READY, SET, LAUNCH

A Country-Level Launch Planning Guide for Global Health Innovations

Supplemental Toolkit

CENTER FOR ACCELERATING INNOVATION AND IMPACT
USAID | GLOBAL HEALTH

Overview of Supplemental Toolkit

This toolkit is intended to provide practical country-level launch planning guidance to global health practitioners—built from private sector principles and public health best practices.

We have compiled these templates, examples, and tools to provide inspiration and guidance as you move through developing a scale-up strategy and operational launch plan. To help see how these tools might be used in practice, **this guide contains:**

(i) Illustrative, pre-populated tools based on the development of an operational launch plan for chlorhexidine (CHX) in Nigeria, and

(ii) Blank tools that you can fill in as you develop your own operational launch plan

These tools are meant to serve as references to consider in helping you think through or address many of the questions and exercises identified in *Ready, Set, Launch: A Country-Level Launch Planning Guide for Global Health Innovations*. To that end, the toolkit is not exhaustive and is intended to be continually updated and refined over time with more examples and templates.

As such, we encourage your comments, new tools, and input at our website *(www.usaid.gov/cii)*.

Let us know how we can make this better and more useful!

CENTER FOR ACCELERATING INNOVATION AND IMPACT
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Tools available only in this Supplemental Toolkit

Note: All hyperlinks will only work in the 'Slide Show' mode.

Step 1.1: Shortlist countries for launch

1. Country Prioritization Matrix Tool

Step 1.2: Finalize country selection

1. Country Prioritization Table Tool
2. Go/No-Go Checklist Tool

Tools available only in this Supplemental Toolkit

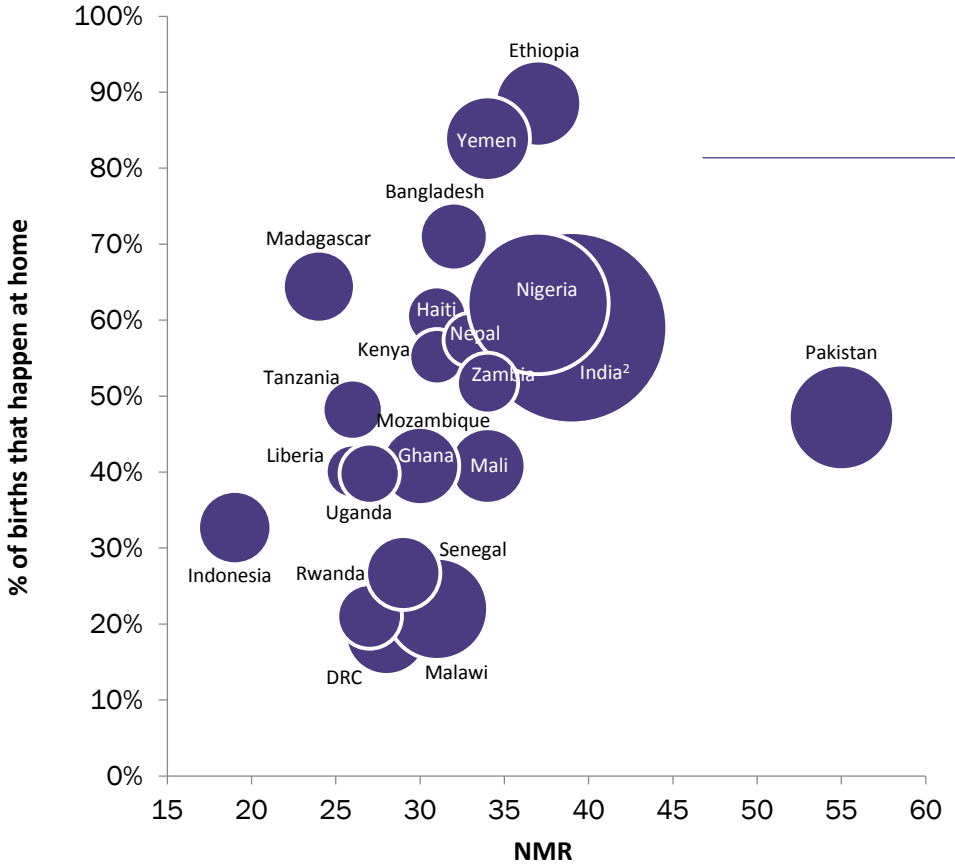
STEP 1.1 EXERCISE 1

Country Prioritization Matrix Tool

Illustrative

Evaluation of country need based on neonatal mortality rate (NMR) and home births across USAID's 24 priority countries

Analysis is limited to a select number of countries based on priorities



Analysis examines **two quantifiable data points** that are most relevant to the product

Short List of Countries

Short list of countries is **split according to qualitative preferences**

Larger market size countries:

Pakistan
Ethiopia
Yemen
Nigeria
India

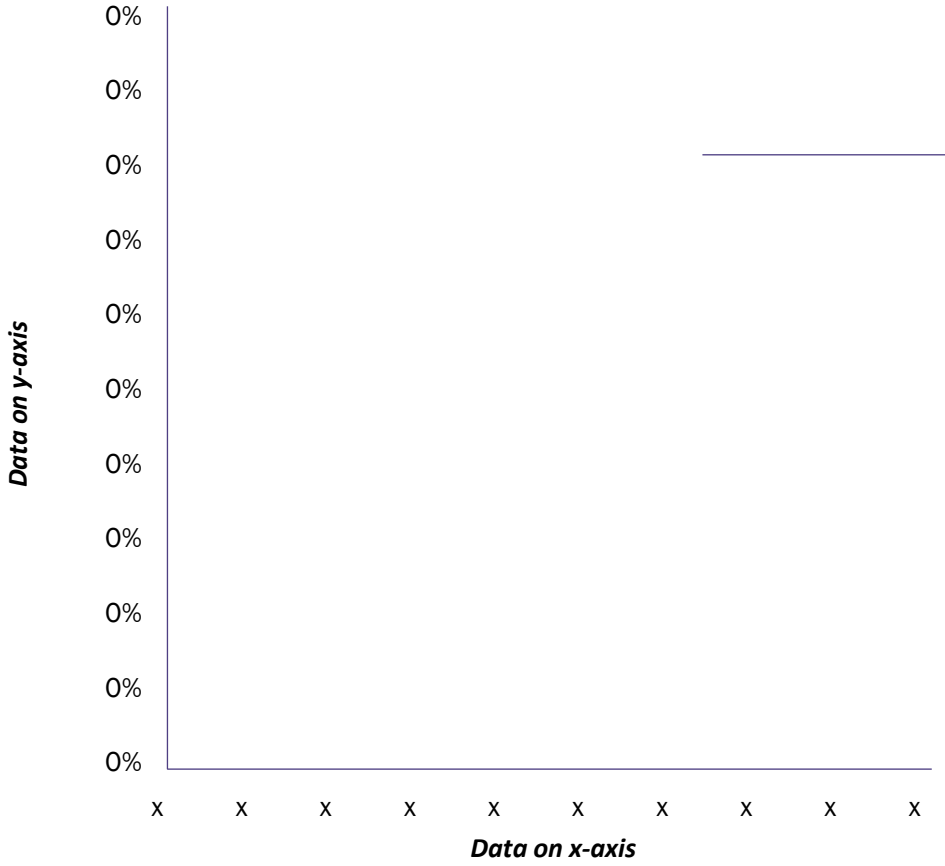
Demonstration effect countries:

Haiti
Nepal
Kenya
Zambia

STEP 1.1 EXERCISE 1

Country Prioritization Matrix Tool

Evaluation of country need based on _ and _ across _ priority countries



Short List of Countries

Larger market size countries:

Country
Country
Country
Country
Country

Demonstration effect countries:

Country
Country
Country
Country

STEP 1.2 EXERCISE 1

Country Prioritization Table Tool

Illustrative

Market size will apply a limiting factor to the total population impacted by the disease/health issue to estimate **the addressable market**

Measures of feasibility **blend qualitative and quantitative information**

Track feasibility vs. market size in a scorecard to populate underlying data for bubble chart

	Market Size		Feasibility[1] (Measures of feasibility **blend qualitative and quantitative information**)						
Country	Burden	Addressable market size	Uptake of similar products	Existing substitutes	Product registered	Product on EML or related list	Align with national priorities	In country relationships	Overall feasibility[2,3]
Uganda	10m	2m	◑	○	●	●	●	◑	7
Bangladesh	3m	1m	◔	◑	○	○	◑	◑	4

Note: (1) Use Harvey Balls to track feasibility variables with the exception of 'overall feasibility.' Other variables can be used as identified; (2) Roll up individual countries' feasibility variables to score overall on a scale of 1 (lowest feasibility) to 10 (highest feasibility); (3) Create bubble chart based on these two metrics.

● ◔ ◑ ◔ ○

Harvey Balls are visually easier to absorb but **each rating can map back to a specific number**

Overall feasibility = (distribution mechanism) + (2 * payers) – (other products) + (.5 * substitutes)…

Overall **feasibility formula will use simple math and favorably weight inputs** that are more credible or that are better indicators of success

STEP 1.2 EXERCISE 1

Country Prioritization Table Tool

	Market Size		Feasibility[1] (Measures of feasibility **blend qualitative and quantitative information**)						
Country	Burden	Addressable market size	Uptake of similar products	Existing substitutes	Product registered	Product on EML or related list	Align with national priorities	In country relationships	Overall feasibility[2,3]

Note: (1) Use Harvey Balls to track feasibility variables with the exception of 'overall feasibility.' Other variables can be used as identified; (2) Roll up individual countries' feasibility variables to score overall on a scale of 1 (lowest feasibility) to 10 (highest feasibility); (3) Create bubble chart based on these two metrics.

Overall feasibility = (distribution mechanism) + (2 * payers) – (other products) + (.5 * substitutes)…

STEP 1.2 EXERCISE 2

Go/No-Go Checklist Tool

Core component	Relevant no-go signals and principles	Example	Guidance on how to interpret signal
MARKET AND USER	**Challenging market dynamics/limited product differentiation**	Product **substitutes are priced lower and/or are more effective**	If a substitute product is firmly entrenched, priced lower, and offers a similar value proposition, *signal to reconsider*
	Signals of low demand	**Poor uptake on similar products** previously introduced in-country	If similar products have had poor uptake due to market/non-market factors that would similarly affect product, *signal to reconsider*
MANUFACTURING AND DISTRIBUTION	**Mismatch between production economics and pricing potential**	**Price/production economics are higher** than ability/willingness to pay, and economics cannot be improved	If production economics cannot be improved, and product necessitates end-user purchase (as opposed to donor funding), *signal to reconsider*
	Lack of infrastructure to accommodate product needs	**Product requirements can't be met** at point of delivery	If distribution and handling requirements (e.g., cold chain, nurse administration, etc.) can't be met, *strong signal to reconsider*
CLINICAL EVIDENCE AND REGULATORY	**Significant delays in country approval process**	Regulatory signals **suggest low likelihood of approval**	If regulators pose skeptical questions in meetings, express doubt and present no solutions, *signal to reconsider*
POLICY, ADVOCACY, AND FINANCING	**Strong opposition to product entry from key decision makers**	A **key stakeholder wishes to block scale-up**	If a senior government official or key opinion leader has expressed a strong objection to scale-up in their country, *strong signal to reconsider*

If research during country selection identified any of these negative scenarios, evaluate the relative impact of the finding and reconsider scale-up and/or return to country selection to consider alternative countries.

Step 2.1: Assess market and barriers to scale

1. Stakeholder Mapping Tool
2. Market Assessment Tool
3. Barrier Assessment Tool
4. Market Segmentation Analysis Tool
5. Patient Journey Mapping Tool
6. Manufacturing Analysis Tool
7. Delivery Channel Analysis Tool
8. Clinical Trial Analysis Tool

Step 2.2: Develop strategy for overcoming barriers to scale-up

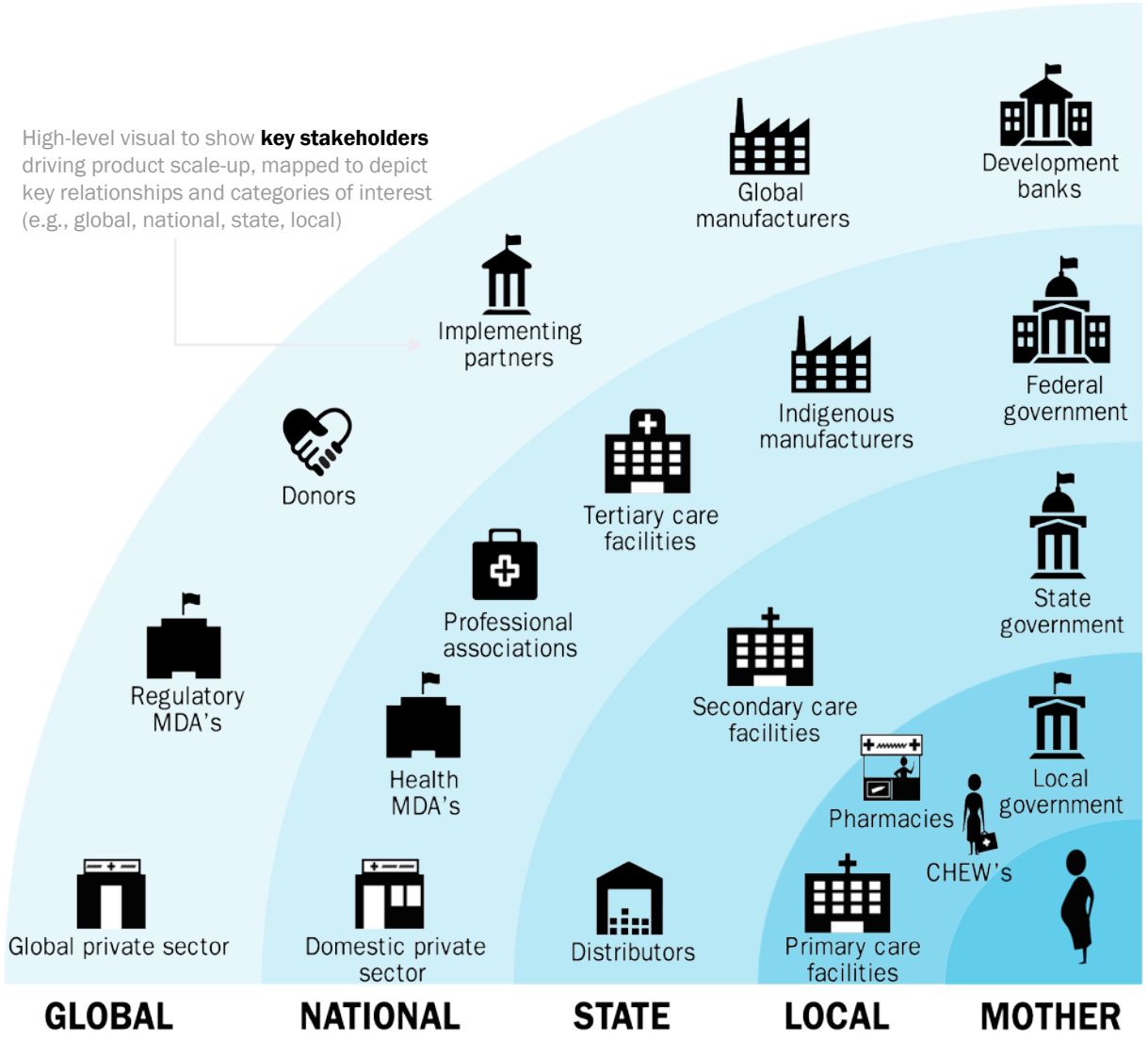
1. Comparable Product Analysis Tool
2. Intervention Design Tool

Tools available only in this Supplemental Toolkit

STEP 2.1 EXERCISE 1

Stakeholder Mapping Tool

High-level visual to show **key stakeholders** driving product scale-up, mapped to depict key relationships and categories of interest (e.g., global, national, state, local)



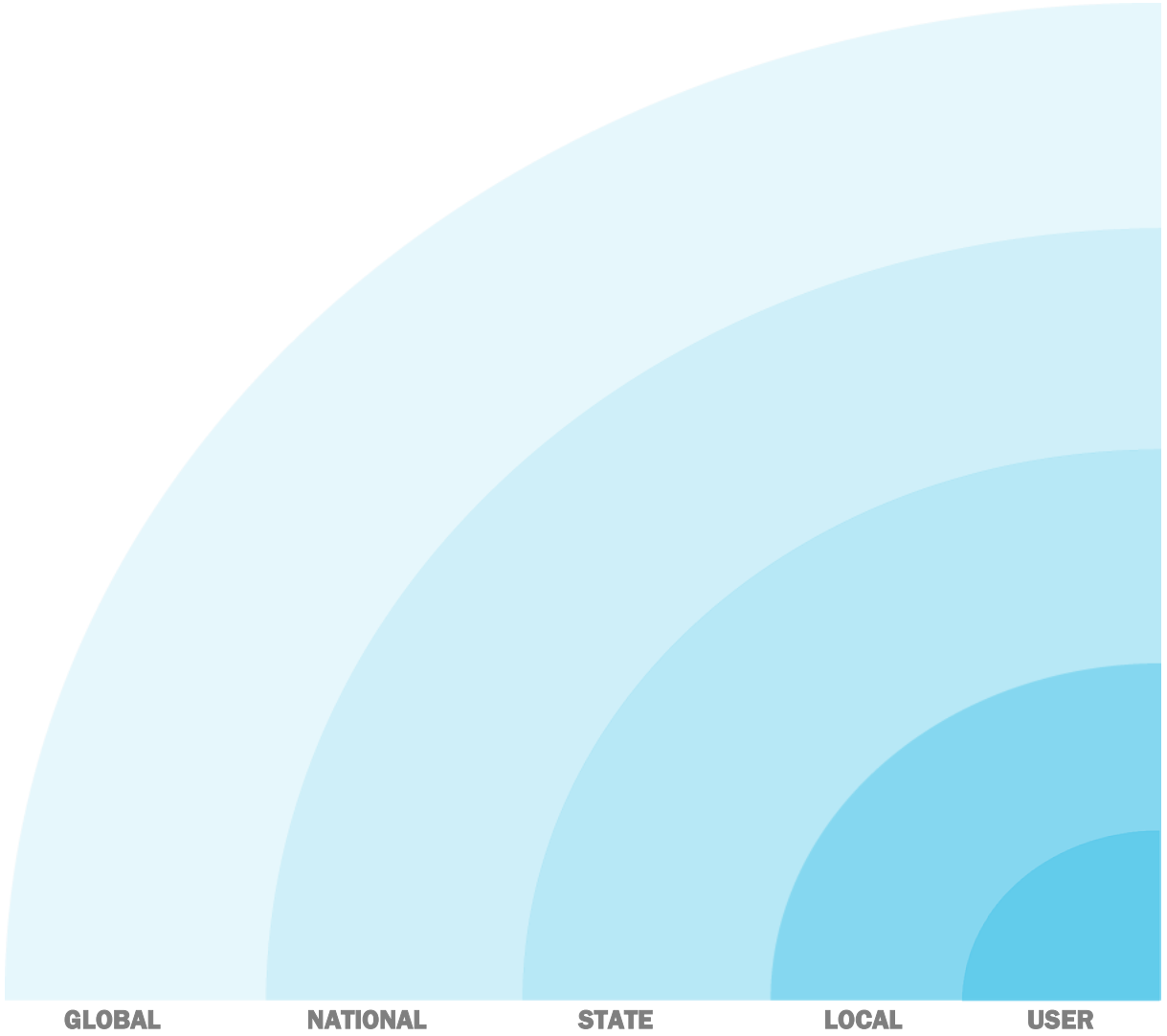
Additional detail on **capabilities, interests, and potential roles of key stakeholders**

Illustrative

Group	Importance	Typical roles and responsibilities in scale up	Examples of stakeholders included
Federal government	Government sets policy and oversees health programs and systems at the national level	Lead/coordinate efforts, set policy, conduct advocacy, provide funding	Department of Family Health, Department of Food and Drug Services
State government	Government sets policy and oversees health programs and systems at the state level	Oversee implementation of scale-up activities at the state level, including procurement and distribution of product	State ministries of health
Other stakeholders	*[Continue for other stakeholders]*	*[Continue for other stakeholders]*	*[Continue for other stakeholders]*
Other stakeholders	*[Continue for other stakeholders]*	*[Continue for other stakeholders]*	*[Continue for other stakeholders]*
Other stakeholders	*[Continue for other stakeholders]*	*[Continue for other stakeholders]*	*[Continue for other stakeholders]*

STEP 2.1 EXERCISE 1

Stakeholder Mapping Tool



Group	Importance	Typical roles and responsibilities in scale up	Examples of stakeholders included
Other stakeholders	[Continue for other stakeholders]	[Continue for other stakeholders]	[Continue for other stakeholders]
Other stakeholders	[Continue for other stakeholders]	[Continue for other stakeholders]	[Continue for other stakeholders]
Other stakeholders	[Continue for other stakeholders]	[Continue for other stakeholders]	[Continue for other stakeholders]
Other stakeholders	[Continue for other stakeholders]	[Continue for other stakeholders]	[Continue for other stakeholders]
Other stakeholders	[Continue for other stakeholders]	[Continue for other stakeholders]	[Continue for other stakeholders]

STEP 2.1 EXERCISE 2

Market Assessment Tool

Core Component	Key questions to ask a part of a market assessment
MARKET AND USER	• Who is the target user? • Who influences the target user? • What is the point of care/point of access that is most relevant? • What competing products exist?
MANUFACTURING AND DISTRIBUTION	• Will the product be supplied via local and/or global manufacturing? • What are the target delivery channels to reach target users (e.g., public, private)? • Are production economics in line with ability and willingness to pay?
CLINICAL EVIDENCE AND REGULATORY	• What additional clinical evidence is needed? • What does the regulatory approval process require? How long does the process take?
POLICY, ADVOCACY, AND FINANCING	• Who is the target payer? What is their ability to pay? Willingness to pay? • What organizations have been involved in or provided resources for scale-up activities for similar activities in the past? • How much have scale-up interventions in the past cost? • What is the process for including the product in appropriate protocols/lists (e.g., essential medicines list, national (protocol)?
COORDINATION	• Who are ideal candidates to lead the launch and scale-up and/or serve the uptake coordinator role? • What entities have owned/managed interventions in the past? How long did these efforts take to carry out?

STEP 2.1 EXERCISE 3

Barrier Assessment Tool | Market and user

Evaluate target users' current awareness of and demand for the product

Provide **details and cite** how you determined the level of need and relevant implications for scale-up

Barrier	Desired outcome	How to determine level of urgency	Barrier (color red, yellow, green)	Key considerations
Target users/payers **don't see a need** for the product	Target users **understand the need** for the product and, therefore, are **more likely to seek out the product**	• Is the **need for treatment known and/or are flaws of current treatment options recognized** by the target user? ***If no, then red.***		How have other sub-optimal health behaviors been improved?
Target users **aren't aware of the value** of the product	Target users **know about the product's benefits** and are motivated to access it	• Do target users know **about the product and want to access it?** ***If no, then red.***		How have other new products generated demand?
Target users **do not know how to use** the product	Target users **know how and when to use the product,** resulting in greater uptake of the product in the right circumstances	• Do target users **know how and when to use the product?** ***If no, then red*** • Can the target user **easily access and understand instructions for use?** ***If no, then red.***		How have target users been trained for other products?
It is **difficult to predict how much product** is demanded	Accurate **projections of market demand will aid in planning** for sufficient supply and scale-up activities	• Are there well informed **calculations that link coverage rates to total market demand** for the product? ***If no, then red.***		How quickly could consumer demand change in-country?
It is **difficult to know where to set the price** of the product	Product is **priced appropriately** based on target user affordability and business needs/costs	• Is the product **affordable to target users?** ***If no, then red*** • Does the price **provide a reasonable margin** for manufacturers and other actors in the supply chain? ***If no, then red.***		What portion of target users are currently priced-out?
The **product and packaging design** is confusing/unclear to users or gate keepers	Product and packaging design **reflects user-centered research to improve appeal and prevent improper usage**	• Is the product **differentiated and attractive to targets?** ***If no, then red.*** • Does packaging **design lend itself to product misuse?** ***If yes, then red.***		Have there been reported cases of misuse? Does the product design resemble others, potentially creating confusion?

High barrier | Medium barrier | Low barrier

Ratings are meant primarily to indicate relative barrier, and are more art than science

STEP 2.1 EXERCISE 3

Barrier Assessment Tool | Manufacturing and distribution

Evaluate how to optimize the supply chain and which delivery channels to prioritize

Barrier	Desired outcome	How to determine level of urgency	Barrier (color red, yellow, green)	Key considerations
There aren't clear/functional **delivery channels**	Functional procurement and distribution systems will **link product supply to all points of access/target users**	• Can the product be placed into the target delivery channels and **assume it will flow seamlessly** to target users? ***If no, then red.***		How have similar products optimized delivery channels previously?
There aren't **incentives to integrate the product into existing delivery channels**	Public and private sector channels **incentivize affordable, fast, and reliable delivery** of the product to target users	• Are there large **bottlenecks in the delivery channels that will hinder the product's movement** to target users? ***If yes, then red.***		What incentives have worked in moving global health product inventory in past scale-ups?
There aren't **local and/or global manufacturers** willing or able to manufacture the product	**Production strategy** (including high-potential manufacturers) exists, and can meet scale-up needs	• Is there a **local manufacturer** that is already producing or ready to immediately produce **or a global manufacturer ready** to export to the country? ***If no, then red.***		What other products has this local or global manufacturer brought to market?
Supply for the product **doesn't meet demand forecasts**	Production strategy includes a **clear plan to support anticipated demand**	• Do both demand and supply **forecasts exist and is supply sufficient to cover demand?** ***If no, then red.***		What are future key points of inflection for manufacturing capacity?
Production economics **don't favor necessary margin requirements**	**Economics** (e.g., pricing, COGS) **are favorable** to manufacturers and distributors in order **to incentivize production and distribution** of the product	• Are the **manufacturers able to make an attractive margin** on the product? ***If no, then red.***		Are there ways to lower COGS or increase price to make production economics more attractive?

High barrier | Medium barrier | Low barrier

Ratings are meant primarily to indicate relative barrier, and are more art than science

STEP 2.1 EXERCISE 3

Barrier Assessment Tool | Clinical and regulatory

Identify clinical data needed or any potential impact that new clinical data could have on scale-up

Barrier	Desired outcome	How to determine level of urgency	Barrier (color red, yellow, green)	Key considerations
There are signals that **additional clinical evidence** is needed and/or would accelerate scale up	Presenting additional clinical evidence from local trials or that present new data **can expedite the approval process or expand the product's approved uses**	• Is **regulatory approval contingent** on additional clinical evidence? ***If yes, then red.***		Have other products in country benefitted from additional or updated clinical data?
Clinical studies/evidence are ongoing in target country and/or other countries	Additional **evidence should be monitored** to determine if the strategy should be adapted	• Are there **active trials set to report data that could impact** the current product registration or regulatory process? ***If yes, then red.***		Would outcomes of active trials impact government acceptance of product?

High barrier | Medium barrier | Low barrier

Ratings are meant primarily to indicate relative barrier, and are more art than science

STEP 2.1 EXERCISE 3

Barrier Assessment Tool | Policy, advocacy, and financing

Establish an enabling environment for scale-up

Barrier	Desired outcome	How to determine level of urgency	Barrier (color red, yellow, green)	Key considerations
There isn't sufficient **commitment from KOLs**	KOL buy-in can aid in **policy makers and clinicians hearing about the benefits** of the product	• Have **policy makers spoken about the need for the product publicly? *If no, then red.*** • Do most **practitioners know about the clinical benefits of the product? *If no, then red.***		What professional associations are key to clinical adoption of the product?
The product doesn't have **placement on EML or other relevant lists**, as needed	Inclusion in clinical lists **elevates the product as a standard of care** and ensure long term utilization at health facilities	• Are there clinical **lists or purchasing ledgers that list a competing product/treatment** as opposed to the product in question? ***If yes, then red.***		What lists are currently used at the point of access?
There is no **clear buyer/payer** for the product (if the user is not the buyer)	Establishing funding beyond early activities **certifies that momentum in scale-up can be maintained**	• Are there buyers/payers who have **committed funds for short, medium, and long-term activities? *If no, then red.***		Will medium and long-term funding for scale-up require a shift in payers?

High barrier | Medium barrier | Low barrier

Ratings are meant primarily to indicate relative barrier, and are more art than science

STEP 2.1 EXERCISE 3

Barrier Assessment Tool | Coordination

Ensure appropriate ownership and execution of strategy over time

Barrier	Desired outcome	How to determine level of urgency	Barrier (color red, yellow, green)	Key considerations
There **aren't phasing plans** in place	Optimize limited resources for specific regions or channels so that **'early wins'** provide demand and test interventions	• Are **resources limited** relative to the human and financial capital required for interventions and coordination? ***If yes, then red.***		How have similar scale-up efforts phased resources?
There aren't clear **roles and responsibilities** for launch and scale of the product *(depending on stage of scale up process)*	Clear delineation of roles and responsibilities **encourages follow through** on implementation	• Are there a large **number of activities and actors,** and very little precedent for coordination during scale-up? ***If yes, then red.***		Do key actors have geographic or functional preferences or strengths that can aid in assigning roles?
Supply and demand forecasts, and timing of supply and demand, **aren't defined or matched**	**Identify any potential volume imbalances** between supply and demand today and in the future	• Do both **demand and supply forecasts exist, and is supply sufficient to cover demand? *If no, then red.***		What is estimated supply capacity? Is it sufficient to cover demand?
There isn't a clear, defined **M&E dashboard**	**Track progress** against key milestones and optimize	• Have **key metrics been identified? *If no, then red.*** Are all **stakeholders aligned? *If no, then red.***		How have similar scale-up efforts created dashboards? How can the metrics be kept lean?
There are signs of an **unhealthy market**	Identify any **market trends that could undermine the long-term sustainability** of the market	• Will **manufacturers continue to make an attractive margin** on the product? ***If no, then red.*** • In smaller 'test markets,' did a **steady state level of demand** remain? ***If no, then red.***		How would the market react to a sudden change in supply or demand?

High barrier | Medium barrier | Low barrier

Ratings are meant primarily to indicate relative barrier, and are more art than science

STEP 2.1

Market Segmentation Analysis Tool

Illustrative

Total Market

7.1M annual births in Nigeria

Provide the total potential market size, before filtering down to your product's addressable market

Point of Delivery

After answering the who, what, where, and when for your product, **base your first division on the most pronounced difference**

Cord care Awareness

88% of deliveries had purchased substance for cord care

Target user/first applier of product

Nurse/Physician - 2.95M (42%)

Includes:
- Nurse/nurse midwife (28.8%)
- Physician (12.2%)
- Auxiliary nurse midwife (3.2%)

CHW/TBA - 1.85M (26%)

Includes:
- Traditional birth assistant (TBA)/volunteer health worker (VHW) (20.8%)
- Community health worker, e.g., CHW or CHEW (2.2%)
- Midwives

Mother/Family - 2.21M (32%)

Includes:
- Mother (11.2%)
- Family member, e.g., mother-in-law, sister, grandmother (20.3%)

If it simplifies the analysis, **group similar roles together to be one target user**

= 1M births

= 500k deliveries

STEP 2.1

Market Segmentation Analysis Tool

Total Market

Fill in total market size

Provide the total potential market size, before filtering down to your product's addressable market

Point of Delivery

% x

% x

After answering the who, what, where, and when for your product, **base your first division on the most pronounced difference**

Cord care Awareness

Input here

Target user/first applier of product

Group 1 - # (%)

Includes:
- List down similar roles together

Group 2 - # (%)

Includes:
- List down similar roles together

Group 3 - # (%)

Includes:
- List down similar roles together

If it simplifies the analysis, **group similar roles together to be one target user**

STEP 2.1

Patient Journey Mapping Tool

Illustrative

Awareness of the need for the product should be added when behavior change is necessary

	Target users become aware of product		Target users access product	
Three target users for product:	**Key influences:** Early gatekeepers	Later reinforcement	**Point of service:**	**Point of access:**
Facility-based health provider	• KOLs within the facility • Training/education • KOLs within professional associations	• Demand from patients • 'Mama kit' lists • Advertisements via radio, posters, print	**Facility - public or private (42%)**	Private pharmacy or PPMV Private facility Public facility
Community health worker	• Health providers at PHCs and/or facilities • Community leaders • Training/education • KOLs within professional associations	• Demand from community members • 'Mama kit' lists • Advertisements via radio or posters	**Home - assisted by non-family (26%)**	Private pharmacy or PPMV Private direct Public pharmacy Public direct
Mother/family member	• Community leaders • Community members, including other mothers • Health providers (e.g., recommendation during ANC visit)	• 'Mama kit' lists • Advertisements via radio or posters	**Home – unassisted or assisted by family (32%)**	Private pharmacy or PPMV Private direct Public pharmacy Public direct

This analysis assumes **the perspective of target**

Map point of service and access to each other if different

Public

Private

STEP 2.1

Patient Journey Mapping Tool

Awareness of the need for the product should be added when behavior change is necessary

	Target users become aware of product		**Target users access product**	
Three target users for product:	**Key influences:** Early gatekeepers	Later reinforcement	**Point of service:**	**Point of access:**
Group 1	• List Here	• List Here	**Write here**	Define here Define here Define here
Group 2	• List Here	• List Here	**Write here**	Define here Define here Define here Define here
Group 3	• List Here	• List Here	**Write here**	Define here Define here Define here Define here

This analysis assumes **the perspective of target**

Map point of service and access to each other if different

Public

Private

STEP 2.1

Manufacturing Analysis Tool

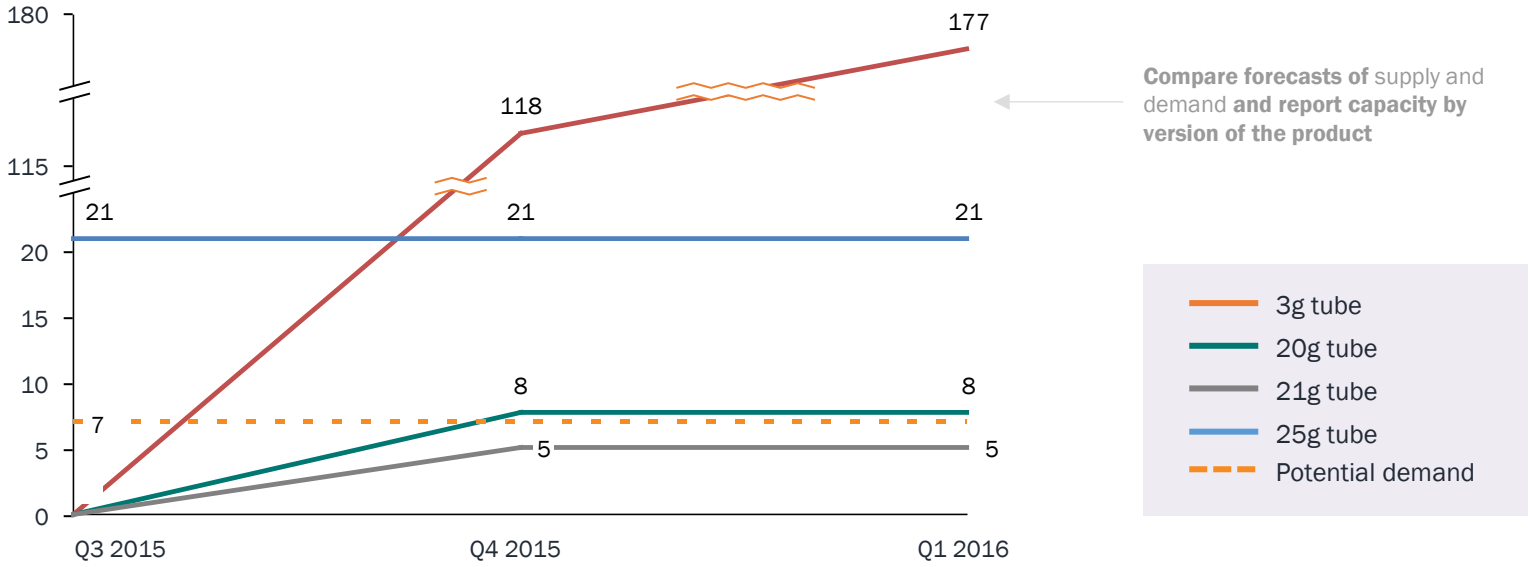
Illustrative

Project supply over time to account for any suppliers entering or leaving the market

Points of access | Distribution | Procurement | Manufacturing

Estimated capacity of local production of product

Millions of tubes per year, Q4 2015 to Q1 2016



Compare forecasts of supply and demand **and report capacity by version of the product**

STEP 2.1

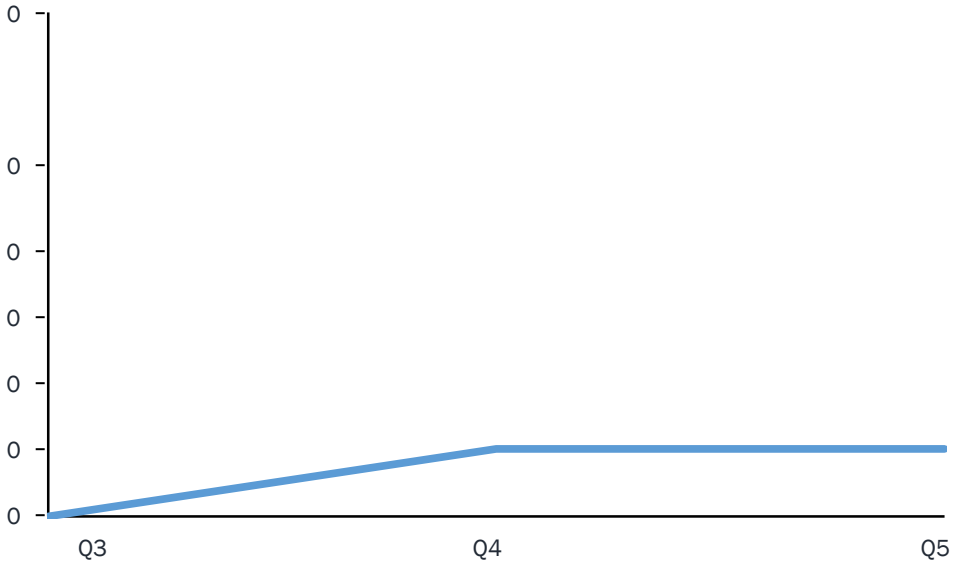
Manufacturing Analysis Tool

Project supply over time to account for any suppliers entering or leaving the market

Points of access | Distribution | Procurement | Manufacturing

Estimated capacity of local production of product

Millions of _ per year, Q4 20__ to Q1 20__



Compare forecasts of supply and demand **and report capacity by version of the product**

KEY

STEP 2.1

Delivery Channel Analysis Tool (1/3)

Illustrative

Points of access	Distribution	Procurement	Manufacturing
Public pharmacy ($)	• Direct to government via state warehouses • Third party contractor	• State government • Donors ($)	**78%** to public sector
Public facility ($)	• Direct to government • Direct to hospital • Third party contractor	• State government • Public hospitals • Donors ($)	
Public direct ($)	• Direct to government • Third party contractor	• Donors • State government ($)	
Private pharmacy or PPMV ($)	• Independent distributor • Open drug markets ($)	• Independent distributor ($)	**Local manufacturing** As of Q4 2015, Drugfield has sold 1.04 million tubes of product in Nigeria
Private facility ($)	• Direct to hospital • Independent distributor ($) • Open drug markets	• Independent distributor • Private hospitals ($)	**22%** to private sector
Private direct ($)	• Independent distributor ($)	• Independent distributor ($)	

Public

Private

($) Requires payment

Separate procurement roles from distribution roles, even if there's overlap in actors

Highlight when product transfers **require payment**

Split past or future sales across relevant channels

STEP 2.1

Delivery Channel Analysis Tool (2/3)

Illustrative

Points of access	Distribution	Procurement	Manufacturing

Public

Direct to government
- Suppliers compete in government tenders and supply directly from their central or regional warehouse to the state central medical store

Direct to hospital
- Suppliers have dedicated sales representatives tasked with clinical advocacy at private and public (secondary and tertiary) hospitals

Third party contractor
- Suppliers contract independent firm specializing in the distribution of consumer and other goods through a propriety distribution system; most common in public sector

Private

Independent distributors
- Suppliers sell to independent distributors who later resell

Informal
- Pooled procurement of PPMVs
- Community-based distribution

Vertically-integrated
Suppliers operate central or regional warehouse connected to distribution network of wholesalers/distributors

Unregulated open drug markets
Up to 80% of drugs on market pass through

Public
Private
$ Requires payment

Provide details on where product is **warehoused, sent to, and sourced from**

Differences in **how regulated the point of distribution is** can be highlighted if relevant

Each state should evaluate which existing channels are best suited for the product, noting that:
- Channels used in each state are often product-specific (e.g., MNCH, family planning)
- Many states are working to integrate and harmonize current channels

STEP 2.1

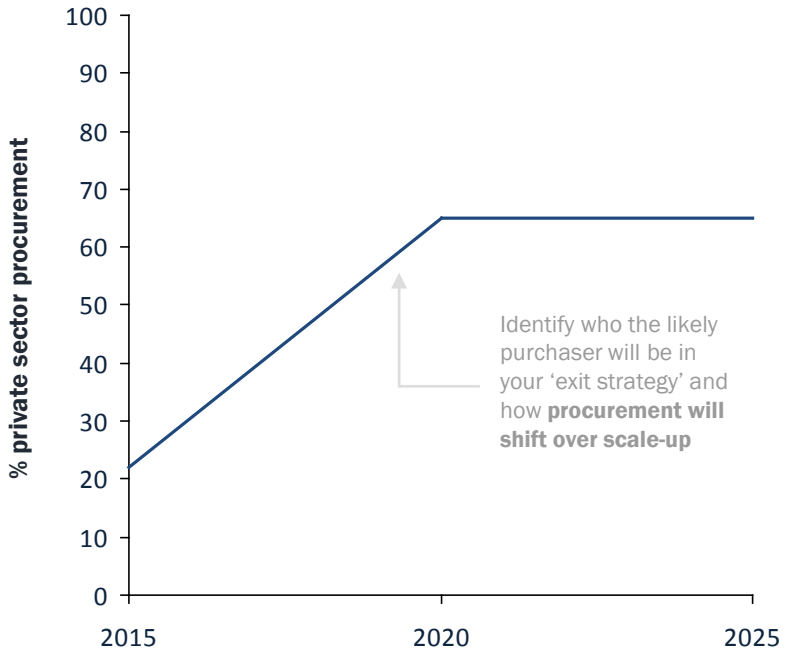
Delivery Channel Analysis Tool (3/3)

Illustrative

Points of access | Distribution | Procurement | Manufacturing

Goal split between public vs. private procurement

% private sector procurement, 2015 to 2025



FMoH and donors play catalytic role to subsidize cost of the product for state-led procurement

States start procuring the product, incentivized by commodity subsidy

Private sector procurement increases over time, motivated by public sector demand

In the long term, **state-level public and private procurement balance out** to match distribution of private/public points of access for the product

If the product requires subsidization, identify for how long and what the long-term goal for procurement is

STEP 2.1

Delivery Channel Analysis Tool (1/3)

STEP 2.1

Delivery Channel Analysis Tool (2/3)

Points of access	Distribution	Procurement	Manufacturing

Public		Private	
List here • xx	**List here** • xx	**List here** • xx	**List here** • xx
List here • xx		**List here** • xx	
		List here • xx	

Public
Private
$ Requires payment

Provide details on where product is **warehoused, sent to, and sourced from**

Differences in **how regulated the point of distribution is** can be highlighted if relevant

Each state should evaluate which existing channels are best suited for the product, noting that:
- Channels used in each state are often product-specific (e.g., xx)
- Many states are working to integrate and harmonize current channels

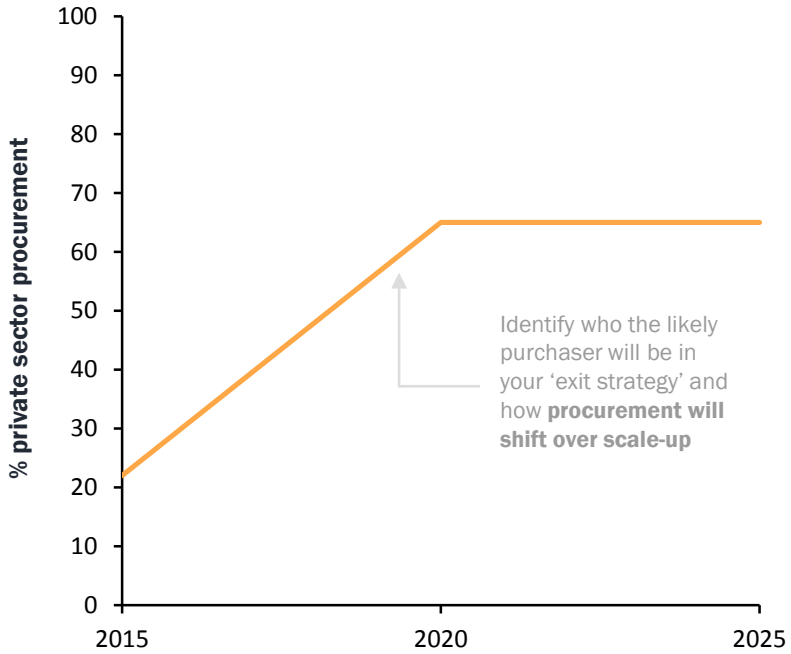
STEP 2.1

Delivery Channel Analysis Tool (3/3)

Points of access | Distribution | Procurement | Manufacturing

Goal split between public vs. private procurement

% private sector procurement, 20__ to 20__



_ catalytic role to subsidize cost of the product for state-led procurement

_incentivized by commodity subsidy

_increases over time, motivated by public sector demand

In the long term, _ **public and private procurement balance out** to match distribution of private/public points of access for the product

If the product requires subsidization, identify for how long and what the long-term goal for procurement is

STEP 2.1

Clinical Trial Analysis Tool

Illustrative

Present **academic literature and trials to date** with key findings

Articles

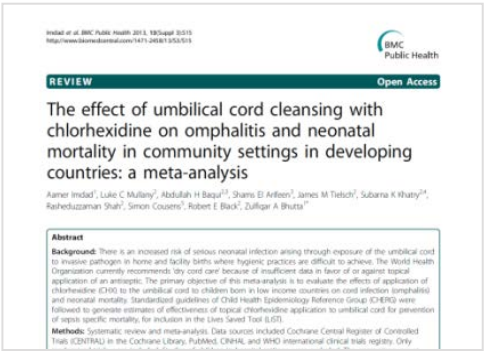
Topical applications of chlorhexidine to the umbilical cord for prevention of omphalitis and neonatal mortality in southern Nepal: a community-based, cluster-randomised trial

Articles

The effect of cord cleansing with chlorhexidine on neonatal mortality in rural Bangladesh: a community-based, cluster-randomised trial

Articles

Topical application of chlorhexidine to neonatal umbilical cords for prevention of omphalitis and neonatal mortality in a rural district of Pakistan: a community-based, cluster-randomised trial


BMC Public Health

REVIEW Open Access

The effect of umbilical cord cleansing with chlorhexidine on omphalitis and neonatal mortality in community settings in developing countries: a meta-analysis

	NEPAL	BANGLADESH	PAKISTAN	META-ANALYSIS
Country				
Journal	Lancet	Lancet	Lancet	BMC Public Health
Year	2006	2012	2012	2013
Findings	24% reduction in newborn mortality CHW application for home births	20% reduction in newborn mortality Cord cleansing on first day of birth	40% reduction in newborn mortality The product provided by traditional birth attendants	23-40% reduction in newborn mortality The product provided by traditional birth attendants

Provide updates on **active clinical trials**

UPDATE

- Clinical study in **India** is now underway to attain local data to support advocacy and accelerate introduction timeline (BMGF, SNL)
- Clinical studies in **Tanzania** and **Zambia** are complete and pending results

STEP 2.1

Clinical Trial Analysis Tool

Illustrative

Present **academic literature and trials to date** with key findings

Country	COUNTRY 1	COUNTRY 2	COUNTRY 3	META-ANALYSIS
Journal				
Year				
Findings				

Provide updates on **active clinical trials**

UPDATE

X

STEP 2.2 EXERCISE 1

Comparable Product Analysis Tool

Select comparable products that have similar target users, delivery channels, and price to ensure relevant insights

Use these interventions as starting points for a long list of interventions that are most relevant to the target product

Illustrative

Organize relevant information according to the key activities required

		Comparable products			
	Activity	**ORS/Zinc**	**Estimated cost**	**Misoprostol**	**Estimated cost**
Market and user	Demand generation	Because of the large target user base a national marketing plan was disseminated through radio and print	**$50,000**	Key intervention was sensitized with community leaders Bundled other maternal and child health products with misoprostol to drive demand	**$10,000**
	Creating awareness	Care-seeking behavior for diarrhea was fragmented so awareness was driven through clinicians and retailers	**$15,000**	Introduced expecting mothers to product at ANC visits	**$1,000**
	Training and education	Care-seeking behavior for diarrhea was fragmented so awareness was driven through clinicians and retailers	**$10,000**	Focused training on community midwives and community-based health volunteers	**$10,000**
Manufacturing and distribution	Delivery channel incentives	Used training and detailing at points of retail to encourage shop owners to improve stocking practices and increase inventory turns	**$5,000**	Community sensitization required meeting with community and religious leaders	**$2,000**
	Production economics	Encouraged manufacturers to enter the market and then provided a COGS analysis to manufacturers who were committed to decreasing price	**$3,000**	Affordable imported product; >50 branded and non-branded versions available globally	**$1,000**
[Additional core components]	Additional activity…	*Description of intervention used*	***cost***	*Description of intervention used*	***cost***
	Additional activity…	*Description of intervention used*	***cost***	*Description of intervention used*	***cost***

STEP 2.2 EXERCISE 1

Comparable Product Analysis Tool

		Comparable products			
	Activity	**Product 1**	**Estimated cost**	**Product 2**	**Estimated cost**
Market and user					
Manufacturing and distribution					
[Additional core components]					

STEP 2.2 EXERCISE 2

Intervention Design Tool

Illustrative

If multiple activities are tied to the barrier they should **map back to specific roles** and identify if those roles are national or sub-national

	Barrier	Recommended interventions + potential associated activities	Potential stakeholder responsible
Market and user	**Low awareness at points of access for target users**		
	Facilities	• **Conduct clinical mentoring and training activities at public and private facilities**, leveraging professional associations for many of the private sector visits and state ministries of health (SMoHs) at select public and private facilities to demonstrate commitment and secure buy-in	• **Manufacturers, implementers, SMoHs, facility directors, professional associations**
	Pharmacies	• **Conduct training activities at private pharmacies and public pharmacies at PHCs**, leveraging professional associations for many of the private sector visits and SMoHs at select public and private pharmacies to demonstrate commitment and secure buy-in; consider clinical mentoring at primary health centers	• **Manufacturers, implementers, SMoHs, PHC directors, professional associations**
	Direct	• **Conduct training activities for donors and private companies** currently distributing delivery/Mama kits or considering this work in the future	• **Implementers, SMoHs**
	Lack of aggregated demand forecasts	• **Support states** with their forecasts • **Compile state projections for demand into a forecast** and check against scale-up plan targets as well as realistic limitations (e.g., available funding) • **Update forecast annually**	• **Uptake coordinator** for national forecasts and aggregating state forecasts • **States/implementers** for state forecasts, with support of uptake coordinator, as needed
[Additional core components]	*List appropriate barriers according to the core components of scaling here...*	*Think through detailed intervention...*	*Determine responsible party...*

STEP 2.2 EXERCISE 2

Intervention Design Tool

	Barrier	Recommended interventions + potential associated activities	Potential stakeholder responsible
MARKET AND USER	*List appropriate barriers according to the core components of scaling here...*		
MANUFACTURING and DISTRIBUTION	*List appropriate barriers according to the core components of scaling here...*		
CLINICAL EVIDENCE and REGULATORY	*List appropriate barriers according to the core components of scaling here...*		
POLICY, ADVOCACY, and FINANCING	*List appropriate barriers according to the core components of scaling here...*		
COORDINATION	*List appropriate barriers according to the core components of scaling here...*		

Step 3.1: Develop operational launch plan

1. Operational Launch Plan Tool
2. Cost Estimate Tool

Step 3.2: Set uptake targets and create monitoring plan

1. Monitoring and Evaluation Tool
2. Goals and Targets Tool
3. Country Dashboard Tool
4. M&E Framework Dictionary Tool

Tools available only in this Supplemental Toolkit

Illustrative

STEP 3.1 EXERCISE 1

Operational Launch Plan Tool

Timeline to show overall sequencing of activities for strategic interventions across the five core components of scale-up

Months after launch

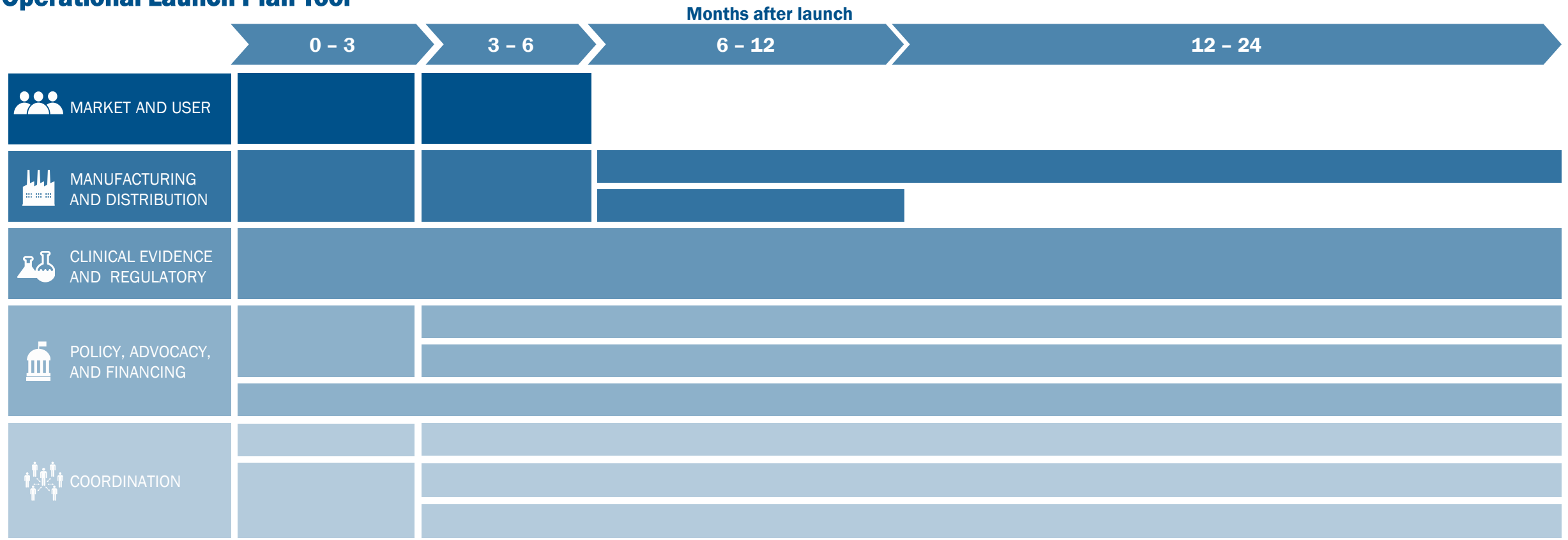
	0 – 3	3 – 6	6 – 12	12 – 24
MARKET AND USER	**Release messaging materials**	Complete national and state demand forecasts		
MANUFACTURING AND DISTRIBUTION	**Create fund to subsidize 75% commodity cost**	Start disbursing funds to states	Oversee efforts to subsidize 75% commodity costs for states launching programs Expand private sector delivery channels	
CLINICAL EVIDENCE AND REGULATORY	Monitor evidence from future studies			
POLICY, ADVOCACY, AND FINANCING	**Close funding gap for scale-up plan**	Conduct in-person advocacy visits to hospitals Send representative to promote product at all relevant professional association conferences		
	Add product to EML/relevant lists			
COORDINATION	**Finalize M&E system**	Conduct M&E activities		
	Formalize coordinating mechanism	Host coordination meetings (monthly for the first year, quarterly thereafter) Update phasing strategy each quarter		

Table to enumerate all activities with clear owner, cost, and timeframe; if helpful, table can also include sub-activities

Owner	Strategy	Activity	Cost (USD)	Timeframe
Donors	1 – Market user	Improve packaging and branding for product	200,000	6-12 months
MoH	1 – Market user	Release messaging materials	Covered by existing staff	0-3 months
MoH	1 – Market user	Update and disseminate training materials	10,000	0-3 months
MoH	2 - Manufacturing and distribution	Create fund to subsidize 75% commodity cost	580,000	0-3 months
MoH	2 - Manufacturing and distribution	Start disbursing funds to states	Covered by existing staff	0-6 months

STEP 3.1 EXERCISE 1

Operational Launch Plan Tool



Owner	Strategy	Activity	Cost (USD)	Timeframe

STEP 3.1

Cost Estimate Tool

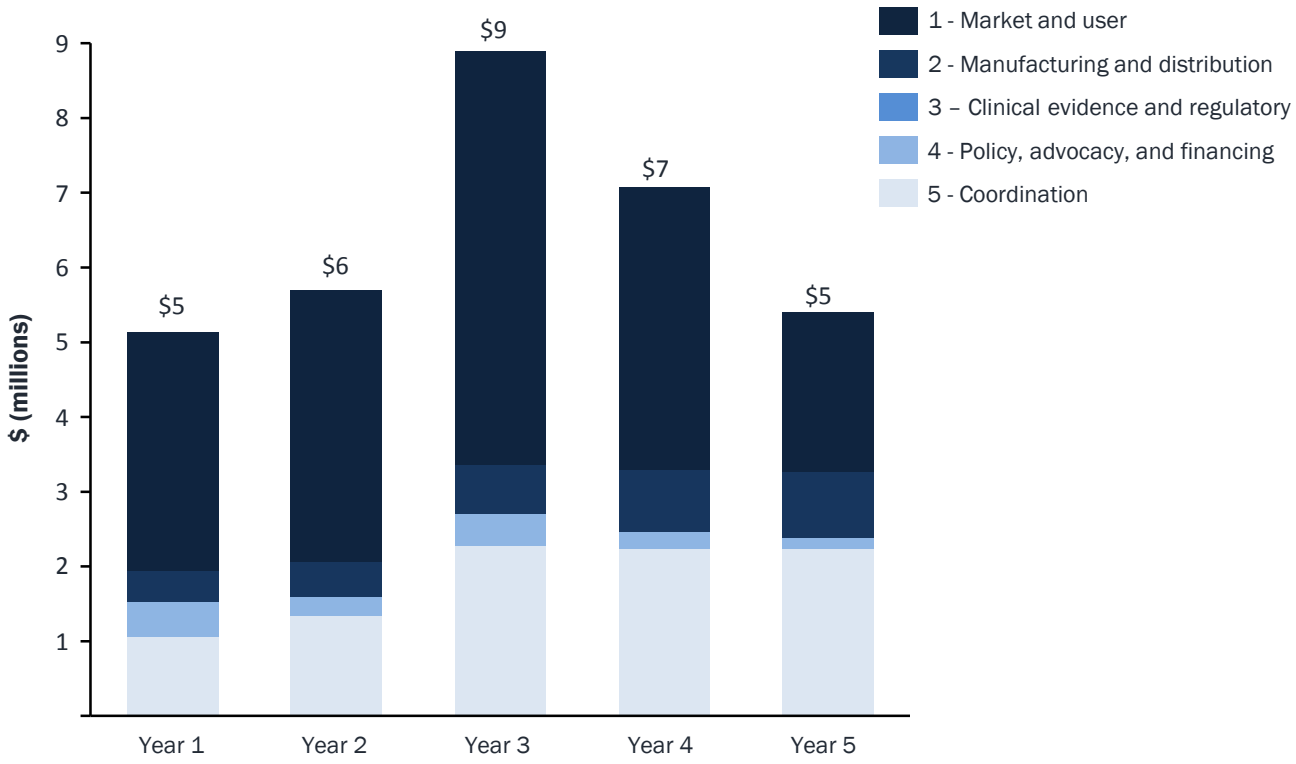
Illustrative

See costing spreadsheet tool in Excel for sample costing template

Consider analyzing **multiple scenarios for costing** to get a reliable range

Total scale-up costs required

Projected $ spend (millions), years 1-5



Aggregate year by year costs **provide a skyline view of costs over the scale-up period**

Accelerated/high investment scenario

Primary drivers of costs:

- **Market and user –** This strategy accounts for ~60% of total costs and the vast majority of that spend is required at the state level to kick start demand
- **Manufacturing and distribution –** This strategy's costs are largely associated with the procurement and distribution of CHX; activities will be designed to incentivize state-level actors to procure and distribute CHX
- **Clinical evidence and regulatory –** No specific interventions are currently costed
- **Policy, advocacy, and financing –** In the first two years, these costs focus on updating state EMLs, as well as advocacy trips conducted throughout the five years of the implementation plan
- **Coordination –** The majority of coordination costs are incurred at the state-level for recurrent M&E activities

Commentary by core component **highlight the key drivers of costs**

STEP 3.1

Cost Estimate Tool

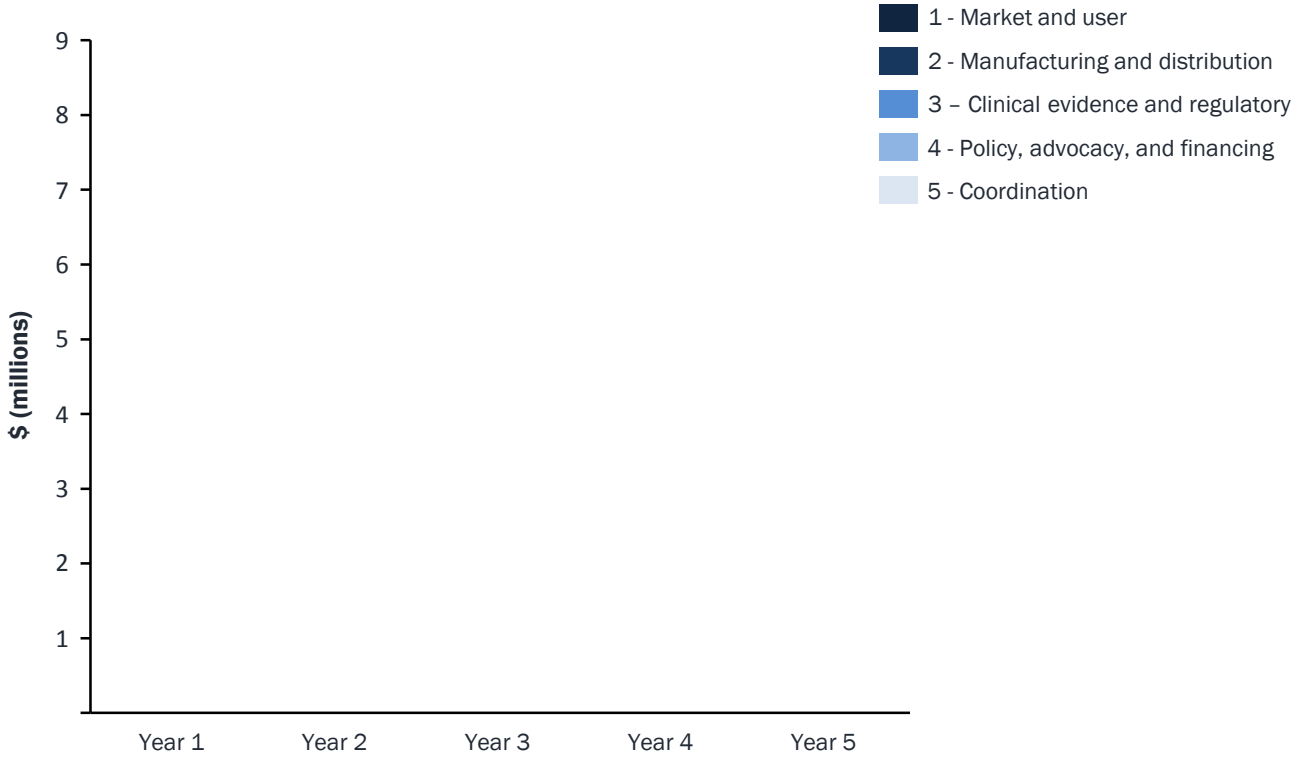
Illustrative

See costing spreadsheet tool in Excel for sample costing template

Consider analyzing **multiple scenarios for costing** to get a reliable range

Total scale-up costs required

Projected $ spend (millions), years 1-5



Aggregate year by year costs **provide a skyline view of costs over the scale-up period**

Accelerated/high investment scenario

Primary drivers of costs:

- **Market and user –** xx
- **Manufacturing and distribution –** xx
- **Clinical and regulatory –** xx
- **Policy, advocacy, and financing –** xx
- **Coordination –** xx

Commentary by core component **highlight the key drivers of costs**

STEP 3.2 EXERCISE 1

Monitoring and Evaluation Tool

Illustrative

Identify the epidemiological impact(s) your product will have

Impact

NMR

	MARKET AND USER	MANUFACTURING AND DISTRIBUTION	CLINICAL EVIDENCE AND REGULATORY	POLICY, ADVOCACY, AND FINANCE	Coordination
Outcomes	**Target users correctly apply CHX** • % of newborns (live births) that received first application of CHX gel to the umbilical cord at birth (home and facility births) • % of women with a live birth in the last two/five years who reported applying no substance other than CHX gel on the umbilical cord • % of health providers who recommended the use of CHX gel • % of skilled birth attendants having comprehensive knowledge and correct skills on CHX gel use and application	**CHX is available to all target users** • % of health facilities that provide maternity services with CHX gel stock out in the last 3 months • % of PCN registered retail outlets (PPMVs and community/private pharmacists) with CHX gel stock out in the last 3 months	**CHX use follows latest clinical evidence and regulatory guidelines** • % of health facilities that have copies of updated national protocols (STG, SOPs, Standing order) • No. of published in country studies on CHX.	**Policies, KOLs, and financing increase use of CHX** • No. of states with budget line for CHX gel • No. of states with at least one development partner supporting CHX scale up • CHX gel incorporated in published national EML (Y/N) • CHX gel incorporated in published national STG (Y/N) • No. of states with CHX gel on state EML • No. of states that procured and distributed CHX gel	• CHX included as agenda item in national child health working group (Y/N)
Output	**Providers are trained to use CHX correctly** • No. of people trained on use and application CHX gel **CHX is widely promoted** • No. of community mobilization activities held to promote CHX gel use • No. of slots for CHX adverts aired	**Production and distribution of CHX is sufficient to meet demand** • No. of CHX gel tubes produced • No. of CHX gel tubes distributed			• Bi annual CHX coordination stakeholder meetings occurred (Y/N)

Pick output metrics that provide effective ways to monitor that your scale-up efforts are on track

Pick outcome metrics that are closely correlated to your desired impact

STEP 3.2 EXERCISE 1

Monitoring and Evaluation Tool

Impact					
	MARKET AND USER	MANUFACTURING AND DISTRIBUTION	CLINICAL EVIDENCE AND REGULATORY	POLICY, ADVOCACY, AND FINANCE	Coordination
Outcomes					
Output					

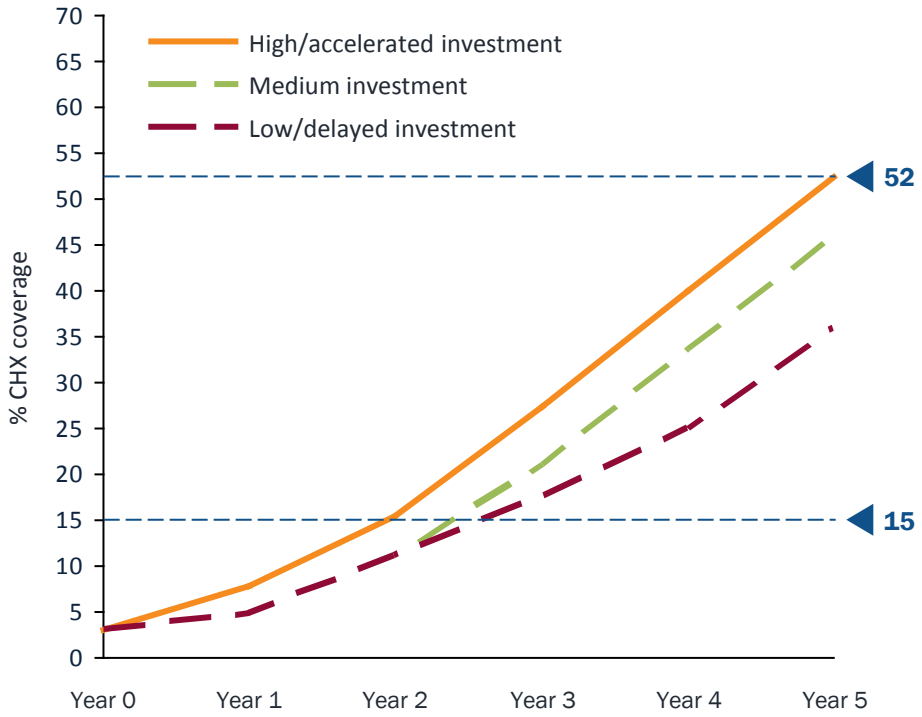
STEP 3.2

Goals and Targets Tool

Illustrative

Projected CHX scale-up across three investment scenarios

% national coverage, years 0-5



Include **graph that shows projected coverage over the time period of interest.** If relevant, include targets for various scenarios (e.g., varying levels of funding).

Highlight key **details from the most likely scenario**

Most likely scenario

Projections for accelerated scenario highlight:

- All **states have begun scale-up by the beginning of year three,** resulting in straight line projections
- The peak projected **five-year coverage (~52%)** is driven by application of CHX in facility and non-facility births, but the facility uptake curve outpaces the non-facility uptake curve

Ultimately coverage will depend on:

- Ability of all states to execute
- Access to required funding

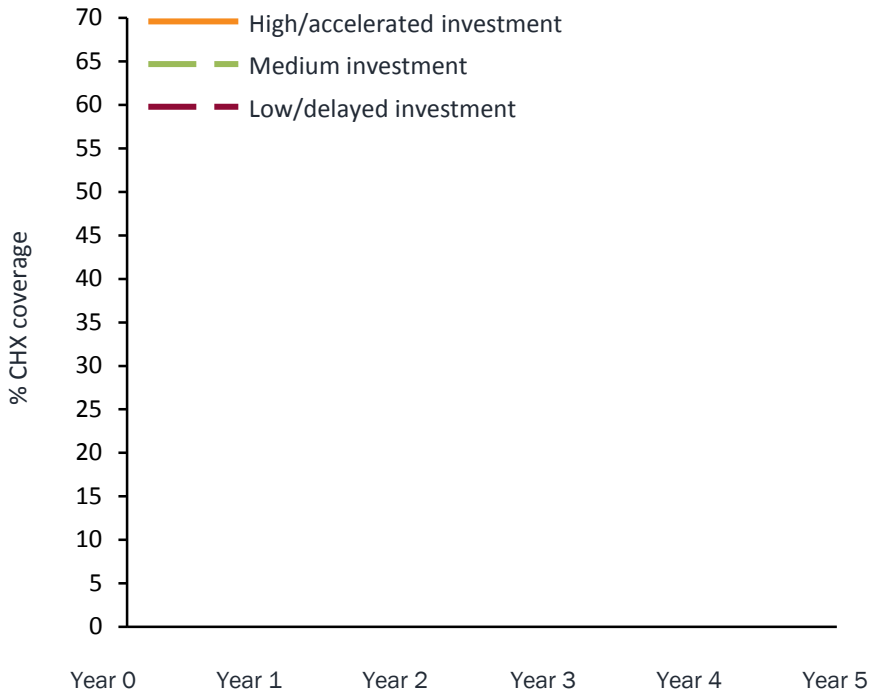
Acknowledge **key assumptions and/or factors that influence targets**

STEP 3.2

Goals and Targets Tool

Projected ___ scale-up across three investment scenarios

% national coverage, years 0-X



Most likely scenario

Projections for accelerated scenario highlight:

- List here

Ultimately coverage will depend on:

- List here

STEP 3.2
Country Dashboard Tool

Illustrative

	Status	Year 1	Year 2	Year 3	Year 4	Year 5
Neonatal mortality rate	🟡	32	32	30	29	27
Percentage of newborns (live births) that received first application of CHX gel to the umbilical cord at birth (home and facility births)	🔴	8%	15%	27%	40%	52%
Percentage of women with a live birth in the last two/five years who report applying no substance other than CHX gel to the cord	🟡	5%	10%	20%	25%	29%
Percentage of health providers who recommended the use of CHX gel	🟡	10%	15%	20%	30%	40%

- Behind targets
- Ahead of targets
- Meeting targets

Binary metrics:
- Product approved by local regulatory authority
- Product included in national EML and National Procurement List
- Product included in national STG

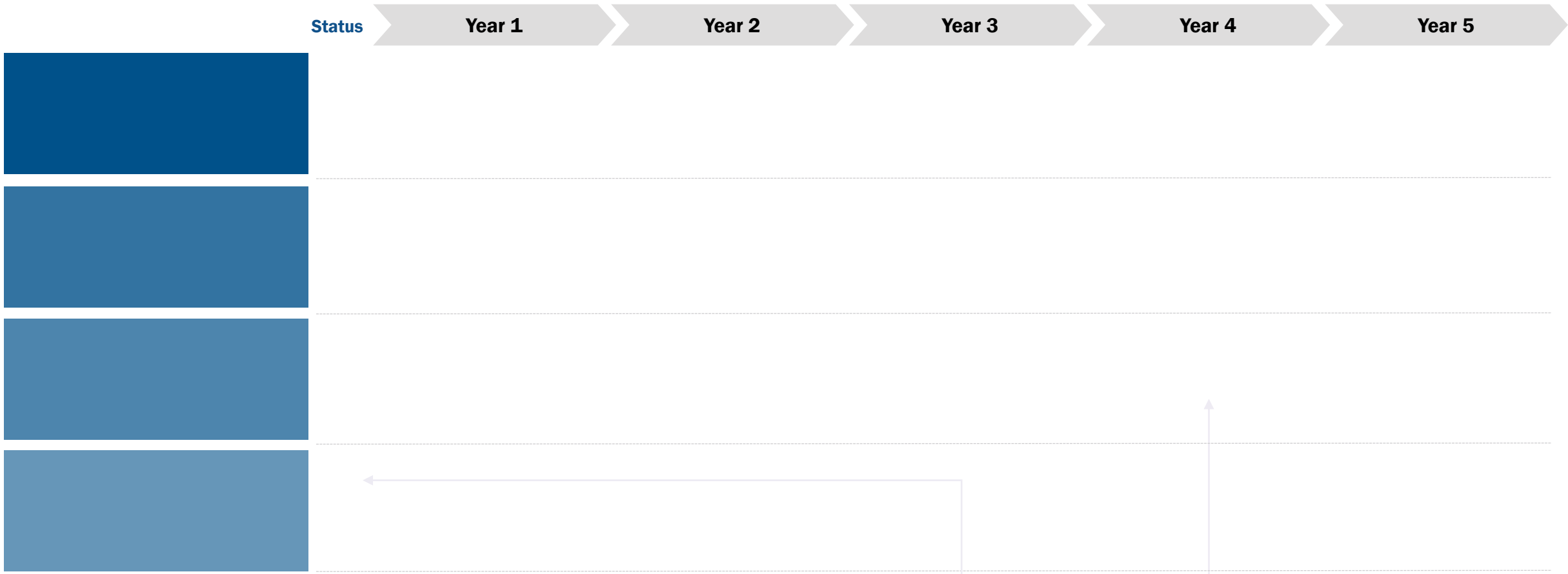
Status of each indicator can be updated at regular intervals (e.g., each quarter)

National dashboard includes key metrics to track over time; supporting pages can contain additional metrics to track at the national or subnational levels

STEP 3.2

Country Dashboard Tool

Illustrative



STEP 3.2

M&E Framework Dictionary Tool

Illustrative

SN	Indicator	Measurement	Type	Data Source	Collection Method	Geographic Focus	Disaggregation	Reporting Frequency
1	Neonatal Mortality Rate	**Numerator:** Number of deaths within first month of life. **Denominator:** Total number of live births in the same year. **Unit of measurement:** Rate (per 1,000 live births)	Impact	NDHS	Report review	National	Sex Geopolitical zones State	End line
2	Percentage of newborns (live births) that received first application of CHX gel to the umbilical cord at birth (home and facility births)	**Numerator:** Number of newborns that received first application of CHX gel on the umbilical cord at birth **Denominator:** Total live births **Unit of measurement:** Percentage	Outcome	NDHS SMART HMIS LDR	Report review	National Geo-political zones State	State Place of delivery Level of facility	Every five years Annually Quarterly Monthly
3	Percentage of women with a live birth in the last two/five years who report applying no substance other than CHX gel to the cord	**Numerator:** Number of women 15-49 years with a live birth in the last two/five years who report applying no substance other than CHX gel to the cord **Denominator:** Total number of live births Unit of measurement : Percentage	Outcome	NDHS SMART	Report review	National	State Place of delivery	Every five years Annually
4	Percentage of health providers who recommended the use of CHX gel	**Numerator:** Number of health providers who reported recommending the use of CHX **Denominator:** Total number of health providers and caregivers interviewed **Unit of measurement:** Percentage	Outcome	ISS SMART	Interview	State	State LGA Level of Facility	Quarterly Biannually Annually

STEP 3.2

M&E Framework Dictionary Tool

Illustrative

SN	Indicator	Measurement	Type	Data Source	Collection Method	Geographic Focus	Disaggregation	Reporting Frequency
1								
2								
3								
4								