of enablers and obstacles to scale
- Benchmark milestones, timespans of activities, and comparisons across products
  - Understanding how fast (the speed at which) activities occur. Note that 'fast' is not necessarily better, but understanding timelines of launch and scale gives an idea of how long it may take an intervention to reach end users.
- Enable investment scoping and selection
- Provide portfolio view and measurement of launch and scale
- Assist planning and monitoring of intervention introduction and uptake
- Measure longitudinal scale-up
- Support retrospective and prospective evaluation of end-to-end scaling journey
- Support product designer and implementing agencies in their design of new innovations that take account of delineated barriers (or enablers) in the design process and implementation plans

This user guide presents an opportunity to anyone interested in understanding and tracking the variety of scaling pathways of health interventions. This may include donors, product developers, implementers, or anyone engaged with the end-to-end process of scaling health interventions from R&D through sustainable scale. Furthermore, through its tracking of an intervention along the stages from product development and implementation, through scale, the Framework creates an informational bridge, which can be used to identify which organization, or partner may be most effective at each stage along the journey to scale, and reaching the intended population.

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Appendix I: Data Dictionary

Table 1: Milestones at the Global Level

Global Milestones (1st order)	Global Milestones (2nd order)	Definition	Definition details
Higher impact milestones	*Milestones that are lower impact but are important to understand the full timeline*	*What is input into the database*	*Additional information on the scope of the indicator*
	First Discovery (original innovation)	Date of discovery for the original product or intervention from which the current intervention is adapted.	Earliest date found for the intervention idea or development (e.g., date that pre-clinical trials completed, date of SRA approval or patent, date when idea was proposed to regulators such as in case of HIVST, date that platform for product was invented such as GeneXpert for Xpert MTB/RIF diagnostic)
Ideation (specific intervention)		Date of discovery or idea for specific intervention	
	Patent approved	Date of patent approval	
First reference of intervention		Date that the intervention was first found in the literature describing the product and its potential impact	Earliest date that the intervention was referenced in the literature, usually after preliminary testing for its intended purpose (can include publication date of pre-clinical trials, reports, etc.)
	Application to begin testing submitted to SRA	Date that new device, drug, or diagnostic application was submitted to a stringent regulatory authority (SRA) body for initial approval to begin testing. For devices of non-significant risk, date of (Institutional Review Board) IRB submission	This includes Investigational New Drug (IND) applications for new drugs (US Food & Drug Administration (FDA) only) or equivalent for other SRA approval bodies. For devices of significant risk, this includes Investigational new device (IDE) or equivalent for other SRA bodies. Devices of non-significant risk date do not require IDE, but they must have an IRB approved
Proof of Concept		Date intervention demonstrated to be safe and effective for intended purpose in humans	Date results shared (e.g. publication) from clinical trials for drugs, diagnostics, and other interventions that require SRA approval (Phase II studies or equivalent). If no SRA approval necessary, then date that efficacy was demonstrated (randomized control trial (RCT) or equivalent published)

Global Milestones (1st order)	Global Milestones (2nd order)	Definition	Definition details
Higher impact milestones	*Milestones that are lower impact but are important to understand the full timeline*	*What is input into the database*	*Additional information on the scope of the indicator*
	Phase III complete	Date of completion of Phase III clinical trial	
	Application for product approval submitted to SRA	Date that application for drug, device, or diagnostic was submitted to SRA	Includes (new drug application) NDA application new drugs (FDA only) or equivalent for other SRA approval bodies. Also includes pre-market notification or pre-market approval for devices
SRA Approval		Date of Stringent Regulatory Authority (SRA) approval or clearance	Approval from a stringent regulatory body defined by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) including FDA, European Medicines Agency (EMA), CE Marking (European FDA), Japan, Swiss Medic of Switzerland, Health Canada, Australia, Norway, Iceland, Liechtenstein
	Post-marketing research complete	Date of completion of Post-marketing research or Phase IV clinical trial	
1st In-country Introduction		Date the intervention was used in a low and middle-income (LMIC) country for the first time outside of a research study	Date the intervention was used (launched / commercialized / procured) in a LMIC country for the first time outside of a research study
WHO Emergency Use Listing		Date that intervention listed by the World Health Organization (WHO) for emergency use	
Application submitted to WHO approval body or other global procurement list		Date of application for list (WHO Prequalification (WHO PQ) or equivalent) that is referenced for country procurement	Approval submissions for other global lists include United States Agency for International Development (USAID) approved product list, World Health Organization Pesticide Evaluation Scheme (WHOPES), Essential Medicines List
	WHO Site inspection	Date of completion of Site inspection for WHO Prequalification	

Global Milestones (1st order)	Global Milestones (2nd order)	Definition	Definition details
Higher impact milestones	*Milestones that are lower impact but are important to understand the full timeline*	*What is input into the database*	*Additional information on the scope of the indicator*
	WHO Lab evaluation	Date of Laboratory Evaluation for WHO Prequalification	
Approval by WHO body or other global procurement list		Date of intervention approved for global list (WHO prequalification, endorsement or equivalent)	Global lists include USAID approved product list, WHOPES, Essential Medicines List, President's Emergency Plan for AIDS Relief (PEPFAR) approval list
WHO initial policy guidelines		Date that the WHO recommended the intervention in an official guideline	
	WHO policy update	Date of updated WHO recommendation (if any between initial and latest)	
WHO latest policy guidelines		Date of most recent recommendation update	
Global uptake of the intervention at 20%		Date that coverage of the intervention reached 20% globally using one of the global coverage indicators and an appropriate denominator (see Table 6)	Global coverage can be measured through: 1) Demand-side measures (most preferred) 2) Supply-side measures 3) Policy measures See Table 6 below for specific indicators and how to determine denominator
Global uptake of the intervention at 50%		Date that coverage of the intervention reached 50% globally using one of the global coverage indicators and an appropriate denominator (see Table 6)	
Global uptake of the intervention at 80%		Date that coverage of the intervention reached 80% globally using one of the global coverage indicators and an appropriate denominator (see Table 6)	

Global Milestones (1st order)	Global Milestones (2nd order)	Definition	Definition details
Higher impact milestones	*Milestones that are lower impact but are important to understand the full timeline*	*What is input into the database*	*Additional information on the scope of the indicator*
	Intervention no longer in use	Date intervention data showed lack of effectiveness for specific indication	
	Intervention no longer being produced	Date intervention was pulled off the market or manufacturing stopped	

Table 2. Characteristics of interventions and external environment for understanding pathways affecting launch and scale speed

Characteristics associated with launch and scale speed	Measurement	Definition Details
	What is input into the database	*Additional information on the scope of the indicator*
INTERVENTION LEVEL		
Scientific Name	Free Text	Scientific name for drug or general product name for devices, diagnostics, etc. Use the International Nonproprietary Name (INN) for drugs
Commercial Name(s)	Free Text	Brand name for specific intervention we are following
Description	Free Text	One to two sentence text description of the intervention
Intervention Type	Drop down	Categorical: drug, device, diagnostic, procedure, supplementation/fortification, vaccines, behavioral, infrastructure, service delivery, vector control, other (free)
General Health Topic	Drop down	Categorical: Infectious disease, neglected tropical diseases (NTDs), maternal, newborn & child health (MNCH), nutrition, non-communicable diseases (NCDs), trauma/injury
Specific Disease / Health Topic	Drop down multi select (can include selection of multiple disease topics or health issues)	Name of disease or health issue intervention is addressing. Current categories include: HIV, malaria, tuberculosis (TB), postpartum hemorrhage, club foot, jaundice, neonatal sepsis, preeclampsia, abnormal fetal heart rate, diarrhea, Syphilis, Human African Trypanosomiasis, contraception, vitamin A deficiency
Developer	Free Text	Name of original developer that made the product
Cost to develop	Free text (number)	Specific amount (if possible)

Characteristics associated with launch and scale speed	Measurement	Definition Details
	What is input into the database	*Additional information on the scope of the indicator*
INTERVENTION LEVEL		
Cost-effectiveness	Demonstrated cost-effective OR no evidence cost-effective	Demonstrated cost-effective (published review), No evidence cost-effective
Significant safety concern	Significant safety concern OR no significant safety concern	After research trials, concerns that product will be implemented safely among all groups
Significant improvement in standard of care	1) Distinctly more effective than current practice (including previous generations of the product) 2) Incremental improvement / not significantly more effective	Interventions that are distinctly more effective than previous generations, or have no equivalent predecessor E.g., Tafenoquine is risky for people with a certain genetic marker and so there must be a test for the gene prior to prescribing the drug. Also, Chlorhexidine was recalled for packaging that led to people putting it in infants' eyes and blinding them
Low and middle-income country specific	LMIC specific OR Not LMIC specific	Interventions developed specifically for LMIC country use
Requires behavior change	Requires behavior change for the END USER OR No/ little behavior change	Interventions whose effective use requires significant change in behavior of end users E.g., Long-lasting insecticidal nets (LLINs) require the end user to put up and sleep under the net. Chlorhexidine requires parents to spread the substance on the newborn instead of traditional materials
PROCESS AND REGULATORY RELATED		
WHO PQ approved or equivalent	WHO approved OR Not WHO approved	Equivalent to WHO PQ would be something like WHOPES
Clear champion(s)	Clear champion(s) OR No clear champion(s)	Interventions whose development and procurement were led/championed by prominent global organizations E.g., Global health campaign initiated for product like for Sayana Press with multiple partners or the TB Alliance.
Continuum of care	Categorical: Prevention/ Wellness; Awareness; Screening; Diagnosis; Treatment; Monitoring/ After Care	Where the intervention sits along the continuum of care

Characteristics associated with launch and scale speed	Measurement	Definition Details
	What is input into the database	*Additional information on the scope of the indicator*
PROCESS AND REGULATORY RELATED, CONT.		
WHO Essential Medicines List (EML) or Essential Diagnostics List (EDL)	On List OR Not on list	
Type of pathway to scale	Open Source/licensing, Organic Growth, Organic growth with selective outsourcing, multi-stakeholder partnership, sustained service, licensing out, franchising, acquisition, other (free text)	Scale pathways taken from USAID/United Nations Children's Fund (UNICEF): see categorizations and links in Appendix 1
MARKET RELATED		
Significant product competition	Significant product competition OR No significant competition	Multiple generic versions of the intervention/ Significant competition among brands
Requires targeting	Requires targeting OR does not require targeting	Interventions requiring targeting at specific sub-populations to be cost-effective E.g., Interventions like Sayana Press that require targeting at specific sub-populations (mostly young women in need of modern contraceptive) to be cost-effective
Global pricing agreement in place	Global pricing agreement OR No Global agreement	Any global pricing agreement organized by international partners E.g., Negotiated global price by partners such as for Sayana Press or for Xpert.
Centralized buying environment	Centralized OR Decentralized, or N/A	Centralized buying environments are where ~80% or more of the product is procured by one or several large buyers (organizations / large governments) E.g., Centralized—LLINs are mostly procured through large global buyers like the Global Fund Decentralized—Uterine balloon tamponades

Characteristics associated with launch and scale speed	Measurement	Definition Details
	What is input into the database	*Additional information on the scope of the indicator*
MARKET RELATED, CONT.		
Public vs. mixed target channel	Public, Private, or Mixed	Public is where ~80% or more of product is targeted to public channels as opposed to private pharmacies and facilities. Private is where ~80% or more of product is targeted to private channels as opposed to public pharmacies and facilities. Mixed channels have more distribution across public and private facilities E.g., LLINS are Public mostly, MiracleFeet is Private, and Sayana Press is Mixed
Main market type	Global, Institutional, OR Consumer	See definitions in this article: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4168618/ E.g., LLINS are global because they are procured and finalized through centralized channels. Chlorhexidine is Institutional because national institutions (like Ministries of Health (MOHs')) purchase for newborn care. Sayana Press is a consumer market mainly because consumers purchase it for their own use

Table 3. Milestones at the Country level

Milestones 1st order	Milestones 2nd order	Milestones 3rd order	Definition	Definition details
Priority/Higher impact milestones	*Milestones that are lower impact but are important to understand the full timeline*	*Milestones to track if found during research, not a search priority*	*What is input into the database*	*Additional information on the scope of the indicator*
		Ethics committee submission	Submission date to the country IRB or Ethics Committee to do a research project with the intervention	Research projects can include clinical trials, or field trials, or implementation research
	Ethics approval in-country		Date of approval of research by Ethics Board	
		Country's first definitive research study starts	Start date of research studies in country with intervention (e.g., country clinical trials, validation studies, or demonstration/ implementation trials)	Can include country clinical trials, validation studies, or demonstration/ implementation trials

Milestones 1st order	Milestones 2nd order	Milestones 3rd order	Definition	Definition details
Priority/Higher impact milestones	*Milestones that are lower impact but are important to understand the full timeline*	*Milestones to track if found during research, not a search priority*	*What is input into the database*	*Additional information on the scope of the indicator*
	Country's first definitive research study complete		Date study results of first research study/ studies entered public domain (e.g., country clinical trials, validation studies, or demonstration/ implementation trials)	Field/Implementation research differs from a pilot and is to demonstrate feasibility and acceptability of intervention.
		Country pilot starts	Start date of country implementation pilot for intervention	Pilots can be sponsored by sub-national governments as well as national governments
Country Pilot complete			Date implementation pilot results entered public domain	
	Product Dossier Submission to Country Regulatory Body		Submission date to the country regulatory body (e.g., National Regulatory Agency (NRA))	Drugs, devices, diagnostics, etc. that require approval before purchase and/or distribution
Emergency Use Authorization			Date intervention was authorized for emergency use in country	
Country Regulatory Approval (NRA approval)			Approval date to the country regulatory body	
National Essential List (medicines, diagnostic, or other list)			Date intervention is added to a national list of essential health products (e.g., Essential Medicines List (EML) or Essential Diagnostics List (EDL))	
National policy guidelines			Date of recommendation by the country for the intervention within the country's guidelines	

Milestones 1st order	Milestones 2nd order	Milestones 3rd order	Definition	Definition details
Priority/Higher impact milestones	*Milestones that are lower impact but are important to understand the full timeline*	*Milestones to track if found during research, not a search priority*	*What is input into the database*	*Additional information on the scope of the indicator*
Implementation plan national level			Date of the implementation plan released by the Ministry of Health (MOH)	
		Implementation plans sub-national	Date that the first implementation plans are released for the first sub-national level	
		Budget Allocation Request	Date that budget request is made for procurement/ implementation plans by the MOH	
		Budget Allocation approved	Date that budget allocation request for procurement/ implementation plans are approved	
Launch of intervention in country			Date the intervention was used (launched / commercialized / procured) in a LMIC country for the first time outside of a research study in any part of the country	Pilots can count as introduction
		First procurement request sent by country	Date the procurement request was sent by country to supplier or centralized global buyer	
		First shipment with intervention clears customs	Date that first shipment of the product clears customs	

Milestones 1st order	Milestones 2nd order	Milestones 3rd order	Definition	Definition details
Priority/Higher impact milestones	*Milestones that are lower impact but are important to understand the full timeline*	*Milestones to track if found during research, not a search priority*	*What is input into the database*	*Additional information on the scope of the indicator*
Country uptake of the intervention at 20%			Date that coverage of the intervention reached 20% in country using one of the country coverage indicators and an appropriate denominator (see Table 6)	Country coverage can be measured through: 1) Demand-side measures (most preferred) 2) Supply-side measures 3) Policy measures See Table 6 below for specific indicators and how to determine denominator
Country uptake of the intervention at 50%			Date that coverage of the intervention reached 50% in country using one of the country coverage indicators and an appropriate denominator (see Table 6)	
Country uptake of the intervention at 80%			Date that coverage of the intervention reached 80% in country using one of the country coverage indicators and an appropriate denominator (see Table 6)	

Table 4. Characteristics of country environment for understanding pathways affecting launch and scale speed

Characteristics associated with launch and scale speed	Definition	Definition details
	What is input into the database	*Additional information on the scope of the indicator*
National procurement cycle - frequency of funding request opportunities for health products	Annual, biannual, OR other	Refers to the public health sector's procurement procedures for the type of intervention/health product (may be different for drugs and devices for instance). If the intervention is not procured in the public sector, choose N/A.
Existence of national health product distributor / purchaser	National distributor exists OR no national distributor exists (public or private)	National distributor can refer to either the public sector or private sector but they must be the centralized distributor is for the country.

Characteristics associated with launch and scale speed	Definition	Definition details
	What is input into the database	*Additional information on the scope of the indicator*
Frequency of product delivery from national distributor to local levels	Monthly, Quarterly, Semi-Annual, Upon Request	The frequency of delivery from the national distributor (public or private) to the sub-national or local levels.
Pricing agreement	Country-specific pricing agreement OR No agreement	Refers to a price agreement negotiated by the MOH or public health sector (not a global price for all countries) and applies to the price of purchasing from manufacturing or global buyer, not cost for end user.
Price of intervention	Price-agreement price of intervention	Specific price of the intervention specified by the country -specific pricing agreement
Free or subsidized for end user	Free/subsidized for end user OR no significant cost support of end user	Intervention is provided for free or at a significant discount (subsidized) for the end user. E.g., LLINs are often provided for free through mass distribution campaigns
Ease of Regulatory pathways	Clear pathway OR Not clear pathway	Clearly defined pathway for intervention to move through the regulatory process. (e.g., Often countries have clear pathways for drugs that must follow clinical trial guidelines and have specific submission requirements.)
Speed of regulatory pathways	Fast OR Not fast/slow Pathway	Pathway for regulatory approval that moves relatively quickly compared to other countries or even to similar health products for different health issues (e.g., approval can be granted with WHO approval and no additional country requirements)
High-level country champion	Champion OR No champion	Can be a person or group in the public or private sector at the country level that helps launch and scale the intervention. E.g., Minister of Health, Head of Regulatory Agency, etc.
Names of champions	Name the main country champions (no more than 3)	
Cultural acceptance issue	Cultural acceptance issue OR No cultural issues	Intervention not easily accepted in country or parts of the country due to social norms of the population or policy-related acceptance issues. There is any cultural acceptance issue in the country for the intervention specifically or for the use of similar health products. (e.g., contraceptive drugs or devices and generally sexual and reproductive health (SRH) interventions can be considered taboo in some countries making it harder for women to access them)
Corruption Index	Score of country on Corruption Perception Index (CPI) in 2019 (or latest available)	The CPI is published by Transparency International every year

Characteristics associated with launch and scale speed	Definition	Definition details
	What is input into the database	*Additional information on the scope of the indicator*
Disease/health topic burden in country	High, Medium, OR Low	Determined by the ranking of the relevant health issue for death or disability of the country. Access the Institute for Health Metrics and Evaluation's (IHME) country profiles to consult the top 10 health issues for health and disability. If the health issue for which the intervention addresses is in the top 5 for either death or disability, mark high burden. If the health issue is in the top 10, mark medium burden. If the health issue is not in the top 10 for either death or disability, mark low burden. (e.g., Neonatal disorders are #1 for causing death in Ethiopia in 2017 so Chlorhexidine would be an intervention for a high burden disease).
Burden numbers	Number of people with health issue or disease in 2019 (or latest available)	Prevalence or incidence of health issue or disease based on what is reported and relevant (e.g. Malaria incidence (estimated cases) from the past year is reported in the World Malaria Report)
Gender inequality	World Economic Forum (WEF) gender gap report ranking from most recent ranking (range 1-149)	The Gender Gap Report is published by World Economic Forum
Poverty	Poverty headcount ratio from latest year available (% of population)	% of population living under the poverty line according to the World Bank latest data using $1.90 a day
Quality of healthcare system	Score on IHME Healthcare Access and Quality Index from 2016 (range of 0 to 100)	The Healthcare Access and Quality Index is published by the Institute for Health Metrics and Evaluation
Health expenditures per person	Health expenditures per person in US$ during 2019 (or latest year available)	Health expenditures per person is published by the Institute for Health Metrics and Evaluation in their country profiles

Table 4. Characteristics of country environment for understanding pathways affecting launch and scale speed

Order of importance	Types of coverage	What we are measuring	Global level		Country level	
		Indicators to track (annually)				
1	Demand-side	Population in need reached by intervention	Numerator	Denominator	Numerator	Denominator
			Total global population in LMICs reached by intervention through distribution or use of the intervention	Global LMIC population with health issue or disease* (in some situations can also be the addressable market or the unmet need, e.g. contraception)	Total country population reached by intervention through distribution or use of the intervention	Country population with health issue or disease* (in some situations can also be the addressable market or the unmet need, e.g. contraception)
2	Supply-side	Availability of intervention	Numerator	Denominator	Numerator	Denominator
			Total number of units of intervention procured by LMICs	Global LMIC population with health issue or disease* (in some situations can also be the addressable market or the unmet need, e.g. contraception)	Total number of units of intervention procured for country	Country population with health issue or disease* (in some situations can also be the addressable market or the unmet need, e.g. contraception)
			Total # of LMIC countries providing the intervention (where it is available)	Total # of LMICs that have populations with health issue or disease*	Total # of subnational country units providing the intervention (where it is available)	Total # of subnational country units that have populations with health issue or disease
			Global sales of intervention in terms of value (US$) in LMICs	Target global sales in terms of value (US$) in LMICs	Total country purchase amount of intervention in terms of value (US$)	Target country purchase amount in terms of value ($)

Order of importance	Types of coverage	What we are measuring	Global level		Country level	
		Indicators to track (annually)				
3	Policy	Support of intervention	Numerator	Denominator	Numerator	Denominator
			Total # of LMICs with policy or implementation plans supporting roll-out of intervention^	Total # of LMICs that have populations with health issue or disease*	Total # of subnational units with policy supporting intervention^	Total # of subnational country units that have populations with health issue or disease

Notes	
* Denominator generally applies to intervention in order to calculate coverage rate. Each intervention is different though and requires specific calculations for that intervention (e.g., diagnostics need to be procured at a higher rate than population with disease). Some may also require incidence of disease (e.g. TB) and some require prevalence (e.g. HIV). Denominator should focus on low- and middle-income countries (LMICs) with the health issue/disease. In some cases, it may be that international efforts are focused on a subset of particularly burdened LMICs with the health issue/disease (e.g. FP 2020 60+ countries it focuses on for increased access to contraception). This would be a good denominator in this case if most of the data was specific to this subset of countries. Explain the denominator in the Notes section.	^ Most likely only applies to public level health systems. Can include: recommendation in a national (subnational) health policy, inclusion in a national (subnational) implementation plan for the disease area, inclusion on the national EML, or regulatory authority approval

Appendix II

Types of Pathways to Scale from USAID and UNICEF

	Main feature	Details
1 Organic growth with selective out-sourcing	Scale-up led and coordinated by the innovator, selectively out-sourcing activities to partners. The innovator often creates a new entity to drive the scale-up	▪ Select functions are outsourced to partners, including any combination of the following: – Upstream partners to help facilitate clinical, regulatory and policy requirements – Contract manufacturers and suppliers – Partners to provide logistics/distribution and servicing capacities – Partners to help generate user demand and ensure user adoption (e.g., marketing, user training) – Partners to reach and acquire buyers (e.g., sales, tender response)
2 Multi-stakeholder partnership	Multiple partners (including the innovator) with common or complementary interests work together to drive scale-up. This often includes private sector partners and can be referred to as public-private partnerships	▪ Partnership provides partners with a platform to work together and pursue a common agenda, sometimes with formally outlined objectives, key policies and principles to guide actions ▪ A project manager (one individual or a team) could be chosen to coordinate activities among the partners. This role is also referred to as an "uptake coordinator" ▪ Innovator retains ownership and some decision-making power, and could handle selected scale-up functions
3 Licensing out	Licensing rights to parties to drive commercialization and generate a financial payback to the innovator	▪ Licensing can occur at all stages, from early product development to scale-up ▪ Rights that are licensed out could be limited by geography, market segment, and/or "field of use" (with the innovator retaining ownership of the IP) ▪ Innovator's degree of engagement and control can vary widely, based on the contract's terms
4 Open licensing	Replicating the product technology by setting up an open license that allows others to use the IP	▪ IP owner allows others to use the technology through an open license with few or no restrictions. Other organizations can build on the IP to enhance the product ▪ Innovator could choose to remain involved and provide ongoing support to replicators of the technology ▪ This model can be extended to include cases when an innovator does not create any license and simply allows others to freely use the technology (particularly relevant for hardware innovations, which could be more costly and burdensome to establish IP for than software innovations)
5 Getting acquired	Sale of innovation or business to a buyer	▪ Sale can occur at all stages, from early product development to scale-up ▪ Aspects being sold could be limited to intellectual property (through a full technology transfer, where the innovator loses ownership of the innovation), or include physical assets, part or all of the organization

Source: USAID. (2016). Pathways to scale: A guide on business models and partnership approaches to scale-up. https://www.usaid.gov/cii/pathways-scale

Table 1: Scale models and their deployment by UNICEF

An overview of major scale models that we have studied and synthesized, and our use of them to scale innovations.

	Scale models	Which innovations apply them
Less influence	**Open Source** *An Open Source license grants permission to access, re-use, make alterations or additions, share, improve, and build upon a work with few or no restrictions.*	• Digital health • Generation Unlimited Youth Challenge 2019 • Human Centred Design for Health • RapidPro platform • UPSHIFT
	Organic growth *Deploying in-house expertise to expand innovation to other locations as opportunities arise and with demand. Also referred to as branching.*	• Generation Unlimited Youth Challenge 2018 and 2019 • Internet of Good Things • U-Report • UPSHIFT
	Organic growth with selective outsourcing *Outsourcing only part of the functions required to scale and performing the rest in-house.*	• Digital Health • Human-Centred Design • Real-time information applications on RapidPro
Moderate influence	**Sustained service** *Initiative/intervention that provides service/ products as is with incremental improvements, should have a sustainable business model.*	Internet of Good Things
	Licensing *Licensing is a legal relationship where a party is granted a limited right to use its Intellectual Property or manufacture the licensor's products or technology in exchange of a royalty fee.*	Biosensors
More influence	**Franchising** *The franchisee pays fees for the right to operate a business, participate in a standard operating system, and use the brand name and proprietary information of the franchise.*	Not yet applied
	Acquisition *Acquisition is the outright purchase of an innovation by another organization. Through acquisition, the purchasing organization can achieve economies of scale, increase the client base, gain efficiencies and enhanced market visibility.*	TextIt to become RapidPro

Source: UNICEF. (2019). Scaling innovation for every child. https://www.unicef.org/innovation/reports/scaling-innovation-every-child

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