Federal Ministry of Health

National Strategy For Scale-Up Of Chlorhexidine in Nigeria

MARCH 2016

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March 2016

Contents

FOREWORD

Neonatal causes continue to account for the largest proportion (32%, WHO/CHERG 2014) of under-five deaths in Nigeria. Notable among these neonatal causes are prematurity, birth asphyxia and sepsis. Preliminary reports from the Verbal Autopsy Survey show that sepsis including infections & neonatal pneumonia actually account for well over half of these neonatal deaths (VASA 2014 Reports, NPC). Sepsis from infected umbilical stump is one of the main routes for infection leading to death and WHO recommends the use of Chlorhexidine for cord care for home births in areas where neonatal mortality rate (NMR) is above 30/1000 live births. The current NMR of 37/1000 live births and a home delivery rate of about 63% (NDHS 2013) clearly puts Nigeria in this category.

Chlorhexidine a bisbiguanide compound with broad spectrum antimicrobial properties (active against gram –ve and +ve microbes). Its mechanism of action is by disrupting the bacterial cell membrane which leads to increased bacterial cell membrane permeability and leakage.

Chlorhexidine was first introduced in Nigeria through the USAID/TSHIP project in Sokoto and Bauchi states as 4% Chlorhexidine gel. The Federal Ministry of Health gleaned experiences from other countries, reviewed output of local studies and also consulted widely with stakeholders in order to standardize the specifications and use of this product in Nigeria which is presented as:

"4% Chlorhexidine gel in 25g tubes for multiple applications starting from within 2hours of birth then daily till cord drops off or till gel finishes"

As one of the 15 life-saving commodities adopted for accelerated access and use in Nigeria, it suits us to see that this commodity becomes rapidly available and is being used in all parts of the country. This is the reason for this **National Chlorhexidine scale up strategy document**. Here, the specific scale up strategies have been grouped under five domains namely *market & user; manufacturing & distribution; clinical & regulatory; policy, advocacy, & financing*; as well as *coordination* strategies. An implementation plan has also been attached to guide the process of operationalizing this strategy.

This strategy has been designed to be precise, flexible, robust and practicable to ensure consistency, quality and speed in the Chlorhexidine scale up efforts. The Government is indeed grateful to all the players that have been involved in this process.

The first call is to the Child health working group within MNCH Core Technical Committee to immediately recognize and deliver on this critical mandate. I will also call all our partners to uphold their commitments by working according to plan and sustain their support in ensuring that Chlorhexidine is delivered to the last mile, reaching all babies in Nigeria.

Prof Isaac F. Adewole, FAS, DSC (HONS).
Honourable Minister of Health
March, 2016
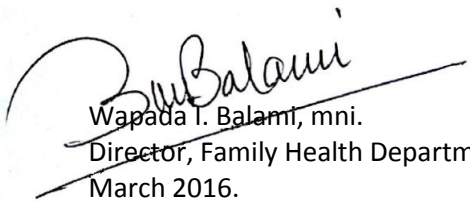
ACKNOWLEDGEMENT

This National scale up strategy for 4% Chlorhexidine gel was developed to build on the gains of success stories in Bauchi and Sokoto States. It has evolved through series of consultations between the Federal Ministry of Health and her agencies working with a robust network of stakeholders.

Notable among these are the State Ministries of Health, Professional groups, Regulatory bodies, pharmaceutical firms as well as Local and international development partners. The Ministry appreciates the sustained inputs of all these players in seeing that this work is completed.

The immense contribution of International consulting firm, Dalberg Global Development Advisors, is well appreciated.

Finally my sincere gratitude goes to the Staff of the Child health Division, especially Dr Femi James, under the leadership of Dr A.R Adeniran for their commitments throughout the entire process

Wapada I. Balami, mni.
Director, Family Health Department.
March 2016.

PREFACE

Building on "Nigeria's Call to Action to Save Newborn Lives," the Federal Ministry of Health (FMoH) has developed the National Strategy and Implementation Plan for Scale-up of Chlorhexidine in Nigeria. The Ministry incorporated existing maternal, newborn, and child health plans with additional comprehensive strategic planning and consultation to develop a comprehensive, five-year costed scale-up plan. The strategy and implementation plan is intended to guide programming, resource allocation, and commitments to achieve the national objective of Chlorhexidine uptake of 52% after the fifth year of national scale-up.

Consultants worked under the direction of the FMoH's Family Health Department to define the priorities, activities, and associated costs required to reach the neonatal objectives of the country.

Throughout the process, stakeholders have provided significant inputs to ensure that the strategy and implementation plan represents the best interests of the women, newborns, and citizenry of Nigeria. Elements of the strategy and implementation plan were based on market research conducted in 2014 and the successes of development partners that have initiated Chlorhexidine scale-up. The strategy and implementation plan also draws on content from existing plans, including 100,000 Babies Survive and Thrive Initiative, Midwives Service Scheme (MSS), SURE-P, and the UN Commission on Life-Saving Commodities. Interviews with more than 50 government departments, development partners, and donors highlighted priorities and current and future responsibilities. A series of consultative meetings provided revisions and feedback to the strategy and implementation plan — which are reflected throughout.

Neonatal Mortality in Nigeria

The current neonatal mortality rate in Nigeria is **37 deaths per 1,000 live births** (NDHS 2013) — although this is an improvement over the 40 per 1,000 live births reported in 2008, progress has slowed over the past five years.

Nigeria is committed to reducing the neonatal mortality rate. Given that approximately one in three neonatal deaths in Nigeria is due to severe infection, **the scale-up of Chlorhexidine** — an over-the-counter gel applied to the umbilical cord with efficacy in reducing infection — **can drive significant reductions in neonatal mortality**.

National uptake of Chlorhexidine in Nigeria remains low since its adoption as one of the 15 life-saving commodities — estimated to be significantly under 5%. By achieving the national objective of Chlorhexidine uptake of 52% after its fifth year of scale-up, an estimated **55,000 neonatal deaths will be averted**.

Increased commitments from federal, state, and local governments, donors, and all stakeholders are needed to meet these ambitious goals and save newborn lives.

CONTRIBUTING ORGNISATIONS

The following stakeholders made valuable contributions to the development of the National Strategy and Implementation Plan for Scale-up of Chlorhexidine:

- Federal Ministry of Health and Parastatals
  - Child Health Division, Department of Family Health
  - Department of Food and Drug Services
  - National Primary Health Care Development Agency
  - National Agency for Food and Drug Administration and Control
  - Pharmacists Council of Nigeria
  - Community Health Practitioner Registration Board
- State Ministries of Health and State Primary Health Care Development Agency Boards
  - Bauchi
  - Cross River
  - Ebonyi
  - Gombe
  - Kaduna
  - Katsina
  - Ogun
  - Rivers
- Paediatrics Association of Nigeria
- Pharmaceutical Society of Nigeria
- Society of Gynaecologists and Obstetrics of Nigeria
- National Association of Nigeria Nurses and Midwives
- National Association of Proprietary Patent Medicines Vendors
- Nigerian Urban Reproductive Health Initiative
- Nigerian Society of Neonatal Medicine
- Drugfield Pharmaceuticals
- Emzor Pharmaceuticals
- World Health Organization
- Clinton Health Access Initiative
- USAID/Nigeria
- USAID/Maternal and Child Survival Program
- Targeted States High Impact Project
- Jhpiego
- John Snow Inc.
- Marie Stopes International
- Save the Children International
- Bill and Melinda Gates Foundation
- USAID/Center for Accelerating Innovation and Impact
- Society for Family Health
- UNFPA
- UNICEF
- PATH for Global Chlorhexidine Working Group
- PACT
- Strengthening Health Outcomes through the Private Sector
- Insight Health Consulting
- Private Sector Health Alliance of Nigeria
- Dalberg Global Development Advisors

ABBREVIATIONS

BEmONC	Basic Emergency Obstetric Newborn Care
CHERG	Child Health Epidermiology Reference Group
CHW	Community Health Worker
CHEW	Community Health Extension Worker
CHX	Chlorhexidine
CNBC	Community Based Newborn Care
CORPS	Community Oriented Resource Persons
CTC	Core Technical Committees
DHIS	District Health Information System
DHPRS	Department of Health Planning Research and Statistics
EML	Essential Medicines List
ENCC	Essential Newborn Care Course
FCT	Federal Capital Territory
FMC	Federal Medical Centre
FP	Family planning
FTE	Fulltime employee
FTH	Federal Teaching Hospital
ICCM	Integrated Community Case Management
ICMI	Integrated Management of Child Illness
IEC	Information Education Communication
ISS	Integrated Supportive Supervisory
KOL	Key Opinion Leader
LASUTH	Lagos State University Teaching Hospital
LDHF	Low Dose High Frequency
LGA	Local Government Area
LMIS	Logistics Management Information System
LSS	Life Saving Skills
LUTH	Lagos University Teaching Hospital
HISP	Health Information System Programme
HMIS	Health Management Information Systems
MCH	Maternal Child Health
MDA	Ministries, Departments, Agencies
MICS	Multiple Indicator Cluster Survey
MIS	Management Information System
MNCH	Maternal, Newborn, and Child Health
MSF	Monthly Summary Form
MSS	Midwives Service Scheme
NDHS	Nigeria Demographic Health Survey
NHA	National Health Act

NHIS	National Health Insurance Scheme
NHMIS	National Health Management Information System
NPC	National Population Commission
NPHCDA	National Primary Health Care Development Agency
NMR	Neonatal Mortality Rate
Lo-ORS	Low–Osmolar Oral Rehydration Salts
OTC	Over the Counter
PA	Professional Association
PCN	Pharmacy Council of Nigeria
PHC	Primary Health Center
PPMV	Proprietary Patent Medicine Vendors
RDQA	Routine Data Quality Assessment
RH	Reproductive Health
SDI	Service Delivery Indicator
SMART	Standardized Monitoring and Assessment of Relief and Transition
SOP	Standard Operating Procedure
SPHCDA	State Primary Healthcare Development Agency
STG	Standard Treatment Guidelines
SURE-P	Subsidy Re-Investment Programme
TBA	Traditional Birth Attendants
UCH	University College Hospital
UNCoLSC	United Nation Commission on Life-Saving Commodities
UNTH	University of Nigeria Teaching Hospital
VASA	Verbal And Social Autopsy Survey

EXECUTIVE SUMMARY

The current neonatal mortality rate in Nigeria is 37 deaths per 1,000 live births (NDHS 2013). While this is an improvement over the 40 deaths per 1,000 live births reported in 2008, the rate of progress has slowed over the past five years. The Federal Ministry of Health has committed to stemming this trend, building on previous Maternal, Newborn, and Child Health (MNCH) initiatives in Nigeria, including Midwives Service Scheme (MSS), SURE-P, the UN Commission on Life-Saving Commodities and 100,000 Babies Survive and Thrive Initiative,.

Given that approximately one in three neonatal deaths in Nigeria is due to severe infection, the scale-up of Chlorhexidine – an over-the-counter gel applied to the umbilical cord with efficacy in reducing infection – **can play a significant role in reducing neonatal mortality.**[1] While the estimate of national uptake of Chlorhexidine remains low – interaction with stakeholders and preliminary analysis estimate it to be significantly under 5% – Chlorhexidine programs are gaining traction in a handful of states (e.g., Bauchi, Kaduna, Kano, Katsina, Ogun, Sokoto). Many stakeholders – from manufacturers to professional associations to development partners – have contributed to these early efforts in introducing Chlorhexidine.[2]

Building on the initial efforts to scale Chlorhexidine in Nigeria, the FMoH has developed this strategy and implementation plan to lead national scale-up efforts and overcome key barriers in realizing widespread coverage. This strategy seeks not only to integrate Chlorhexidine into existing health programs but also to strengthen the underlying systems that will support the scale-up of other products for mothers and children in Nigeria.

With this well-defined and costed strategy, the Ministry's vision is to ensure that about half of all newborns across all regions in Nigeria receive Chlorhexidine by the end of 2020 using a multi-channel, integrated, market-shaping approach.

To achieve this vision, this strategy proposes concrete interventions across five core components of scale-up: market & user; manufacturing & distribution; clinical & regulatory; policy, advocacy, & financing; and coordination. These interventions address key needs across the scale-up curve and build upon the previous work of stakeholders. While a strategy has been developed for each of these five core components, it is critical to recognize the linkages between these components.

- The **market & user strategy** generates awareness of and demand for Chlorhexidine across all target users – mothers, community health workers, and health care providers – as well as the gatekeepers (e.g., husbands, mothers-in-law) and points of access (e.g., PPMVs, CORPS, community pharmacists) for each target user. Interventions address low awareness across these groups by conducting trainings at key points of access; disseminating key messages with local content across multiple channels; and improving communications to draw consumer attention to Chlorhexidine. Moreover, advocacy interventions targeting key opinion leaders closely relate

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[1] N. Orobaton, "A Report of At-Scale Distribution of Chlorhexidine Digluconate 7.1% Gel for Newborn Cord Care to 36,404 Newborns in Sokoto State, Nigeria: Initial Lessons Learned," PLoS ONE 10(7), July 2015.
[2] This underscores the need for concrete data regarding the uptake of Chlorhexidine.

to demand generation and should precede population-level interventions *(see policy, advocacy, & financing).*

- The **manufacturing & distribution strategy** leverages existing public and private delivery channels to increase the volume of Chlorhexidine flowing from indigenous manufacturers to points of access (e.g., public pharmacies, public facilities, public outreach[3], community pharmacies or PPMVs, private facilities, mission homes, and/or private outreach channels) across Nigeria. Given the need to stimulate widespread procurement and distribution, interventions include encouraging states to procure Chlorhexidine – potentially relying on an initial catalytic procurement using matching funds from development partners; providing technical support to indigenous manufacturers (e.g., developing sales targets and distribution strategies); and conducting wholesale activation by sending a representative to warehouses to promote Chlorhexidine to PPMVs and other purchasers to encourage substitution of Chlorhexidine for alternative cord care products.

- The **clinical & regulatory strategy** monitors clinical evidence from recent studies in India, Tanzania, and Zambia, as well as future studies, but does not require immediate interventions given the government is convinced that there is sufficient evidence to scale Chlorhexidine in Nigeria. The release of additional clinical evidence will be weighed in accordance with WHO guidance to apply Chlorhexidine in high-risk settings, and the strategy should be adapted accordingly.

- The **policy, advocacy, & financing strategy** strengthens the enabling environment for Chlorhexidine by finalizing national and subnational policies favorable to Chlorhexidine (e.g., EML and STG); soliciting buy-in from key opinion leaders and gatekeepers via advocacy visits; and mobilizing sources of funding necessary to implement the scale-up strategy. Potential sources of funding include state governments (e.g., state matching and free MNCH programs), the National Health Act, the National Health Insurance Scheme, World Bank loans to states, private sector investment, and donor funds to support select catalytic or enabling activities.

- The **coordination strategy** seeks to ensure strong leadership and accountability to execute the strategy by the Newborn Sub-Committee of the National Child Health Technical Working Group (NCHTWG) of the MNCH Core Technical Committee (MNCH-CTC). At a national level, the FMoH will appoint a chair to lead the Sub-Committee, as well as an uptake coordinator – one full-time employee (FTE) from a partner organization who will help implement and sequence the recommended interventions across the public and private sectors; track progress over time; execute a strategic approach to roll-out across states; and troubleshoot as needed. At a state level, each state's CTC-MNCH will appoint one development partner focal point for Chlorhexidine in each state, in addition to relying on the RH coordinator to oversee state-level coordination and ensure strong linkages with the Newborn Sub-Committee.

The two-year action plan distills these strategic interventions into concrete targets, a costed implementation plan, and a dashboard to guide scale-up activities and track progress. The plan

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[3] Outreach is defined as target users who receive chlorhexidine without any proactive efforts to procure – for example, it comes in a delivery kit given directly to caregivers.

ensures that all actors are aligned on the overarching goals for scale-up – as well as the stakeholder-specific activities and funds needed to reach them.

The overarching target for national uptake is 15% after the second year of scale-up and 52% after the fifth year of national scale-up – reaching over 10.9 million newborns during this period. This target assumes that Chlorhexidine scale-up will begin in 16 states after the first year of national scale-up and reach all states by the beginning of the third year. Exact targets for national uptake will depend on the speed of roll-out to states and available resources to fund activities. **Implementation of this strategy could save up to 55,000 newborn lives in Nigeria after its fifth year of implementation.**

Given Nigeria's three-tiered healthcare system and its overarching diversity, the implementation plan identifies different activities for national and subnational actors. The national-level action plan requires many interventions in the first 0-3 months, followed by ongoing coordination and advocacy activities. In the state-level action plan, states create a tailored plan and then launch demand generation, delivery channel and advocacy activities. To account for varying needs across states, the implementation plan provides guidance on how to tailor interventions and activities based on the most prominent delivery channels and points of access for Chlorhexidine in each state.

Lastly, a country dashboard will help track the progress of interventions against key milestones and targets. The dashboard tracks output and outcome indicators across each of the five core scale-up components and requires significant coordination between FMoH, SMoHs, development partners, and the uptake coordinator to collect, analyze, disseminate, and utilize the data. The FMoH and uptake coordinator will play a crucial role in overseeing M&E efforts and recommending continuous adjustments to activities based on progress and learnings to date.

Over the first five years of national scale-up, implementation of the strategy will cost US $32 million, with the majority of costs going toward state-level activities. Of the five core components, market & user interventions account for the largest share, and spending will be highest in year 3 of the plan. **The average cost to scale Chlorhexidine in each state over the five-year plan is less than US $200,000 per year.**

By jointly committing to this plan, the Ministry, its agencies, and all partners will ensure that Nigeria quickly progresses towards its goal of reducing neonatal mortality by 2030 in keeping with the Sustainable Development Goals (SDGs).

CHAPTER 1: INTRODUCTION

1.1 The Global Context

In 2013, an estimated 2.9 million infants died within the first 28 days of their lives across the globe.[4] These deaths (termed neonatal or newborn) account for over 40% of all child deaths under the age of five.[5] The vast majority of these deaths can be averted with cost-effective interventions. Of the 2.9 million neonatal deaths, ~21% are due to infections.[6] In high-income countries, cord stump infection is rare, with an estimated incidence of 0.2-0.7%.[7] In low-income countries, though, incidence is estimated to be between 2-7% and is higher still in communities with certain risk factors such as traditional umbilical cord care practices or unhygienic birthing conditions.[8] Outside of umbilical cord infection, sepsis from infected umbilical stumps is one of the main routes for infection leading to death. More than half of neonatal deaths in the world are concentrated in India, Nigeria, Pakistan, and Democratic Republic of Congo.[9] As a result, progress in reducing neonatal deaths globally is closely linked to results in Nigeria. The current neonatal mortality rate in Nigeria is 37 deaths per 1,000 live births.[10] While this is an improvement over the 40 deaths per 1,000 live births reported in 2008, the rate of progress has slowed over the past five years. The Federal Ministry of Health has committed to stemming this trend.[11] The three major causes of neonatal deaths in Nigeria are preterm birth complications (33%), intrapartum related events (27%), and sepsis/meningitis/tetanus (21%).[12]

Chlorhexidine, a low-cost antiseptic, has been recognized to have the potential to drive significant reductions in neonatal mortality. In particular, Chlorhexidine has been found to have high efficacy in reducing neonatal sepsis in high-risk settings. If applied to the umbilical cord in high-risk settings, Chlorhexidine, on average, results in a 68% reduction in severe infection and a 23% reduction in all-cause neonatal mortality.[13] In addition to being highly effective in high-risk settings, Chlorhexidine is simple to use, safe, easy to manufacture, and affordable at an estimated wholesale cost of roughly NGN 150 or an ex-factory cost of roughly NGN 70 per seven-day application.[14]

As a result of Chlorhexidine's efficacy, numerous countries have initiated scaling efforts. Nepal, an early adopter of Chlorhexidine, has seen significant success in scaling Chlorhexidine across the country. Nepal's Chlorhexidine program, the Chlorhexidine Navi Care Program, is estimated to have prevented

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[4] Lawn JE, Blencowe H, Oza S, You D, Lee AC, Waiswa P, et al. Every Newborn: progress, priorities, and potential beyond survival. Lancet. 2014; 384(9938):189–205. Epub 2014/05/24.

[5] Lawn JE, Blencowe H, Oza S, You D, Lee AC, Waiswa P, et al. Every Newborn: progress, priorities, and potential beyond survival. Lancet. 2014; 384(9938):189–205. Epub 2014/05/24.

[6] Lawn JE, Blencowe H, Oza S, You D, Lee AC, Waiswa P, et al. Every Newborn: progress, priorities, and potential beyond survival. Lancet. 2014; 384(9938):189–205. Epub 2014/05/24.

[7] Paediatric Surgery: A Comprehensive Text for Africa, Global Help: Health Education Using Low-Cost Publications, 2011, p. 124.

[8] Paediatric Surgery: A Comprehensive Text for Africa, Global Help: Health Education Using Low-Cost Publications, 2011, p. 124.

[9] N. Orobaton, et al., "A Report of At-Scale Distribution of Chlorhexidine Digluconate 7.1% Gel for Newborn Cord Care to 36,404 Newborns in Sokoto State, Nigeria: Initial Lessons Learned," PLoS ONE 10(7), July 2015. Statistic is per 2013 data.

[10] NDHS 2013.

[11] N. Orobaton, et al., "A Report of At-Scale Distribution of Chlorhexidine Digluconate 7.1% Gel for Newborn Cord Care to 36,404 Newborns in Sokoto State, Nigeria: Initial Lessons Learned," PLoS ONE 10(7), July 2015.

[12] Child Health Epidemiology Reference Group (CHERG), Child Causes of Death Annual Estimates by Country, 2000 – 2010. Percentages apply to estimates for year 2010. If pneumonia is included, the percent increases from 21% to 29%.

[13] A. Imdad, et al., "The effect of umbilical cord cleansing with Chlorhexidine on omphalitis and neonatal mortality in community settings in developing countries: a meta-analysis," 13(3), BMC Public Health, Sep. 2013.

[14] Stakeholder interviews, Sep. – Nov. 2015.

over 8,000 neonatal deaths since its inception in 2011. The program is operational in 74 of 75 districts – with over 1.3 million newborns treated with Chlorhexidine and an uptake of greater than 60%.[15]
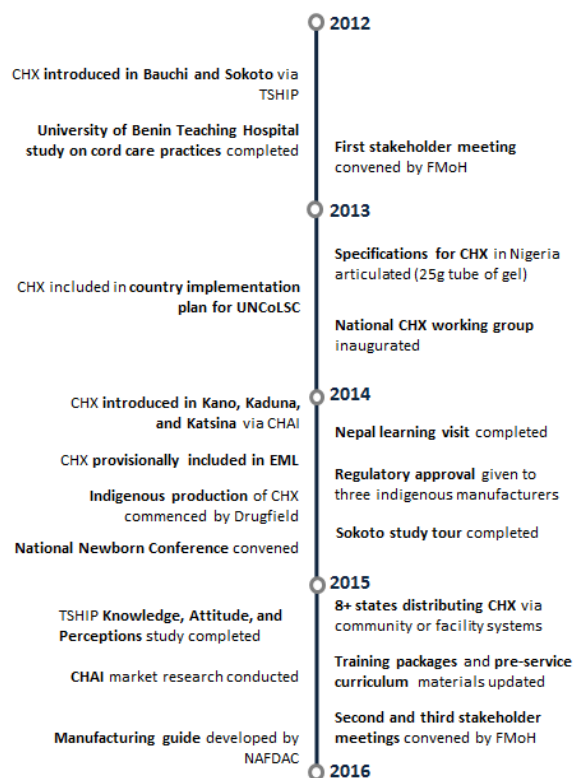
1.1.1 WHO Recommendation

In 2013, the World Health Organization (WHO) added 7.1% Chlorhexidine digluconate (delivering 4% Chlorhexidine) to the WHO List of Essential Medicines for Children, specifically for umbilical cord care.[16] In January 2014, the WHO issued a new recommendation for umbilical cord care:

> "Daily Chlorhexidine 7.1% Chlorhexidine digluconate aqueous solution or gel, delivering 4% Chlorhexidine) application to the umbilical cord stump during the first week of life is recommended for newborns who are born at home in settings with high neonatal mortality (30 or more neonatal deaths per 1000 live births). Clean, dry cord care is recommended for newborns born in health facilities and at home in low neonatal mortality settings. Use of Chlorhexidine in these situations may be considered only to replace application of a harmful traditional substance, such as cow dung, to the cord stump."[17]

1.1.2 Country Response to WHO Recommendation

In Africa, Nigeria has been a leader in scaling Chlorhexidine. In Nigeria, Chlorhexidine was initially introduced in 2012 under JSI's Targeted States High Impact Project (TSHIP), funded by United States Agency for International Development (USAID), in the states of Bauchi and Sokoto. At the end of 2012, the FMoH convened the first stakeholder meeting with support from Save the Children and PATH – during which the use of Chlorhexidine for core care was adopted. By July 2015, coverage of Chlorhexidine in Bauchi and Sokoto was 24% and 17%, respectively.[18] Learnings and best practices from scaling Chlorhexidine in Bauchi and Sokoto provided a strong foundation to scale Chlorhexidine throughout the country.

To accelerate the uptake and coverage of

2012
- CHX introduced in Bauchi and Sokoto via TSHIP
- University of Benin Teaching Hospital study on cord care practices completed
- First stakeholder meeting convened by FMoH

2013
- Specifications for CHX in Nigeria articulated (25g tube of gel)
- National CHX working group inaugurated
- CHX included in country implementation plan for UNCoLSC

2014
- CHX introduced in Kano, Kaduna, and Katsina via CHAI
- CHX provisionally included in EML
- Indigenous production of CHX commenced by Drugfield
- National Newborn Conference convened
- Nepal learning visit completed
- Regulatory approval given to three indigenous manufacturers
- Sokoto study tour completed

2015
- TSHIP Knowledge, Attitude, and Perceptions study completed
- CHAI market research conducted
- Manufacturing guide developed by NAFDAC
- 8+ states distributing CHX via community or facility systems
- Training packages and pre-service curriculum materials updated
- Second and third stakeholder meetings convened by FMoH

2016

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[15] JSI CHX Navi Cord Care Program, Annual reports up to 2015 and stakeholder interviews, Sep. – Nov. 2015.
[16] Chlorhexidine Working Group, "Chlorhexidine for Umbilical Cord Care: A new, low-cost intervention to reduce newborn mortality," updated November 2015.
[17] World Health Organization, WHO Recommendations on Postnatal Care of the Mother and Newborn, 2013.
http://apps.who.int/iris/bitstream/10665/97603/1/9789241506649_eng.pdf.
[18] TSHIP Final Dissemination Meeting presentation, July 7, 2015.

Chlorhexidine, in September 2015, the Federal Ministry of Health convened a stakeholder meeting to support the development of a multifaceted, actionable scale-up strategy to enumerate the specific and actionable steps needed to rapidly scale-up Chlorhexidine use. The draft National Strategy and Implementation Plan for Scale-up of Chlorhexidine was presented at an additional stakeholder meeting in December 2015 and has been finalized within this document.

The government's scale-up vision for Chlorhexidine is to ensure that about half of all newborns receive Chlorhexidine by 2020. The principles to achieve this include:

- **Government-led**: Coordinate donors, development partners, professional associations, traditional and religious groups in implementing this strategy, with the Ministry driving at both the national and state levels
- **Integrated**: Integrate the distribution of Chlorhexidine into existing MNCH programs, product supply chains, and the full continuum of care
- **Multi-channel**: Promote the use of Chlorhexidine through both formal health and community settings and supply Chlorhexidine through public and private delivery channels
- **Market building**: Build a competitive, sustainable market for Chlorhexidine

1.2 The Nigerian Context

With a population of more than 175 million, Nigeria is the most populous country in Africa and is projected to be the third largest country in the world by 2050.[19] Annual population growth is estimated to be 2.7% with a total fertility rate of 5.5, though there is significant variation across states and regions.[20] There are approximately 35 million women of reproductive age in Nigeria, and the country had more than 7 million births in 2015 alone.[21]

Nigeria's gross domestic product (GDP) grew consistently above 6% per annum between 2006 and 2010. In 2011 and 2012, however, GDP growth dipped below 5% but returned to levels above 6% by 2014.[22] However, GDP per capita has grown more slowly at approximately 4% per annum. Income inequality remains a significant issue – with the top 10% of earners receiving 34% of income share, whereas the bottom 10% of earners receive less than 2%. This pattern has been relatively stable for the last 20 years and persists along regional lines given oil revenues in the South.[23]

Nigeria is divided into 36 States and a Federal Capital Territory (FCT). Nigeria operates a a semi-autonomous system of governance, with state governments wielding significant influence over budgets and political power. Approximately 50% of government revenues are controlled by states. As a result, the implementation of health policies benefits greatly from the support of state governments – especially governors.[24]

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[19] World Bank World Development Indicators and http://www.un.org/apps/news/story.asp?NewsID=51526#.Vp5gUovIa6M.
[20] World Bank World Development Indicators and NDHS survey, 2013.
[21] Nigeria Family Planning Blueprint, Scale-up Plan and http://www.unicef.org/infobycountry/nigeria_statistics.html.
[22] World Bank World Development Indicators.
[23] Nigeria Family Planning Blueprint, Scale-up Plan.
[24] Nigeria Family Planning Blueprint, Scale-up Plan.

States are divided into Local Government Areas (LGAs) – with 774 LGAs in total across Nigeria. Each LGA is run by a local government council comprised of a chairman and elected councilors. LGAs are ultimately responsible for managing and implementing the primary healthcare system – which is the most extensive channel for healthcare delivery in the country. Ward Development Committees (WDCs) and other community groups often support primary healthcare centers (PHCs) – and as a result, there are disparities in the way PHCs are funded, staffed, and stocked across the country.[25]

The FMoH is charged with developing policies, strategies, guidelines, and plans that provide direction for the Nigerian healthcare system. With that, implementation of the guidelines ultimately falls on the State Ministries of Health (SMoH) and State Primary Healthcare Development Agencies (SPHCDA). SMoHs are responsible for overall policy direction and coordination while SPHCDAs (where they exist) oversee program implementation and coordination. The State Ministries of Local Government (SMoLG) are responsible for hiring, managing, and paying health workers at the primary healthcare level. Change in neonatal health requires effort, coordination, and clear alignment from all levels of government – beginning at the federal government and flowing down to the LGAs.[26]

In 2013, the neonatal mortality rate in Nigeria was 37 deaths per 1,000 live births.[27] This is a decline from 40 deaths per 1,000 live births in 2008 and from 48 deaths per 1,000 live births in 2003.[28] Of the 254,000 estimated neonatal deaths in Nigeria, roughly 52,000 of these are due to sepsis, meningitis, and tetanus – with an additional 22,000 neonatal deaths due to pneumonia.[29] Infection is the third largest driver of neonatal death in Nigeria, following preterm birth complications and intrapartum related events, respectively.[30]

The FMoH is committed to continuing to decrease the neonatal mortality rate. Given that approximately one in three neonatal deaths in Nigeria is due to infection, the scale-up of Chlorhexidine — an over-the-counter gel applied to the umbilical cord with high efficacy in reducing neonatal sepsis — can drive significant reductions in neonatal mortality.[31] Estimated national uptake of Chlorhexidine, according to stakeholder estimates and preliminary analysis, remains low at significantly under 5% — though Chlorhexidine programs are gaining traction in a handful of states.[32] Market research conducted in 2014 in four states indicates that over 85% of caregivers apply some substance to the cord, suggesting a significant opportunity to scale Chlorhexidine by encouraging its substitution for other products.[33] The coverage of Chlorhexidine in Nigeria was stimulated by TSHIP's efforts in Bauchi and Sokoto, in which

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[25] Nigeria Family Planning Blueprint, Scale-up Plan.
[26] Nigeria Family Planning Blueprint, Scale-up Plan.
[27] NDHS survey, 2013.
[28] NDHS survey, 2013.
[29] Child Health Epidemiology Reference Group (CHERG), Child Causes of Death Annual Estimates by Country, 2000 – 2010. Percentages apply to estimates for year 2010.
[30] Child Health Epidemiology Reference Group (CHERG), Child Causes of Death Annual Estimates by Country, 2000 – 2010. Percentages apply to estimates for year 2010.
[31] NDHS survey, 2013.
[32] Stakeholder interviews, Sep. – Nov. 2015.
[33] "Market Research for 7.1% Chlorhexidine Digluconate: Nigeria," conducted by PATH in 2014 with funding from US Agency for International Development. Market research was conducted in Kano, Nasarawa, Osun, and Cross Rivers.

the scale-up of Chlorhexidine has saved an estimated 1,000 newborn lives since 2012.[34] Approximately nine other states have begun scale-up.[35]

1.3 Needs Assessment of Chlorhexidine in Nigeria

Prior to the development of the National Strategy and Implementation Plan for Scale-up of Chlorhexidine, a needs assessment was conducted across five scale-up components:[36]

- Market & user
- Manufacturing & distribution
- Clinical & regulatory
- Policy, advocacy, & financing
- Coordination

1.3.1   Market & User

Of the over 7 million annual live births in Nigeria, 36% are delivered in a facility. 63% of live births are categorized as non-facility births.[37]

Of live births, 38% are delivered in the presence of a doctor, nurse/midwife, or auxiliary nurse/midwife; 2% in the presence of a CHEW; 22% in the presence of a TBA; 23% in the presence of a relative or other, and 13% self-assisted.[38] As demonstrated below, high variability exists across regions in terms of the split between facility and non-facility births.[39]

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[34] N. Orobaton, et al., "A Report of At-Scale Distribution of Chlorhexidine Digluconate 7.1% Gel for Newborn Cord Care to 36,404 Newborns in Sokoto State, Nigeria: Initial Lessons Learned," PLoS ONE 10(7), July 2015 and TSHIP Final Dissemination Meeting, July 7, 2015.
[35] Based on stakeholder interviews, the following states have procured Chlorhexidine (or have had development partners do so): Bauchi, Edo, Gombe, Kaduna, Kano, Katsina, Lagos, Ogun, Ondo, Plateau, and Sokoto. Stakeholder interviews, Sep. – Nov. 2015.
[36] "Idea to Impact: A Guide to Introduction and Scale of Global Health Innovations," USAID, Center for Accelerating Innovation and Impact, 2015.
[37] NDHS survey, 2013; Nigerian FMoH/Save The Children, "Nigeria State Data Profiles." The delivery locations of ~1% of births are categorized as "missing" or "other."
[38] NDHS survey, 2013; Nigerian FMoH/Save The Children, "Nigeria State Data Profiles." The assistance provided by ~2% of births is categorized as "don't know/missing."
[39] NDHS survey, 2013; Nigerian FMoH/Save The Children, "Nigeria State Data Profiles."

Figure 1: Annual neonate deaths by region[40]

Annual neonate deaths by region
# of neonate deaths 2013

	North West	North East	South South	North Central	South West	South East
Total	97,064	47,300	26,880	34,965	45,513	26,492
% Facility deliveries	13%	21%	51%	51%	76%	81%
% Non-facility deliveries	87%	79%	49%	49%	24%	19%
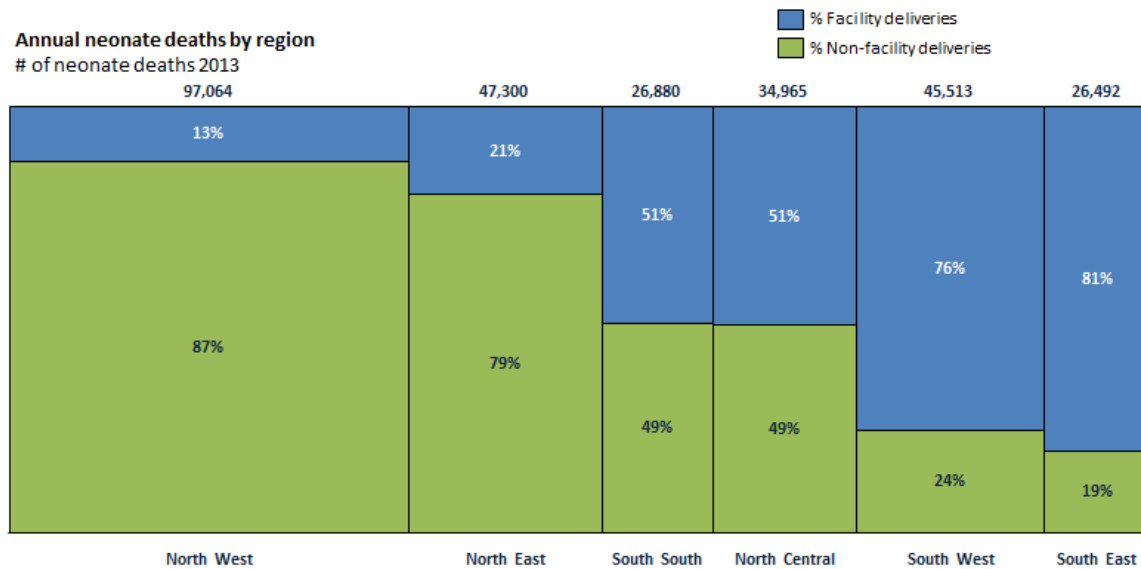
Across Nigeria, it is a cultural norm to apply a substance or mix of substances to the umbilical cord for the first three to six days until the cord falls off.[41] Market research indicates that over 85% of caregivers apply some substance to the cord, though the substance varies.[42] Of cord care substances used, oil and methylated spirits are most popular, accounting for over 60% of substances applied.[43]

Figure 2: Cord care substance applied[44]

Pie chart values:
- Oil: 31%
- Methylated spirit: 30%
- Toothpaste: 13%
- Ash: 8%
- Ointment/powder: 7%
- Other: 11%

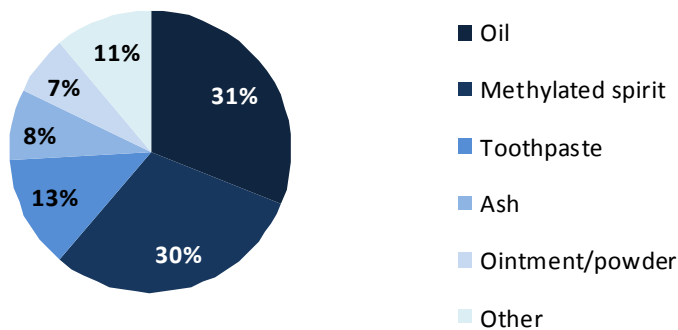The preferred cord care substance applied can vary greatly by region, demographic constitution, and delivery location. For example:

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[40] NDHS survey, 2013; Nigerian FMoH/Save The Children, "Nigeria State Data Profiles."
[41] Nigeria market shaping strategy for CHX developed by the Federal Governemnt with support from CHAI.
[42] "Market Research for 7.1% Chlorhexidine Digluconate: Nigeria," conducted by PATH with funding from US Agency for International Development. Market research was conducted in Kano, Nasarawa, Osun, and Cross Rivers.
[43] NDHS survey, 2013.
[44] Data reflect only newborns that have had a cord care substance applied (e.g., excludes newborns with no cord care substance used). NDHS survey, 2013.

- In Yenagoa, an estimated 29% of caregivers used only methylated spirits – while 62% used methylated spirits in combination with other substances.[45]
- In Sagamu, an estimated 70% of women used methylated spirits – yet only 13% of women deliver with an SBA present.[46]
- In Kano and Nasarawa, an estimated 20% of caregivers used a hot compress.[47]

Initial market research indicates that most caregivers purchase cord care substances prior to delivery – indicating potential channels for mothers to be sensitized to, and obtain, Chlorhexidine.

Figure 3: Timing of cord care purchase[48]
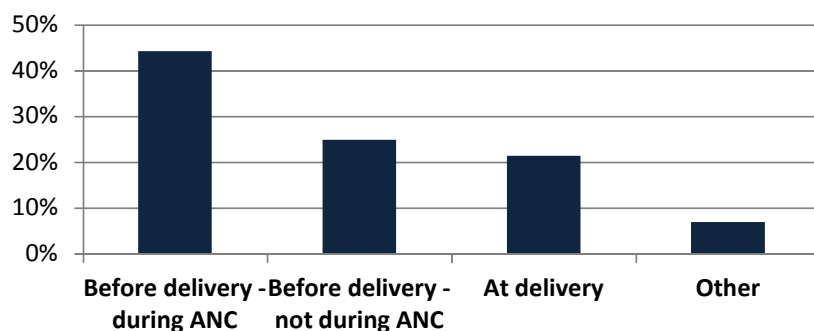
Initial research conducted by PATH and CHAI has indicated that there is willingness-to-pay for Chlorhexidine amongst caregivers. While the average price of cord care substances purchased is NGN 167,[49] small-scale focus groups indicate that women have an average willingness-to-pay of NGN 350 – with a range of NGN 200 to 500.[50] Current pricing of Chlorhexidine meets the range specified. Early estimates of Chlorhexidine's pricing – at a wholesale cost of NGN 150 and an ex-factory cost of NGN 95 – indicate that it could be priced comparably to methylated spirits.[51]

Furthermore, the initial research indicates that women would most likely purchase Chlorhexidine in the private sector – therefore, chemists, PPMVs, and community pharmacies are important points of access for obtaining Chlorhexidine.[52]

[45,] Nigeria market shaping strategy for CHX by the Federal Governemnt with support from CHAI.
[46] Nigeria market shaping strategy for CHX developed by the Federal Governemnt with support from CHAI.
[47] "Market Research for 7.1% Chlorhexidine Digluconate: Nigeria," conducted by PATH with funding from US Agency for International Development. Market research was conducted in Kano, Nasarawa, Osun, and Cross Rivers.
[48] "Market Research for 7.1% Chlorhexidine Digluconate: Nigeria," conducted by PATH with funding from US Agency for International Development. Market research was conducted in Kano, Nasarawa, Osun, and Cross Rivers.
[49] "Market Research for 7.1% Chlorhexidine Digluconate: Nigeria," conducted by PATH with funding from US Agency for International Development. Market research was conducted in Kano, Nasarawa, Osun, and Cross Rivers.
[50] Nigeria market shaping strategy for CHX developed by the Federal Governemnt with support from CHAI.
[51] Stakeholder interviews, Sep. – Nov. 2015; "Market Research for 7.1% Chlorhexidine Digluconate: Nigeria," conducted by PATH with funding from US Agency for International Development. Market research was conducted in Kano, Nasarawa, Osun, and Cross Rivers.
[52] "Market Research for 7.1% Chlorhexidine Digluconate: Nigeria," conducted by PATH with funding from US Agency for International Development. Market research was conducted in Kano, Nasarawa, Osun, and Cross Rivers.

1.3.2 Manufacturing & Distribution

In Nigeria, three indigenous manufacturers have been approved to manufacture Chlorhexidine: Drugfield Pharmaceuticals, Tuyil Pharmaceuticals, and Emzor Pharmaceutical. Annual manufacturing capacity of Chlorhexidine in Nigeria far exceeds the number of live births in the country. Drugfield Pharmaceuticals alone can produce over 20 million 25-gram tubes per year running only a single shift.[53] In addition, other manufacturers are awaiting approval to produce Chlorhexidine.[54]

As a result, the greatest need related to manufacturing & distribution in Nigeria is to address the low volumes of Chlorhexidine flowing through delivery channels. To date, at least 11 states have procured Chlorhexidine - mostly through the public sector.[55] Development partners have also played a role in scaling Chlorhexidine – for example, TSHIP and CHAI developed community-based distribution systems for Chlorhexidine in their priority states.

Overall, though, large volumes of Chlorhexidine are not flowing through existing procurement and distribution systems, partially due to limited incentives to push the product. Few PPMVs and community pharmacies stock Chlorhexidine given the lack of demand and therefore absence of profit incentive.[56]

1.3.3 Clinical & Regulatory

The government is convinced that there is sufficient evidence to scale Chlorhexidine in Nigeria based on randomized controlled trials conducted in Bangladesh, Nepal, and Pakistan. These trials show that, on average, applying Chlorhexidine to umbilical cords reduces all-cause neonatal mortality by 23%.[57] Regulatory approval for Chlorhexidine in Nigeria was secured in 2014.[58]

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[53] Stakeholder interviews, Sep. – Nov. 2015; Drugfield, "Update on local manufacturing of Chlorhexidine," Sep. 2015.

[54] Stakeholder interviews, Sep. – Nov. 2015.

[55] Based on stakeholder interviews, the following states have procured Chlorhexidine (or have had development partners do so): Bauchi, Edo, Gombe, Kaduna, Kano, Katsina, Lagos, Ogun, Ondo, Plateau, and Sokoto. Stakeholder interviews, Sep. – Nov. 2015.

[56] Stakeholder interviews, Sep. – Nov. 2015; Nigeria market shaping strategy for CHX developed by the Federal Governemnt with support from CHAI.

[57] "The effect of umbilical cord cleansing with Chlorhexidine on omphalitis and neonatal mortality in community settings in developing countries: a meta-analysis," 13(3), BMC Public Health, Sep. 2013.

[58] Stakeholder interviews, Sep. – Nov. 2015.

Figure 4: Clinical evidence to date related to Chlorhexidine's efficacy[59]

Country	NEPAL	BANGLADESH	PAKISTAN	META-ANALYSIS
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 • CHX provided by traditional birth attendants	23-40% reduction in newborn mortality • CHX provided by traditional birth attendants

New clinical evidence from ongoing studies in India, Tanzania, and Zambia should be monitored. The release of additional clinical evidence should be weighed in accordance with WHO guidance to apply Chlorhexidine in high-risk settings, and the strategy and implementation plan should be adapted accordingly.

1.3.4 Policy, Advocacy, & Financing

The Nigerian government has been a leader in scaling Chlorhexidine in Sub-Saharan Africa. Scaling Chlorhexidine dovetails with many of Nigeria's overall policy objectives for neonatal health, including providing skilled obstetric and newborn care for sepsis and jaundice management; promoting cleanliness (skin, eye, and cord care); promoting healthy newborn care practices in the community; and conducting operational research on socio-cultural, family, and community factors that affect newborn and maternal health.[60] It also builds on previous maternal and child health initiatives, such as Midwives Service Scheme, SURE-P, the UN Commission on Lifesaving Commodities and 100,000 Babies Survive and Thrive Initiative.

At a national level in Nigeria, Chlorhexidine has received provisional approval in the Essential Medicines List and the Standard Treatment Guidelines. Certain states have also added Chlorhexidine to their Essential Medicines Lists. The Federal Ministry of Health has convened three stakeholder meetings – one of which was in 2012 and two of which were in 2015 – to advocate for the scaling of Chlorhexidine.[34] 34 states also conducted study tours of TSHIP's work in Bauchi and Sokoto, and representatives from the

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[59] L. Mullany, et al., "Topical applications of Chlorhexidine to the umbilical cord for prevention of omphalitis and neonatal mortality in southern Nepal: a community-based, cluster-randomised trial," 367(9514), The Lancet, Mar. 2006; S. Arifeen, et al., "The effect of cord cleansing with Chlorhexidine on neonatal mortality in rural Bangladesh: a community-based, cluster-randomised trial," 379(9820), The Lancet, Feb. 2012, S. Soofi, et al., "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," 379(9820), The Lancet, Mar. 2012; A. Imdad, et al., "The effect of umbilical cord cleansing with Chlorhexidine on omphalitis and neonatal mortality in community settings in developing countries: a meta-analysis," 13(3), BMC Public Health, Sep. 2013.
[60] "Country Implementation Plan for United Nations Commission on Life-Saving Commodities for Women and Children," Federal Republic of Nigeria, Aug. 2013.

Ministry attended site visits in Nepal in 2014. However, at a state and local level, significant advocacy is needed to mobilize support.

While at least 11 states have initiated the procurement of Chlorhexidine, there is limited financial support for its scale-up.[61] Manufacturers have invested significant resources to produce Chlorhexidine; however, activities related to demand generation are needed to further incentivize private sector engagement. Donors and development partners have funded national-level activities (e.g., UN Commission grant on Life Saving Commodities/WHO developed job aids/messaging and USAID funded stakeholder convenings) and state-level activities (e.g., USAID funded JSI's TSHIP in Bauchi and Sokoto, and NORAD funded CHAI's work in Kano, Katsina, and Kaduna).

1.3.5 Coordination

As will be discussed in detail below, an uptake coordinator is often a key success factor in implementation of scale-up. It is critical that an uptake coordinator for Chlorhexidine be identified by the FMoH. The uptake coordinator can support the FMoH's leadership of this scale-up strategy, aid in aligning on the specific metrics to be tracked, support roll-out across states, and support planning for advocacy visits. Successful coordination mechanisms in Nigeria, such as that of Zinc/ORS, can serve as an example for Chlorhexidine scale-up.

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[61] Based on stakeholder interviews, the following states have procured Chlorhexidine (or have had development partners do so): Bauchi, Edo, Gombe, Kaduna, Kano, Katsina, Lagos, Ogun, Ondo, Plateau, and Sokoto. Stakeholder interviews, Sep. – Nov. 2015.

CHAPTER 2: STRUCTURE OF NATIONAL STRATEGY AND IMPLEMENTATION PLAN FOR SCALE-UP OF CHLORHEXIDINE IN NIGERIA

2.1 Goal

By implementing this National Strategy and Implementation Plan for Scale-up of Chlorhexidine, uptake of Chlorhexidine will increase to 52% after the fifth year of national scale-up, saving up to 55,000 newborn lives.

2.2 Objectives

By the fifth year of national scale-up, Nigeria intends to accomplish the following:

- Provide accurate and comprehensive knowledge of Chlorhexidine to every segment of the population through easily accessible channels to generate demand and behavior change
- Initiate Chlorhexidine scale-up in all 36 states and the Federal Capital Territory
- Ensure that Chlorhexidine is applied to umbilical cords in 61% of facility births and in 46% of non-facility births (for a national average of 52% – see Figure 12)
- Leverage existing private and public delivery channels in each state to integrate Chlorhexidine with other products
- Integrate metrics related to Chlorhexidine into existing data and logistics management systems to allow for tracking progress of scale-up

2.3 Structure of the National Strategy and Implementation Plan for Scale-up of Chlorhexidine

As part of the development of the strategy and implementations plan, the FMoH, in conjunction with key stakeholders, has prioritized a set of interventions to achieve Nigeria's target of a 52% uptake of Chlorhexidine after the fifth year of national scale-up. These priorities crystallized based on existing neonatal work, a needs assessment of the Chlorhexidine landscape in Nigeria, and government and development partner experiences working in neonatal health programming across the country. The successful implementation of this plan depends on commitment from a variety of stakeholders, as mapped below.

Figure 5: Stakeholder mapping related to scale-up of Chlorhexidine[62]
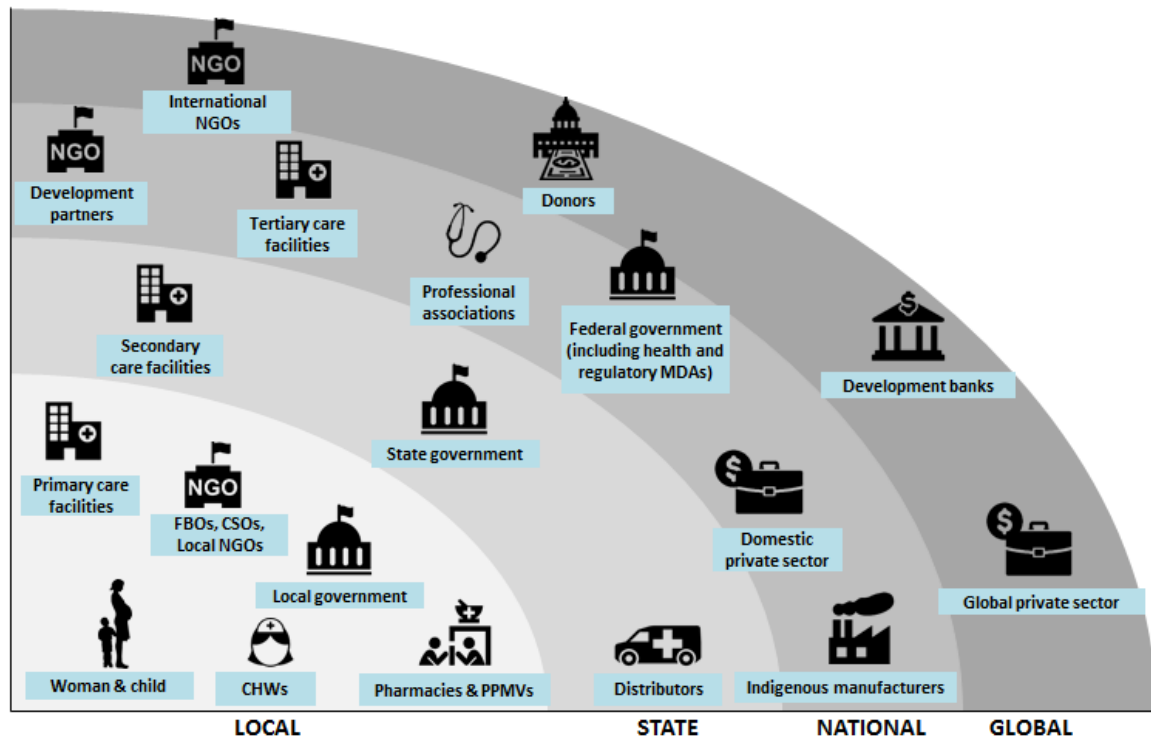
As demonstrated above, the National Strategy and Implementation Plan for Scale-up of Chlorhexidine relies on commitment across numerous stakeholders in the public and private sectors – as well as close coordination amongst them.

The following summary of strategic priorities is intended to help align activities across the maternal, newborn, and child health landscape going forward.

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[62] Stakeholder interviews, Sep. – Nov. 2015.

Figure 6: Summary of strategic priorities to scale-up Chlorhexidine
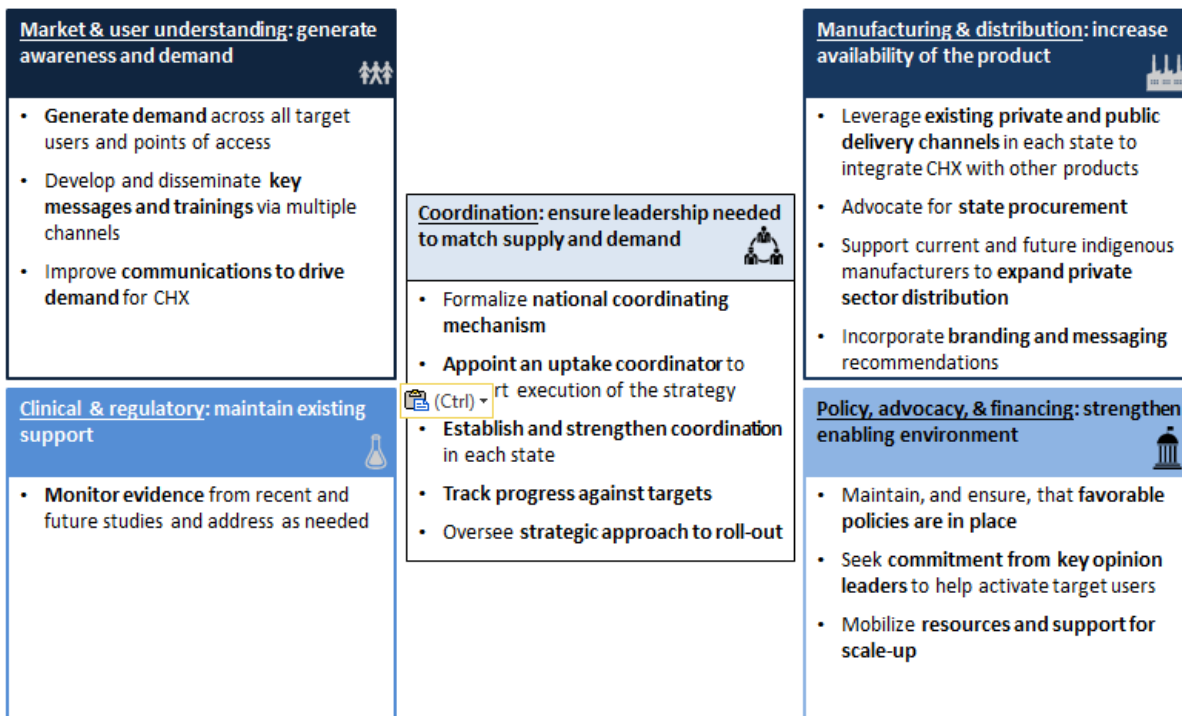
- **Market & user:** Generate awareness and demand across all target users and points of access by developing and disseminating key messages and trainings via multiple channels and conducting user-centered research to better understand how to generate demand for Chlorhexidine and encourage the use of Chlorhexidine in place of alternate cord care products.

- **Manufacturing & distribution:** Increase the availability of the product by leveraging existing private and public delivery channels and integrating Chlorhexidine distribution with other products, advocating for states to procure and distribute Chlorhexidine, and supporting current and future indigenous manufacturers to expand private sector distribution.

- **Clinical & regulatory:** Maintain existing government support of Chlorhexidine by monitoring evidence from future studies and address as needed.

- **Policy, advocacy, & financing:** Strengthen the enabling environment by maintaining, and ensuring, that favorable policies are in place, seeking commitment from key opinion leaders to help activate target users, and mobilizing resources and support for scale-up.

- **Coordination**: Government will provide leadership to match supply and demand by formalizing a national coordinating structure, appointing an uptake coordinator to support the execution of the strategy, establishing and strengthening coordination in each state, tracking progress against targets, and overseeing the strategic approach to roll-out.

2.3.1 Market & User (M&U)

a. Justification

TSHIP's work in Bauchi and Sokoto highlights the importance of proactive demand generation in accelerating the uptake of Chlorhexidine. To stimulate demand of Chlorhexidine, widespread knowledge of its benefits in promoting the health of newborns, of its instructions for usage, and of its availability is needed. Advocates at the national, state, and LGA levels can increase interest in Chlorhexidine within communities – creating an enabling environment, reducing normative barriers, and mobilizing community support. Similarly, professional associations, development partners, and facilities can play a role in raising awareness of Chlorhexidine and umbilical cord care at key points of access for target users. Successful demand generation interventions will also aid in stimulating private sector distribution of Chlorhexidine – key in reaching all newborns in Nigeria.

The strategy will build from previous Chlorhexidine interventions related to market & user, such as:
- Inclusion of Chlorhexidine in training packages for doctors, nurses, and midwives, as well as updated ENCC packages
- Inclusion of Chlorhexidine in pre-service training and in standard operating procedures for CHWS
- TSHIP, CHAI, and others have trained community health volunteers in Chlorhexidine use
- Launching of radio jingles in Adamawa, Borno, Lagos, Sokoto, and Yobe
- Development of social behavior change communication materials on Chlorhexidine for targets such as health care workers, PPMVs, and caregivers
- Some manufacturers and partners have hosted clinical meetings at several hospitals (including LUTH, LASUTH, UCH, UNTH, FMC Abeokuta, FTH Gombe, specialist and general hospitals)
- Sales representatives have visited some PPMVs (though limited and Chlorhexidine awareness among PPMVs remains a major barrier)
- Initial demand forecast of Chlorhexidine for ten states under UN Commission on Life Saving Commodities grant has been completed by the FMoH

    b. Strategy

The market & user strategy enumerates the required interventions needed to generate awareness of, and demand for, Chlorhexidine across target users, gatekeepers, and points of access for each target user.

Target users are segmented into three categories based on the first applier of Chlorhexidine to a newborn:
- Facility-based healthcare provider (e.g., nurse, nurse/midwives, midwives, or physician) for newborns birthed in facilities – 36% of all births[63]
- Community health workers/traditional birth attendants for newborns not birthed in facilities but assisted by non-family members – 26% of all births[64]

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[63] Point of delivery calculated using NDHS survey, 2013 and Nigeria state data profiles. Assumes the 36% of births in facilities are assisted by a nurse, midwife, auxiliary nurse/midwife, or physician ("facility-based healthcare provider") given that 38% of all births in Nigeria are assisted by one of these persons according to NDHS survey, 2013. For "community health workers/traditional birth attendants," 'community extension health worker' and 'traditional birth attendant' in NDHS survey, 2013 are summed. For "mothers/family members," 'relative/other' and 'no one' in NDHS survey, 2013 are summed. The assistance provided by ~2% of births is categorized as 'don't know/missing' in NDHS survey, 2013.

- <u>Mothers/family members</u> for newborns not birthed in facilities with no assistance by non-family members – 36% of all births[65]

The market & user strategy recognizes that each of these target users faces unique gatekeepers and points of access in obtaining Chlorhexidine.

Figure 7: Gatekeepers and points of access for target users of Chlorhexidine[66]
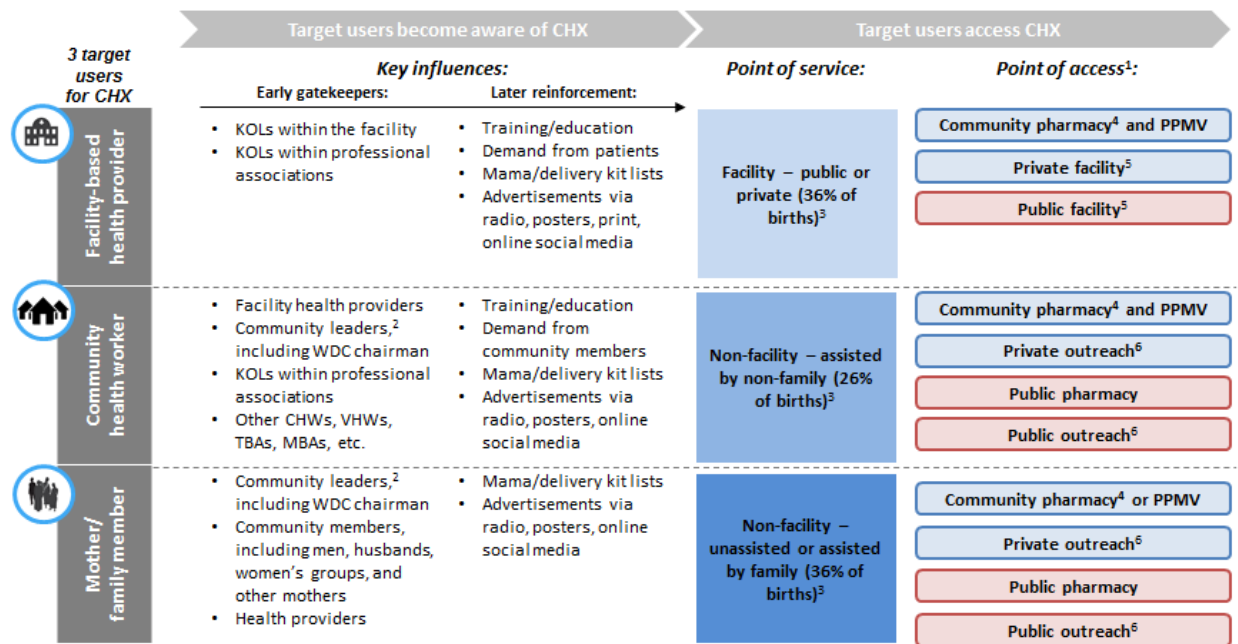
Note: (1) Point of access information does not account for any 'leakage' between the systems; e.g. CHX moving from a private to public facility; (2) Community leaders include religious, traditional, and political figures; (3) Points of service are based on the latest data but may shift in future years; (4) Analogous to private pharmacies; (5) Includes Mission Homes; (6) Receives CHX without any proactive efforts to procure, e.g., comes into a delivery kit given directly to caregivers

Demand generation will require interventions addressing gaps in awareness amongst the three target users of Chlorhexidine and their points of access for Chlorhexidine. The key interventions aim to recognize the key influencers in obtaining/using Chlorhexidine, as well as the unique decision-making processes involved for each target user. Interventions address low awareness by conducting trainings at key points of access and disseminating key messages with local content across multiple channels. Advocacy interventions targeting key opinion leaders closely relate to demand generation and should

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[64] Point of delivery calculated using NDHS survey, 2013 and Nigeria state data profiles. Assumes the 36% of births in facilities are assisted by a nurse, midwife, auxiliary nurse/midwife, or physician ("facility-based healthcare provider") given that 38% of all births in Nigeria are assisted by one of these persons according to NDHS survey, 2013. For "community health workers/traditional birth attendants," 'community extension health worker' and 'traditional birth attendant' in NDHS survey, 2013 are summed. For "mothers/family members," 'relative/other' and 'no one' in NDHS survey, 2013 are summed. The assistance provided by ~2% of births is categorized as 'don't know/missing' in NDHS survey, 2013.

[65] Point of delivery calculated using NDHS survey, 2013 and Nigeria state data profiles. Assumes the 36% of births in facilities are assisted by a nurse, midwife, auxiliary nurse/midwife, or physician ("facility-based healthcare provider") given that 38% of all births in Nigeria are assisted by one of these persons according to NDHS survey, 2013. For "community health workers/traditional birth attendants," 'community extension health worker' and 'traditional birth attendant' in NDHS survey, 2013 are summed. For "mothers/family members," 'relative/other' and 'no one' in NDHS survey, 2013 are summed. The assistance provided by ~2% of births is categorized as 'don't know/missing' in NDHS survey, 2013.

[66] NDHS survey, 2013.

precede population-level interventions (see policy, advocacy, & financing). The key interventions aim to sustain support for Chlorhexidine from the highest policy levels and promote awareness at all levels – from the national-level to the community-level.

At a high level, interventions will:
- **Develop key messages with local content** that communicate the benefit of Chlorhexidine, instructions on use, and where to purchase the product – and then **promote these messages** across relevant channels to reach targets depending on user, the user's pathway to gaining awareness of and access to Chlorhexidine (often via key influencers), and the state context
- **Update curricula** of pre-service trainings of doctors (Medical and Dental Council of Nigeria), nurses/midwives (Nursing and Midwifery Council of Nigeria), and other regulatory bodies
- **Build capacity in-service** by scaling up Essential Newborn Care Course (and other relevant training packages – LSS, CBNC, IMCI, iCCM) to frontline health workers in states, as well as build capacity of those providing the product
- **Forecast demand** for remaining states at the state level and aggregate into a national forecast

c. *Activities*

Need		Recommended interventions	Responsible
M&U1: Low awareness amongst target users	Facility provider	• **Update pre-service curricula** for doctors, nurses, and midwives • **Disseminate and orientate** health workers on updated pre-service curricula • **Build capacity** of in-service health workers on updated ENCC packages • **Promote key messages with local content** across multiple channels, tailored by state and target user – focus on health talks, job aids, posters, and information in facilities • **Conduct user-centered research** to understand how to generate demand for CHX and strengthen communication accordingly	• FMoH, SMoHs, professional associations to disseminate updated training packages and messages to their networks • SMoHs, development partners to decide on media and disseminate messages (see implementation plan and Annexes B and C for guidance on state-level decisions) • FMoH, professional associations to lead research efforts and disseminate updates and new innovations, with support from donors
	Community health	• **Disseminate and orientate tutors on pre-service**	• FMoH, states, professional associations to disseminate

	worker	• **curricula** • **Build capacity** of in-service health workers on updated mENCC packages • **Promote key messages with local content** across multiple channels, tailored by state and target user – focus on materials in PHCs, job aids, radio/TV	updated training packages and messages to their networks • <u>SMoHs, development partners</u> to decide on media and disseminate messages (see implementation plan and Annexes B and C for guidance on state-level decisions)
	Mother/ family (men included)	• **Promote key messages with local content** across multiple channels, tailored by state and target user – focus on print and electronic media (radio, TV, social media, and materials in PPMVs) – messages should also reach men, who act as key gatekeepers for mother/family target users	• <u>FMoH and professional associations</u> to lead research efforts and disseminate updates and new innovations, with support from <u>donors</u> • <u>FMoH, SMoHs, professional associations, development partners</u> to share messages; <u>states/development partners</u> to decide on media and disseminate messages
<u>**M&U2: Low awareness at points of access for target users**</u>	Facilities	• **Utilize ENCC and other training packages** that incorporate CHX at public and private facilities to build capacity	• <u>SMoHs, manufacturers, development partners, in-charges of facilities, professional associations</u>
	Pharmacies /PPMVs	• **Conduct sensitization training activities at private PPMVs/pharmacies and public pharmacies at PHCs to build capacity and orientate on newborn care (including cord care)**, 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	• <u>Manufacturers, development partners, SMoHs, PHC directors, professional associations</u>

		clinical mentoring at PHCs	
	Outreach[67]	• **Conduct training activities to build capacity of donors and private companies** currently distributing mama/delivery kits, delivery packs, and delivery lists, or considering this work in the future	• Development partners, SMoHs
M&U3: Lack of aggregated demand forecasts		• **Support remaining states** with their forecasts • **Check national CHX projections** against scale-up plan targets, as well as realistic limitations (e.g., available funding) • **Update forecast bi-annually**	• FMoH, SMoHs for national and state forecasts, respectively • Uptake coordinator to support

Also, see the policy, advocacy, & financing section for KOL/gatekeeper advocacy interventions that relate to demand generation and should come prior to mass media interventions.

2.3.2 Manufacturing & Distribution (M&D)

a. Justification

For successful scale-up of Chlorhexidine, a sustainable supply and distribution of the product is required. Nigeria has been a global leader in encouraging local manufacturing of Chlorhexidine. Three manufacturers – Drugfield, Emzor, and Tuyil – have received approval to produce Chlorhexidine. As a result, capacity of Chlorhexidine production exceeds potential demand. For example, though the annual number of live births in Nigeria is approximately 7 million, Drugfield can produce over 20 million 25-gram tubes each year running a single shift.

To ensure that Chlorhexidine gel reaches all newborns in Nigeria, widespread procurement and distribution is needed. Similarly, to incentivize indigenous production, market & user and advocacy interventions are needed to stimulate delivery channels by generating demand and therefore incentivizing the private sector to obtain and sell Chlorhexidine.

The strategy will build from previous Chlorhexidine interventions related to manufacturing & distribution, including:

- At least 11 states have procured Chlorhexidine, mostly through the public sector[68]

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[67] Outreach is defined as target users who receive Chlorhexidine without any proactive efforts to procure – for example, it comes into a delivery kit given directly to caregivers.
[68] Based on stakeholder interviews, the following states have procured Chlorhexidine (or have had development partners do so): Bauchi, Edo, Gombe, Kaduna, Kano, Katsina, Lagos, Ogun, Ondo, Plateau, and Sokoto. Stakeholder interviews, Sep. – Nov. 2015.

- Bauchi, Kaduna, Kano, Katsina, and Sokoto states have developed community-based distribution systems
- At least one manufacturer has sold Chlorhexidine to PPMVs, pharmacies, private hospitals, and TBAs
- Ogun state has connected both public and private facilities to manufacturers to procure CHX

b. Strategy

The manufacturing & distribution strategy leverages existing public and private delivery channels to increase the volume of Chlorhexidine flowing from indigenous manufacturers to points of access (e.g., public pharmacies, public facilities, public outreach channels, private pharmacies or PPMVs, private facilities, and private outreach channels) across Nigeria. Given the need to stimulate widespread procurement and distribution, interventions include advocating to states to procure Chlorhexidine, potentially with an initial catalytic procurement using matching funds from development partners; providing technical support to indigenous manufacturers (e.g., developing sales targets and distribution strategies); and conducting wholesale activation (sending a representative to promote Chlorhexidine to PPMVs and other purchasers). Interventions also address incorporating communication recommendations to draw consumer attention and prevent misuse. Interventions across manufacturing & distribution will expand the delivery of Chlorhexidine across six points of access via both public and private channels. Each state will oversee a tailored strategy to improve delivery channels, with support from the FMoH, donors, and development partners.

Figure 8: Points of access for obtaining chlorhexidine[69]

Note: (1) Percentage split between public/private procurement is based on the latest data from Drugfield and may shift in future years. Procurement from CHAI and Marie Stopes is considered public given that they are supporting states: Kaduna, Katsina, and Kano and Ogun, respectively; (2) Outreach is defined as target users who receive Chlorhexidine without any proactive efforts to procure – for exampl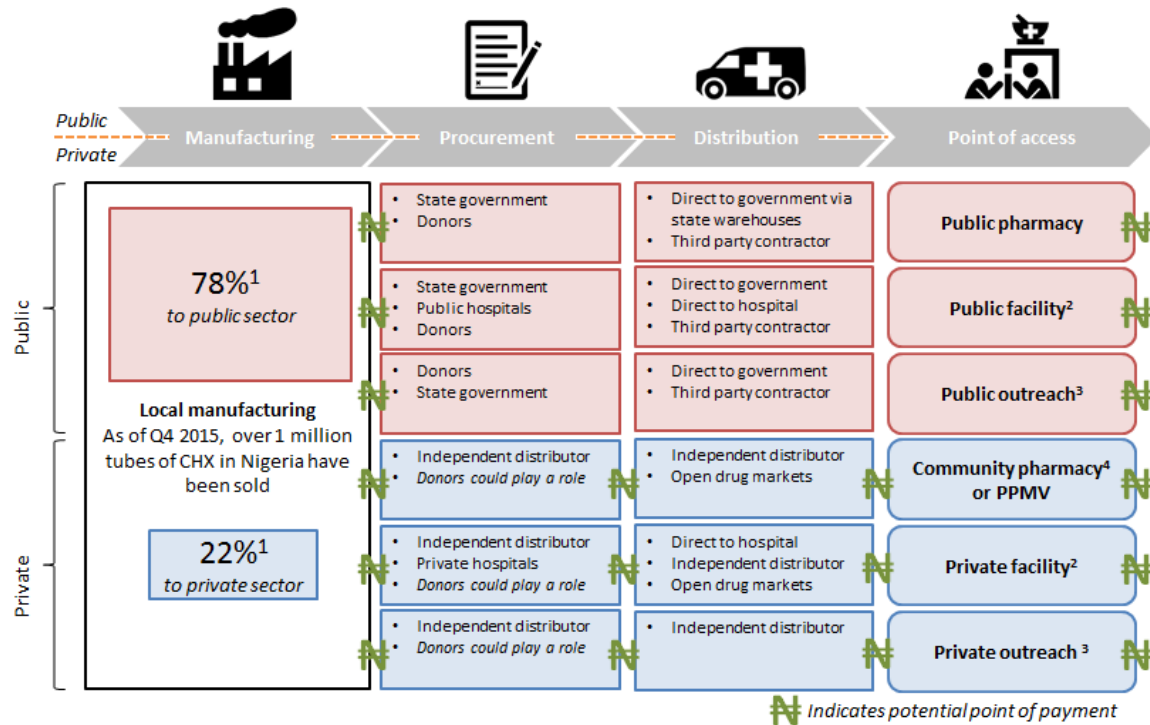e, it comes into a delivery kit given directly to caregivers; (3) Receives CHX without any proactive efforts to procure, e.g., comes into a delivery kit given directly to caregivers; (4) Analogous to private pharmacies

The key interventions aim to ensure that Chlorhexidine is delivered across the country, including the "last mile" and rural areas.

At a high level, interventions will focus on:
- **Encourage and support states to procure and distribute** Chlorhexidine by advocating to SMoHs (see policy, advocacy, & financing interventions) and working with the director of pharmaceutical services or similar person in each state to execute the procurement
- **Leverage existing public and private systems** for procurement and distribution of Chlorhexidine in each state, with emphasis on MNCH and FP channels capable of reaching the last mile
- **Bundle Chlorhexidine with existing MNCH and FP interventions** for sale/transfer to target users: mama/delivery kits, delivery packs, delivery lists, and misoprostol
- **Incorporate Chlorhexidine communication recommendations** via collaborative work between donors/development partners, manufacturers, and NAFDAC, for example
- **Ensure quality and appropriate use of CHX** through pharmacovigilance

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[69] Drugfield, "Update on local manufacturing of chlorhexidine," Sep. 2015, Stakeholder interviews, Sep. – Nov. 2015.

c. Activities

Activity		Recommended interventions	Responsible
M&D1: Increase awareness amongst target users	Public	• **Encourage and support states to procure and distribute** CHX by advocating to SMoHs (see policy, advocacy, & financing interventions) and working with the director of pharmaceutical services or similar person in each state to execute the procurement • **Leverage existing public systems in each** state for procurement and distribution of CHX, with emphasis on MNCH and FP channels capable of reaching the last mile • **Bundle CHX with other MNCH and FP interventions:** mama/delivery kits, delivery packs, delivery lists, misoprostol, etc.	• FMOH to lead advocacy efforts, with support from uptake coordinator • SMoHs to procure CHX, potentially with catalytic matching funds from development partners • SMoHs to determine optimal existing delivery channel(s) for CHX (see implementation plan and Annexes B and C for state-level guidance on decisions)
	Private	• **Leverage existing private systems in each state** for procurement and distribution of CHX, with emphasis on reaching PPMVs and pharmacies at the last mile (desired location of CHX purchase for ~50% of users)[70] through manufacturer sales reps or independent distributors • **Provide technical support to** manufacturers to set sales targets; strengthen marketing and distribution efforts	• Indigenous manufacturers, distributors to push CHX to PPMVs and pharmacies • PMG-MAN to connect manufacturers to PPMVs and other points of access • Development partners to explore providing technical support to indigenous manufacturers as desired • SMoHs and development partners to organize wholesale activation, with support from state-level coordinators

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[70] "Market Research for 7.1% Chlorhexidine Digluconate: Nigeria," conducted by PATH with funding from US Agency for International Development. Market research was conducted in Kano, Nasarawa, Osun, and Cross Rivers.

		around CHX; and secure GMP approval • **Conduct wholesale activation** in target states by sending a representative to promote CHX to PPMVs and other potential purchasers • **Brand PPMVs that regularly stock CHX (>90%) with "seal of approval" for neonatal health** and publicize these PPMVs through demand generation and advocacy efforts *Note: many market & user and advocacy interventions will stimulate CHX private sector delivery channels by generating demand and convincing private sector that CHX is valuable*	• <u>NAPPMED</u> to brand PPMVs, with support from <u>uptake coordinator</u>
M&D2: Improve messaging and branding		• **Incorporate user-centered research recommendations to strengthen communication** to draw consumer attention and prevent misuse via collaboration between donors, development partners, manufacturers, and NAFDAC	• <u>Donor</u> to fund user-centered research • <u>FMoH, NAFDAC, manufacturers, development partners</u> to consider improving communication to generate demand for CHX • <u>Newborn Sub-Committee</u> to approve
M&D3: Ensure quality and appropriate use of CHX		• Ensure quality and appropriate use of CHX through **pharmacovigilance** • **Report** adverse reactions	• <u>NAFDAC, NPHCDA, manufacturers</u> to monitor quality and usage of CHX • <u>FMoH, NAFDAC</u> to collect data on adverse reactions

2.3.3 Clinical & Regulatory (C&R)

a. Justification

To scale-up Chlorhexidine, regulatory approval is required. Chlorhexidine has secured regulatory approval from the government as it is convinced that there is sufficient evidence to scale it in Nigeria based on randomized controlled trials in Nepal, Bangladesh, and Pakistan.

b. Strategy

The clinical & regulatory strategy monitors new clinical evidence from ongoing and future studies in India, Tanzania, and Zambia but does not require immediate interventions given government acceptance of existing evidence and regulatory approval for Chlorhexidine in Nigeria. The release of additional clinical evidence should be weighed in accordance with WHO guidance to apply Chlorhexidine in high-risk settings, and the strategy and implementation plan should be adapted accordingly.

c. Activities

Activity	Recommended interventions	Responsible
C&R1: **Monitor new evidence**	• **Monitor new evidence released from recent studies in India, Tanzania, and Zambia, and other future studies**	• <u>FMoH</u>

2.3.4 Policy, Advocacy, & Financing (PA&F)

a. Justification

To scale-up Chlorhexidine, an enabling environment – including policy, advocacy, & financing – is required. The Nigerian government has been a leader in the African continent in establishing an enabling environment around the scale-up of Chlorhexidine. In Nigeria, Chlorhexidine is in its final stages of being added to the EML and STG. However, successful scale-up of Chlorhexidine hinges on buy-in from key opinion leaders ranging across national (e.g., professional associations, tertiary care providers), state (e.g., state governments, secondary care providers), and local levels (e.g., LGAs and community leaders and primary care providers). Through advocacy across various levels of government and the private sector, it is more likely that the best policies can be presented and implemented. Furthermore, while the overall enabling environment for scaling Chlorhexidine is increasingly positive, it has not been accompanied by a commensurate dedication of national-, state, or LGA-level financial resources.

The strategy will build from previous Chlorhexidine interventions related to policy, advocacy, & financing, including:
- Chlorhexidine has received <u>provisional approval in the national EML and STG</u> and has been added to the EMLs in some states
- Chlorhexidine has been <u>included in some mama/delivery kits, delivery packs, and delivery lists</u>, but not all
- <u>Three stakeholder meetings</u> have been convened with Chlorhexidine as a topic/sole focus
- Study tours have been undertaken to <u>Bauchi and Sokoto</u> by 34 states
- To date, at least <u>11 states have procured Chlorhexidine</u> – mostly through the public sector but some have connected manufacturers to the private sector[71]
- Manufacturers have invested in <u>production capacity</u> of Chlorhexidine

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[71] Based on stakeholder interviews, the following states have procured Chlorhexidine (or have had development partners do so): Bauchi, Edo, Gombe, Kaduna, Kano, Katsina, Lagos, Ogun, Ondo, Plateau, and Sokoto. Stakeholder interviews, Sep. – Nov. 2015.

- Select donors and development partners have worked with the FMoH to develop <u>job aids and messaging</u>, as well as <u>support stakeholder convening</u> and <u>advocacy</u>
- Select donors and development partners have <u>supported state-level demand generation</u> and <u>health systems strengthening</u>

b. Strategy

The policy, advocacy, & financing strategy further strengthens the enabling environment for Chlorhexidine by finalizing national and subnational policies favorable to Chlorhexidine (e.g., EML and STG), soliciting buy-in from key opinion leaders via in-person advocacy visits, and mobilizing additional sources of funding needed to implement the scale-up strategy. Key opinion leaders serve as gatekeepers and influencers needed to generate awareness and demand amongst the three target users of Chlorhexidine (facility providers, CHWs, and mothers/family). Thus, advocacy to key opinion leaders relates to the market & user strategy and should come before mass media activities. Potential sources of funding include the FMoH, state governments (e.g., state matching and free MNCH programs, SMoHs), the National Health Act, the National Health Insurance Scheme, World Bank loans to states, private sector investment, and donor funds to support select catalytic or enabling activities.

Figure 9: Summary of important advocacy efforts and policy changes needed to scale-up Chlorhexidine[72]

Successful scale-up of CHX hinges on buy-in from key opinion leaders:

NATIONAL
- Professional associations
- Tertiary care providers[1]
- State government

LOCAL
- Secondary care providers[1]
- Local government and community leaders
- Primary care providers

Several policies[2] across government require change:

Level	Policy to change/update	Impact of change
National	• EML • STG	• Sets model for states and authorizes procurement • Sets standard for use of CHX in cord care
State	• EML • STG • Contents of mama/delivery kits, delivery packs, and delivery lists	• Eases procurement of CHX for states • Encourages widespread use and substitution of CHX over alternative cord care products
Local	• Contents of mama/delivery kits, delivery packs, and delivery lists	• Encourages substitution of CHX over alternative cord care products

- These key opinion leaders serve as <u>gatekeepers</u> and <u>influencers</u> needed to generate awareness and demand amongst target users of CHX (facility providers, CHWs, and mothers/family)
- Thus, **advocacy to KOLs closely relates to the market & user strategy**
- Given significance of gatekeepers in changing target user behavior, **KOL interventions should come before mass media activities**

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[72] Key opinion leaders in tertiary and secondary facilities include chief pharmacists and heads of neonatal units. Stakeholder interviews, Sep. – Nov. 2015.

Note: (1) Key opinion leaders in tertiary and secondary facilities include chief pharmacists and heads of neonatal units; (2) The strategy takes into account current users, points of service, and points of access for CHX and does not address larger policy shifts related to place of delivery or type of assistance provided during birth.

The key interventions span national, state, and local levels to gain support for Chlorhexidine.

At a high level, interventions will focus on:

- Secure funding needed to **finalize national EML and STG** and advocate to states to adopt national EML by including Chlorhexidine in their own EMLs and ensure the inclusion of 4% Chlorhexidine gel (25g) for cord care in mama/delivery kits, delivery packs, and delivery lists
- **Disseminate scale-up strategy** across Nigeria, advocate to local government service commissions, SMoHs, secondary and private hospitals, tertiary hospitals, and professional associations to secure buy-in for Chlorhexidine
- **Primarily rely on states** (including state matching and free MNCH programs) **and private sector for procurement and distribution**, especially in the long-term, but **seek donor funds as appropriate for supporting activities** (e.g., initial catalytic procurement, demand generation)
- Work with development partners in each state **to incorporate Chlorhexidine-related activities into current programming** in order to help cover state-level costs

c. *Activities*

Need		Recommended interventions	Responsible
PA&F1: Placement on EML or other relevant lists not complete	National	• **Finalize EML and STG** to ensure easy procurement of CHX and promote widespread use (via treatment guidelines); also serves as guiding policy for states • **Disseminate EML and STG** to states via existing federal-to-state government communication channels (e.g., FDS representatives in each state)	• FDS • Uptake coordinator to support
	State	• **Advocate for adoption and enforcement of revised EML and STG**	• FDS
	Local	• Advocate to states, hospitals, and community leaders to **include CHX in all kits/lists and replace alternate cord care products**	• SMoHs
PA&F2:	National	• **Disseminate scale-up**	• FMoH, uptake coordinator to

Limited commitment from key opinion leaders & state leaders		strategy across Nigeria • **Make advocacy visits to SMoHs and tertiary hospitals** with samples of CHX to solicit buy-in via a coalition of FMoH staff and members from the Newborn Sub-Committee of the Child Health Technical Working Group of MNCH-CTC • **Send a FMoH/CHX representative to every professional association conference** in the next two years with samples of CHX; reps will come from a coalition of FMoH staff and the Newborn Sub-Committee of the National Health Technical Working Group of MNCH-CTC	disseminate scale-up strategy • FMoH to make advocacy visits and determine appropriate reps to accompany
	State	• **Make advocacy visits to secondary and private** hospitals with samples of CHX to advocate for CHX via a coalition of SMoH staff and public/private point people in each state • **Make advocacy visits to local governments** with samples of CHX to solicit buy-in	• SMoHs • State coordinators
	Local	• **Make advocacy visits to community leaders** to solicit buy-in via a coalition of people from WDCs; where WDCs are not active, SMoH, state coordinators, and development partners can play a more involved role	• LGAs, WDCs, development partners, SMoHs, state coordinators
PA&F3: Limited financial	Government	• **Catalyze state demand and procurement for CHX** by sourcing matching catalytic	• FMoH, SMoHs, donors to explore opportunities to fund commodity cost for states

support for scale-up		funding from development partners, donors • **States to access National Health Act funding** and use to support scale-up of CHX • Ensure/enforce that CHX is provided for under **National Health Insurance Scheme** • **Mobilize non-donor source of funding at the state-level** through state matching and free MNCH programs	and finalize EML • Uptake coordinator and state coordinators to help states access NHA financing • States to mobilize non-donor funding through existing programs
	Private sector	• Identify private sector players **to match funds** for seed stock of CHX	• FMoH
	Donor	• **Support similar catalytic and enabling activities** in states without high levels of CHX activity, with a specific focus on supporting programs for awareness building, demand generation, and strengthening existing delivery channels; coordinating mechanism in each state will also require partner support • **States to access World Bank loans** and use to support scale-up of CHX	• FMoH to reach out to donors for support related to dissemination of messaging and adding CHX to EML • SMoH to advocate for integrating CHX into other activities led by development partners • Uptake coordinator and state coordinators to help states access World Bank financing

2.3.5 Coordination (C)

a. Justification

Given the complexity of managing interventions across the scale-up components, there is a significant need for a strong coordinating mechanism capable of troubleshooting issues as they arise; liaising with and coordinating work across stakeholders; maintaining a project timeline; helping to prioritize decisions; and tracking progress over time.

The strategy will build from previous Chlorhexidine interventions related to coordination, including:

- FMoH has convened and led at least three stakeholder meetings with Chlorhexidine as a focus and also established the Newborn Sub-Committee of the National Child Health Technical Working Group of MNCH-CTC

- Certain development partners have <u>coordinated Chlorhexidine activities across states</u> – a subset of these partners have conducted <u>M&E on Chlorhexidine activities</u>
- Chlorhexidine was recently <u>added to MICS 5 questions/indicators</u>
- <u>Initial demand forecast</u> of Chlorhexidine has been completed by the FMoH for ten states
- <u>UNCoLSC set a target of 80%</u> for all essential medicines
- <u>Market shaping efforts</u> have been conducted to control costs and price Chlorhexidine below methylated spirits

b. *Strategy*

The coordination strategy seeks to ensure strong leadership and accountability to execute the National Strategy and Implementation Plan for Scale-up of Chlorhexidine. At a national level, coordination for Chlorhexidine scale-up will sit within the Newborn Sub-Committee of the National Child Health Technical Working Group of the MNCH-CTC. The FMoH will appoint a chair of the Sub-Committee to lead scale-up efforts and maintain accountability for overall targets to increase national coverage of Chlorhexidine scale-up. The Sub-Committee will be supported by an uptake coordinator consisting of one FTE from a partner organization with the ability to support the FMoH with scale-up in both private and public sectors. The uptake coordinator will be accountable for overseeing the day-to-day implementation of activities delineated in the strategy and implementation plan. The uptake coordinator, in partnership with the FMoH, will have the authority to convene stakeholders, delegate tasks, and track progress towards scale-up targets.

Figure 10: Coordination mechanism of the National Strategy and Implementation Plan for Scale-up of Chlorhexidine[73]

CHX scale-up coordination will sit within a <u>Newborn Sub-Committee of the National Child Health Technical Working Group</u> of the MNCH-CTC

Sub-Committee leadership roles:

Chair – FMoH Appointee
- **Lead all scale-up efforts and maintain accountability for overall targets** to increase national coverage of CHX
- Chair the sub-committee, including oversight of continuous revisions to the strategy and implementation plan and dissemination of progress and results to all stakeholders
- Raise awareness around CHX and advocate to states, hospitals, and professional associations to implement the scale-up strategy
- Drive national policy favorable to CHX (e.g., EML, STGs)
- Ensure health workers are trained on ENCC and other training packages relevant to CHX
- Develop, update, and/or disseminate CHX demand generation materials for all partners to tailor and use
- Report on supply of CHX currently in the public system

Sub-Committee support role:

Uptake Coordinator – 1 FTE from one development partner organization with ability to support FMoH in both public and private sectors
- **The uptake coordinator will be accountable for overseeing the day-to-day implementation of activities** in the scale-up strategy and for meeting short- and medium-term targets related to key outputs and outcomes across all five core components of the strategy (e.g., number of health providers trained in CHX usage)

Please see the following slide for additional detail on roles & responsibilities and necessary qualifications for the uptake coordinator position

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[73] Stakeholder interviews, Sep. – Nov. 2015.

Figure 11: Job description of uptake coordinator for scale-up of Chlorhexidine[74]

Roles and responsibilities	Necessary qualifications

1 FTE focused on technical support

- **Provide technical support to the Newborn Sub-Committee** throughout the implementation of recommended interventions in both the public and private sectors
- **Maintain accountability for implementation of activities** in scale-up plan as well as short- and medium-term targets related to outputs and outcomes
- **Annually update demand and supply forecasts** to inform prioritization and sequencing of activities in order to match supply and demand
- **Lead efforts to track progress** via monitoring of the dashboard
- **Troubleshoot issues as they arise** in public and private systems
- **Manage relationships and build consensus** by serving as primary point of contact for states, manufacturers, professional associations, and other actors
- **Facilitate** regular Sub-Committee meetings (bi-monthly in the first year and quarterly thereafter), **produce reports,** and **share output of meetings** to all members and the designated public and partner focal points in each state
- **Ensure scale-up is integrated** with other MNCH efforts: biannual MNCH week, Saving One Million Lives, First Ladies projects

- **100% devoted to scale-up of CHX for one year**
- 5+ years experience working in **public and private delivery channels** for essential medicines in Nigeria
- 5+ experience **with relationship management and consensus-building** in complex, multi-stakeholder situations
- 2-5 years **experience in M&E**
- Strong **problem-solving and analytical skills**
- Ability to **liaise across many stakeholders and organizations**
- Excellent **written and oral communication** skills

At a high level, interventions will focus on:

- At a national level, the **FMoH will appoint the chair** of the Newborn Sub-Committee within the National Child Health Technical Working Group of the MNCH-Core Technical Committee (MNCH-CTC)
- At a national level, the FMOH will **engage an uptake coordinator who is a full-time employee from a partner organization** to provide technical support to the Newborn Sub-Committee in its first year to scale-up CHX in both the public and private sectors – the FMoH Newborn Branch will take on most administrative responsibilities with some support from the uptake coordinator
- At a state level, **the RH Coordinator (from government side) and one development partner focal point** will coordinate scale-up efforts in each state, building on existing structure of the state MNCH-CTC
- The FMoH will **oversee a phased approach to scale-up across states** that starts with 16 states with existing partner- and state-led programming related to CHX (Adamawa, Bauchi, Cross River, Ebonyi, Gombe, Kaduna, Kano, Katsina, Kebbi, Kogi, Kwara, Lagos, Ogun, Plateau, Rivers, Sokoto) and then uses two criteria (need and feasibility) to place states from each region into two subsequent phases
- **The FMoH will lead meetings** (bi-monthly for the first year, quarterly thereafter) **to track progress of national and state actors** according to assigned roles and responsibilities, including ensuring continual matching of supply and demand activities and troubleshooting as problems arise

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[74] Stakeholder interviews, Sep. – Nov. 2015.

c. Activities

Need		Recommended interventions	Responsible
<u>**C1: Need for strengthening the Newborn Sub-Committee**</u>	Leadership	• **Newborn Sub-Committee** within the National Child Health Technical Working Group of the MNCH-CTC receives mandate for CHX scale up coordination.	• <u>FMoH</u> • <u>Chair of Newborn Sub-Committee</u>
	National support	• **Appoint 1 FTE from a partner organization to support the coordination efforts of the Newborn Sub-Committee** in its first year, primarily through technical assistance, as the FMoH Newborn Branch will take on most administrative responsibilities	• <u>FMoH</u>
	State support	• **RH Coordinator to work with one development partner focal point** for CHX in each state to oversee the coordination and implementation through the state MNCH-CTC	• <u>Uptake coordinator</u>
<u>**C2: Limited clarity on roles and responsibilities in scale-up**</u>		• **Convene bi-monthly meetings** (for the first year, quarterly thereafter) **to track progress of national and state actors according to assigned roles and responsibilities**, including ensuring continuous matching of supply and demand forecasts and troubleshooting as problems arise • **Create joint workplan** to coordinate all stakeholder activities	• <u>FMoH</u> • <u>Uptake coordinator</u>
<u>**C3: Need for phasing plans for roll-out**</u>		• **Oversee a phased approach to scale-up of CHX across**	• <u>FMoH, Newborn Sub-Committee</u>

	states that begins with states with existing partner- or state-led programming related to CHX and then uses two criteria (need, feasibility) to select states from each region for subsequent phases • **Vet placement of states into three phases;** Phase 1 currently includes 16 states from all six regions (Adamawa, Bauchi, Cross River, Ebonyi, Gombe, Kaduna, Kano, Katsina, Kebbi, Kogi, Kwara, Lagos, Ogun, Plateau, Rivers, Sokoto); the states have high feasibility of scale-up given strong state and/or partner support and account for over 50% of neonatal mortality • **Review phasing strategy each quarter to determine if modifications are necessary** based on recent events/changes in state activities	
C4: Supply not matched with demand and forecasts	• **Support remaining states** with forecasts • **Compile state projections for demand into a national forecast** each year • **Communicate forecasts to manufacturers** on a continual basis and ask manufacturers to report on planned production to ensure matching of demand and supply • **Time supply and demand-related interventions** to align	• FMoH for national forecasts and aggregating state projections into a national forecast • States/development partners for state forecasts, with support from uptake coordinator • State-level coordinators to time activities, with support from uptake coordinator

		with forecasts and gradually raise the supply-demand equilibrium; supply and demand activities must be sequenced together to avoid one piece outpacing the other (e.g., do not launch demand generation campaign in a state where CHX is not available without also addressing supply-side issues) *Note: forecasting is also covered in market & user*	
C5: No unified M&E system to track progress against key milestones & optimize as needed	Leadership	• **Finalize M&E responsibilities in ToR for uptake coordinator & coordinating mechanism** with input from partners to ensure that the dashboard accurately reflects the most important indicators	• Newborn Sub-Committee
	M&E plan	• **Launch dashboard** using M&E plan from strategy and update every six months for metrics requiring collection with this frequency • **Conduct a comprehensive learning review each quarter** to revisit data and course-correct strategy based on findings; this ensures continuous iteration and improvement based on progress to date • **Advocate for inclusion of CHX-related indicators** in national HMIS, community-based HMIS, DHIS, and surveys such as NDHS etc… (CHX has been added to MICS) • **Support implementation research** to create additional	• Uptake coordinator

		evidence for policy-making	
	Targets	• **Build consensus and approve targets from implementation plan** • **Track progress against targets** and update targets, as needed, during each quarterly review, especially if phasing or resourcing shifts	• <u>Uptake coordinator</u>

CHAPTER 3: CHLORHEXIDINE SCALE-UP TARGETS AND COSTING

3.1: Scale-up Targets

By the end of the fifth year of national scale-up, the National Strategy and Implementation Plan for Scale-up of Chlorhexidine will enable over 10.9 million infants to have Chlorhexidine applied to their umbilical cords. This equates to an increase in Chlorhexidine uptake from its estimated current rate of significantly fewer than 5% to 52% after the fifth year of national scale-up.[75]

The uptake curve of Chlorhexidine in Nigeria was based on programmatic experience from Bauchi, Sokoto, and Nepal:

- For facility births, uptake targets were based on an average of uptake across (i) facility births in Nepal and (ii) facility and non-facility births in Nepal.[76]
- For non-facility births, uptake targets were based on average uptake across (i) facility and non-facility births in Nepal, (ii) Bauchi, and (iii) Sokoto.[77]

Using the projected uptake curve, coverage of Chlorhexidine was calculated using a quantitative model accounting for a variety of factors, including:
- State phasing of Chlorhexidine scale-up (as described in Section 4.4);
- Number of births per year in a given state[78];
- Percentage of facility versus non-facility births in a given state[79];
- Birth rate increase[80]; and,
- Existing uptake of Chlorhexidine in Nigeria.[81]

The quantitative model incorporated these factors to estimate coverage of Chlorhexidine on a state-by-state basis over a five-year period.[82] The state-level coverage was then aggregated to estimate uptake on a national basis.

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[75] Current rate based on stakeholder interactions and preliminary analysis.

[76] TSHIP focused on community distribution – thus Nepal's programming was used as a proxy for facility uptake; the average was taken to normalize high facility uptake in Nepal. NDHS survey, 2013; FMoH and Save the Children, "Nigeria State Data Profiles;" USAID, FMoH, and JSI, "Advancing Maternal, Newborn, Child Health in Bauchi/Sokoto State;" JSI CHX Navi Cord Care Program, Annual reports up to 2015.

[77] NDHS survey, 2013; FMoH and Save the Children, "Nigeria State Data Profiles;" USAID, FMoH, and JSI, "Advancing Maternal, Newborn, Child Health in Bauchi/Sokoto State;" JSI CHX Navi Cord Care Program, Annual reports up to 2015. For year five, targets in Bauchi and Sokoto are assumed to be 60%.

[78] Nigerian FMoH/Save The Children, "Nigeria State Data Profiles."

[79] NDHS survey, 2013.

[80] http://www.ifs.du.edu/ifs/frm_CountryProfile.aspx?Country=NG

[81] NDHS survey, 2013; FMoH and Save the Children, "Nigeria State Data Profiles;" USAID, FMoH, and JSI, "Advancing Maternal, Newborn, Child Health in Bauchi/Sokoto State;" JSI CHX Navi Cord Care Program, Annual reports up to 2015.

[82] NDHS survey, 2013; FMoH and Save the Children, "Nigeria State Data Profiles."

Figure 12: Uptake targets for Chlorhexidine in Nigeria
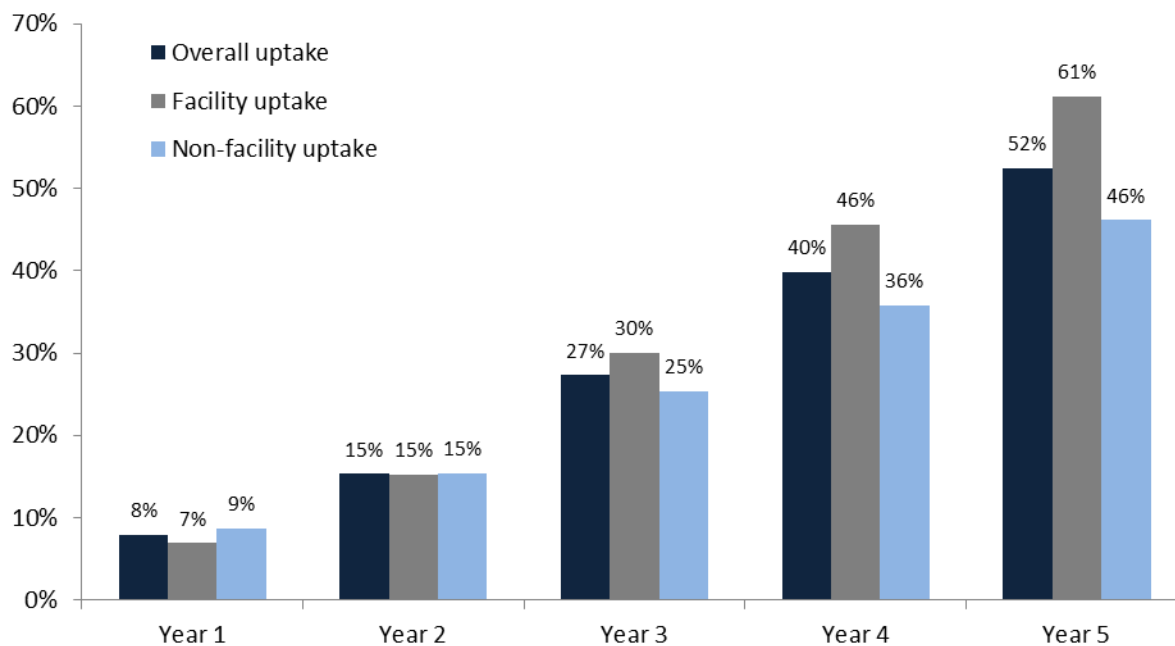
3.2: Costing

The costing sets out to provide a high-level estimate of resources required to reach the national goal of 52% Chlorhexidine coverage after the fifth year of national scale-up. Costs may be revised once the planning for specific areas is completed and learnings are incorporated.

3.2.1 Assumptions

Scale-up costs are calculated over a five-year period and are dependent on the aforementioned projected uptake targets and related activities. To estimate costs, budgets of analogous programs, such as Chlorhexidine in Bauchi and Sokoto and family planning were reviewed. Significant inputs were also provided by the FMoH and development partners through numerous stakeholder interviews. Detailed assumptions of the costing, including rationales and sources, are enumerated in Annex A.

3.2.2 Cost Summary

To estimate the costs of implementing the strategy, a quantitative model was developed. The model calculates total costs of implementing the strategy, as well as a delineation of costs on an activity-, state, and year-level basis. The costing includes both initial investment costs, as well as ongoing costs related to the scale-up of Chlorhexidine. **Costs presented as 'national' and 'state' costs for implementation of activities will be borne by the respective governments with support from private sector, donors and development partners.** This model should be considered to provide broad costing of implementation and not necessarily a tool to allocate funds on an activity-by-activity basis.

The total cost of implementing the National Strategy and Implementation plan over its first five years is US $32 million, divided by the following scale-up components:

- **Market & user**: Generating awareness and demand for Chlorhexidine is a key facet of the scale-up strategy. Interventions related to market & user include demand generation campaigns, training of target users and at key points of access (e.g., healthcare workers, PPMVs), and disseminating Chlorhexidine messaging through media and print campaigns. **Interventions related to market & user account for approximately 57% of total scale-up costs** – with over 99% of market & user costs associated with state-level activities.
- **Manufacturing & distribution**: To ensure access to Chlorhexidine, the interventions related to manufacturing & distribution aim to increase availability of Chlorhexidine. Interventions related to manufacturing & distribution include procurement of Chlorhexidine, expanding private sector delivery channels through technical assistance, and potentially incorporating Chlorhexidine communication recommendations based on user-centered research. **Interventions related to manufacturing & distribution account for approximately 10% of total scale-up costs** – with 95% of manufacturing & distribution costs associated with state-level activities.
- **Clinical & regulatory**: Given the government is convinced that there is sufficient evidence to scale chlorhexidine in Nigeria, there are no interventions that require funding. **As a result, interventions related to clinical & regulatory account for 0% of total scale-up costs.**
- **Policy, advocacy, & financing**: To continue strengthening the enabling environment for Chlorhexidine, interventions around policy, advocacy, & financing relate to adding Chlorhexidine to the EML and conducting advocacy visits to State Ministries of Health, hospitals, professional associations, and the like. **Interventions related to policy, advocacy, & financing account for approximately 5% of total scale-up costs** – with 80% of policy, advocacy, & financing costs associated with state-level activities.
- **Coordination**: The coordination strategy seeks to ensure strong leadership and accountability to execute the strategy. Interventions include, for example, finalizing the M&E framework, formalizing the coordinating mechanism, hosting coordinating meetings, and conducting M&E activities. As each state requires a strong coordinating mechanism, **interventions related to coordination account for approximately 28% of total scale-up costs** – with 96% of coordination costs associated with state-level activities.

Costs are spread over the duration of the scale-up strategy, with earlier years requiring more funding due to higher costs related to market & user interventions. Costs peak at year three – as by the beginning of year three, each state will have initiated scale-up of Chlorhexidine.

Approximately 97% of the US $32 million costs associated with the scale-up of Chlorhexidine involves activities at the state-level. **The average cost to scale Chlorhexidine in each state over the five-year strategy and implementation plan is less than US $200,000 per year.**

Figure 13: Costs by category in US $ million

Total: US$32M

Coordination: $9.1M

Policy, advocacy, & financing: $1.5M

Manufacturing & distribution: US$3.2M

Market & user: US$18.3 M
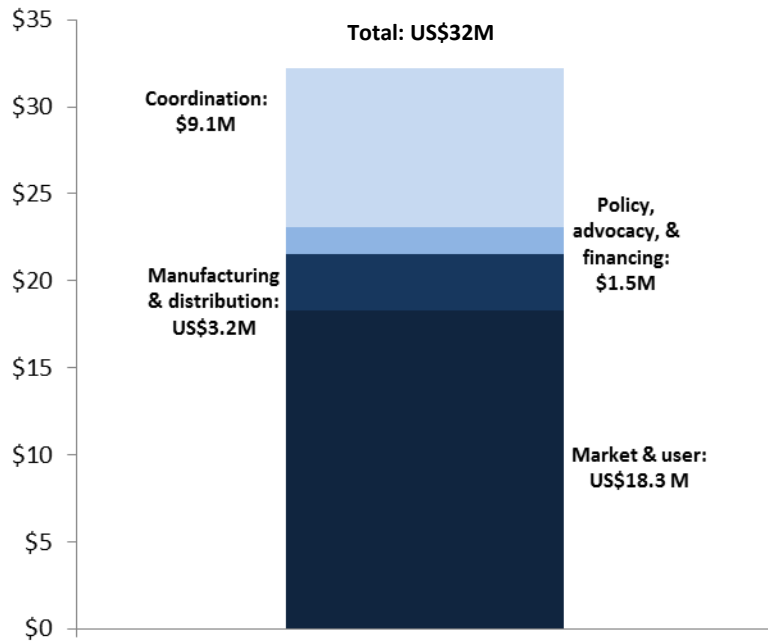
Figure 14: Costs by category per year in US $ million

Total five-year cost: US$32M

US$8.9M

US$7.1M

US$5.7M

US$5.4M

US$5.1M

Year 1   Year 2   Year 3   Year 4   Year 5

■ Coordination ■ Policy, advocacy, & financing ■ Manufacturing & distribution ■ Market & user
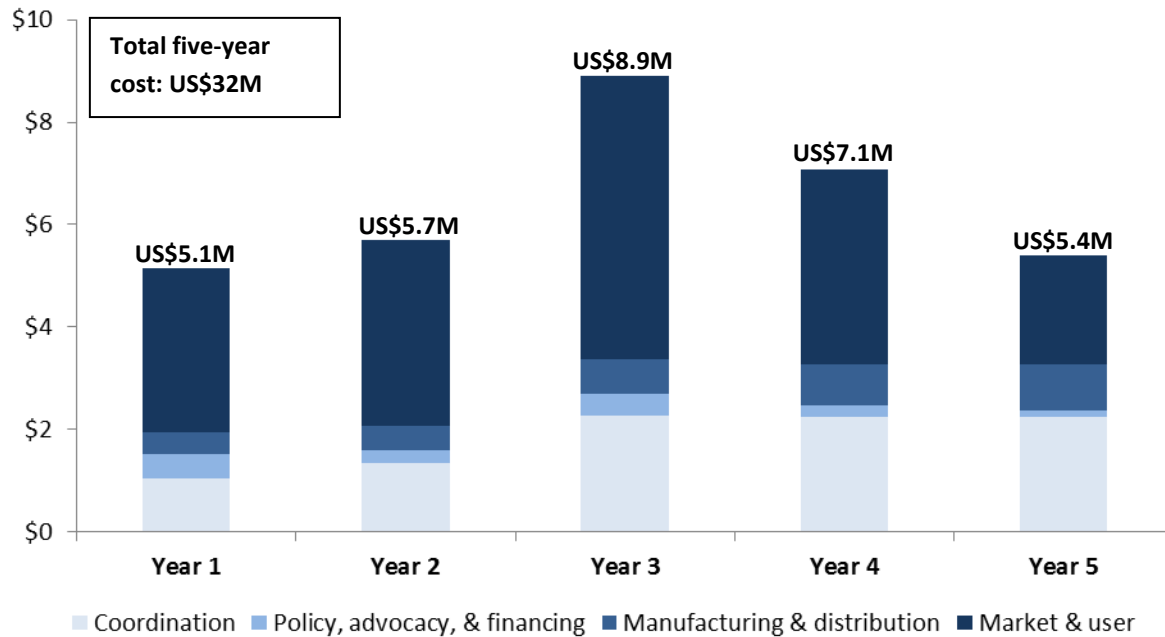
CHAPTER 4: IMPLEMENTATION PLAN

The FMoH developed this National Strategy and Implementation Plan for Scale-up of Chlorhexidine to reach a 52% Chlorhexidine uptake target after the fifth year of national-scale up. Since estimated uptake currently stands at significantly under 5%, two-year national- and state-level action plans have been developed to guide scale-up and implementation.[83] By the beginning of year three, each state and the FCT will have initiated scale-up of Chlorhexidine. Ultimately, Chlorhexidine uptake depends on each state's ability to execute the strategy, as well as access to required funding.

4.1 Two-Year National-Level Action Plan

The FMoH plays a critical leadership role in providing the necessary pre-conditions for scale-up in each of the 36 states and the FCT. At a national-level, the majority of activities are related to advocating for Chlorhexidine scale-up through disseminating messaging and training materals; overseeing efforts for state mobilization of funding and procurement of Chlorhexidine; ensuring a strong monitoring and evaluation system; and supporting coordination activities. The national-level action plan requires many interventions in the first 0-3 months, followed by ongoing coordination and advocacy activities. National-level activities related to the National Strategy and Implementation Plan are depicted below.

Figure 15: Overview of two-year national-level action plan
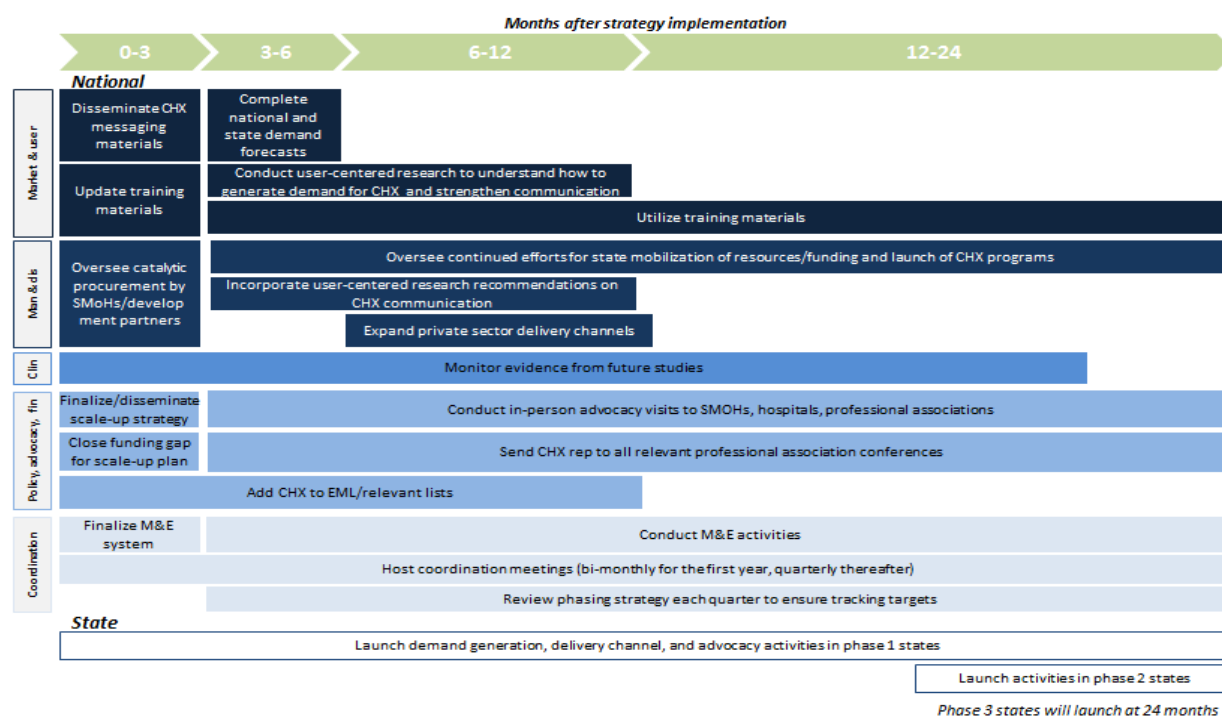
To aid in national-level coordination efforts, activities are mapped to the following anchors:[84]

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[83] Current rate based on stakeholder interactions and preliminary analysis.
[84] Costs related to these activities are detailed in Annex A.

Figure 16: Anchors and overview of timing of activities related to two-year national-level action plan (organized by anchor and timeframe)

Anchor[85]	Scale-up component	Activity	Timeframe
Donors (led by FMoH and professional associations)	Market & user	Support user-centered research to to understand how to generate demand for CHX and strengthen communication accordingly	3 – 12 months
FMoH	Market & user	Disseminate CHX messaging generic materials	0 – 3 months
FMoH, NPHCDA, professional associations	Market & user	Update (as needed) training materials	0 – 3 months
FMoH, NPHCDA, professional associations	Market & user	Utilize training materials	3 – 24 months
FMoH	Policy, advocacy, & financing	Disseminate scale-up strategy across Nigeria	0 – 3 months
FMoH	Policy, advocacy, & financing	Oversee and advocate for closing of funding gap to implement scale-up strategy	0 – 3 months
FMoH	Policy, advocacy, & financing	Add CHX to EML and STG	0 – 3 months
FMoH	Coordination	Designate Newborn Sub-Committee, appoint uptake coordinator, and support states in designating focal points	0 – 3 months
FMoH	Coordination	Finalize M&E system	0 – 3 months
FMoH	Clinical & regulatory	Monitor evidence from future studies	0 – 24 months
FMoH	Coordination	Host coordination meetings	0 – 24 months
FMoH	Market & user	Complete national demand forecasts (and aggregate state forecasts)	3 – 6 months
FMoH	Coordination	Conduct M&E activities	3 – 24 months
FMoH	Coordination	Review phasing strategy to determine if additional states could be 'quick-wins' based on	3 – 24 months

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[85] While FMoH retains leadership over its anchor activities, the uptake coordinator plays a support role as a partner FTE embedded in the government system.

		SMoH/development partner activities	
FMoH	Policy, advocacy, & financing	Conduct advocacy visits to SMoHs, professional hospitals, professional associations	3 – 24 months
FMoH	Policy, advocacy, & financing	Ensure FMoH/CHX representative attends relevant professional association conferences	3 – 24 months
FMoH	Manufacturing & distribution	Oversee resource mobilization efforts to account for costs of procuring Chlorhexidine (e.g., catalytic procurement by donors/SMoHs)	6 – 24 months
Manufacturers, NAFDAC	Manufacturing & distribution	Incorporate communication recommendations for CHX based on user-centered research	6 – 12 months
Manufacturers, NAPPMED	Manufacturing & distribution	Expand private delivery channels	6 – 12 months

Note that these activities should be mapped with specific interventions enumerated in previous sections. This list is intended to provide an overview, but scale-up component categories should be reviewed in parallel with the more detailed interventions listed previously.

At a high level, interventions will focus on:

- **Market & user:** The FMoH will widely disseminate Chlorhexidine messaging materials, including radio jingles, to SMoHs, development partners, professional associations, and manufacturers (who will then also play a role in widespread dissemination). The FMoH will also ensure the dissemination of training materials, in close collaboration with NPHCDA and professional associations, so that the materials can be utilized. The FMOH will work closely with the uptake coordinator to finalize national forecasts, which includes aggregating state demand forecasts, and share with all stakeholders. Finally, any relevant findings from the user-centered research should be, to the extent possible and desired, incorporated into Chlorhexidine communications and disseminated in concert to states in a manner consistent with the phasing strategy.

- **Manufacturing & distribution:** In an effort to incentivize initial procurement of Chlorhexidine, the FMoH will oversee state mobilization of funds to procure Chlorhexidine. In the near-term, the strategy advises states to procure Chlorhexidine using its own funds – however, SMoHs can advocate with donors and development partners to create an initial catalytic fund to spur procurement. The FMoH should not hold any stock of CHX and should instead work exclusively with SMoHs, development partners, and manufacturers to encourage this first state purchase of Chlorhexidine. Finally, manufacturers and NAPPMED can work to expand private sector delivery channels.

- **Clinical & regulatory:** The FMoH will monitor any relevant Chlorhexidine studies and update policies, protocol, and the strategy accordingly.

- **Policy, advocacy, & financing:** The FMoH will disseminate the National Strategy and Implementation Plan. Following this initial dissemination, the FMOH will need to spend the next two years ensuring that SMoHs are tailoring the development of their scale-up strategies to account for unique needs. As funding gaps emerge, the FMoH will assist SMoHs in advocating for necessary funds, as calculated in their costed plan. The FMoH will ensure that a FMoH/Chlorhexidine representative is sent to relevant professional association conferences. The same level of advocacy should be executed by professional associations' national offices to state representatives. State professional associations will also ensure that local healthcare providers review hospital protocols and delivery lists to check for the inclusion of Chlorhexidine. Finally, the FMoH should ensure that the national EML and STG is updated as soon as possible to provide more encouragement for states to update their own politices.

- **Coordination:** Within the first quarter of strategy implementation, the FMoH will finalize the coordinating mechanism, including mandating the Newborn Sub-Committee and appointing an uptake coordinator. The FMoH will also finalize the M&E system. A strong coordination mechanism is instrumental in allocating resources as states begin scale-up and sharing lessons learned from each state's experience scaling-up Chlorhexidine.

4.2 Two-Year State-Level Action Plan

Each state will develop its own Strategy and Implementation Plan. This will require each state to review learnings from existing Chlorhexidine scale-up activities, engage with stakeholders, agree to uptake targets, tailor interventions as appropriate, and prepare a costed plan.[86]

Figure 17: Overview of two-year state-level action plan
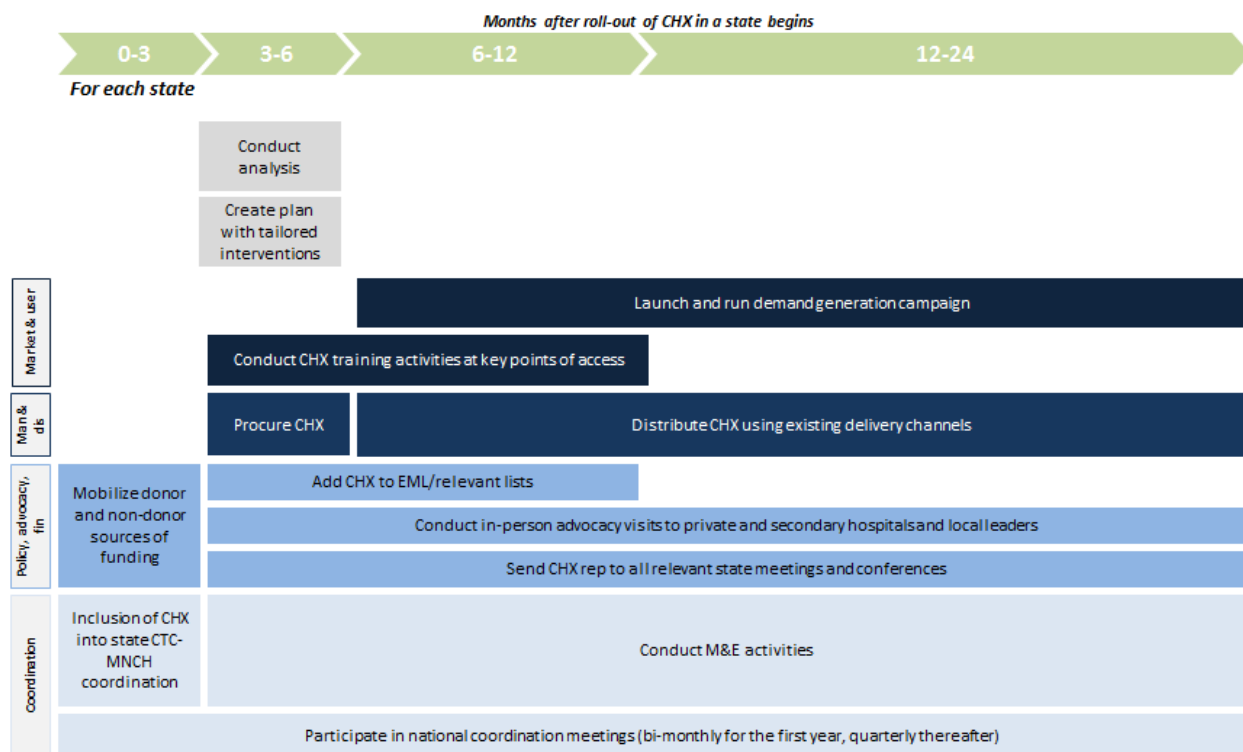
To aid in state-level coordination efforts, activities are mapped to the following anchors:[87]

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[86] States can rely on costing details in Annex A and review assumptions to tailor costing projections as necessary.
[87] Costs related to these activities are detailed in Annex A.

Figure 18: Anchors and overview of timing of activities related to two-year state-level action plan (organized by anchor and timeframe)

Anchor[88]	Scale-up component	Activity	Timeframe[89]
SMoH	Coordination	Create plan with tailored interventions	0 – 3 months
SMoH	Manufacturing & distribution	Procure CHX	3 – 6 months
SMoH	Policy, advocacy, & financing	Add CHX to EML and advocate for inclusion on other relevant lists (e.g., delivery kit lists)	3 – 12 months
SMoH	Market & user	Conduct CHX training activities at key points of access	3 – 12 months
SMoH	Market & user	Launch and run demand generation campaigns	6 – 24 months
SMoH	Manufacturing & distribution	Distribute Chlorhexidine using existing delivery channels	6 – 24 months
RH Coordinator & partner focal point	Policy, advocacy, & financing	Mobilize both donor and non-donor sources of funding at the state-level	0 – 3 months
RH Coordination & partner focal point	Coordination	Conduct analysis and share with SMoH to aid in creation of plan with tailored interventions (see Annexes B and C)	0 – 3 months
RH Coordinator & partner focal point	Coordination	Inclusion of CHX into state MNCH-CTC coordination meetings	0 – 3 months
RH Coordinator & partner focal point	Coordination	Participate in national coordination meetings (bi-monthly for the first year, quarterly thereafter)	0 – 24 months
RH Coordinator & partner focal point	Policy, advocacy, & financing	Conduct advocacy visits to private and secondary hospitals and local leaders	3 – 24 months
RH Coordinator & partner focal point	Policy, advocacy, & financing	Send RH Coordinator and partner focal point to all relevant state meetings and conferences	3 – 24 months

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[88] While SMoH retains leadership over anchor activities, it can be supported by the coordinating structure in each state – the RH coordinator (serving as the SMoH representative) and a focal point from each development partner.
[89] Timeframe corresponds to month after Chlorhexidine roll-out begins in state.

RH Coordinator & partner focal point	Coordination	Conduct M&E activities	3 – 24 months

Note that these activities should be mapped with specific interventions enumerated in previous sections. This list is intended to provide an overview, but scale-up compenent categories should be reviewed in parallel with the more detailed interventions listed previously.

At a high level, state-level interventions focus on:

- **Tailor strategy and implementation plan as appropriate:** Interventions should be tailored based on analysis of current birth practices, cultural norms of the state, and existing knowledge of existing distribution systems in the state. The decision tree in Annex B can help guide the design of the necessary interventions (and the template can help guide delineation of responsibilities and costing). Chlorhexidine uptake targets should also be decided in initial stages, as well as a costed plan associated with these uptake targets. States can rely on costing details in Annex A and review assumptions to tailor costing projections as necessary.
- **Procure Chlorhexidine:** To ensure access and availability, states will work with manufacturers and development partners to procure Chlorhexidine. States can advocate for development partners to provide funding for an initial catalytic stock of Chlorhexidine – though states should be prepared to budget for Chlorhexidine procurement in the near-term given low commodity cost.
- **Engage and advocate with stakeholders:** The SMoH should engage with the State Primary Healthcare Development Agency (SPHCDA), LGA departments, development partners, and professional associations in developing and implementing the Strategy document. This SMoH should also add Chlorhexidine to its EML and other relevant lists.
- **Coordination:** From the outset of scale-up in a state, Chlorhexidine will be integrated into state CTC-MNCH coordination. In addition, a focal point from a development partner active in that state will be appointed.
- **Learn from existing Chlorhexidine scale-up activities:** To date, an estimated 11 states have received a stock of Chlorhexidine.[90] Any state-level action plan should be informed by this initial experience with Chlorhexidine. In almost each of these states, more tubes of Chlorhexidine have been procured than used on newborns.[91] Each state that has procured/received Chlorhexidine should identify the bottlenecks and barriers, and associated opportunities, to increase uptake.

Annexes B and C provide a template that states can use to conduct analysis on Chlorhexidine points of service in its state to help tailor interventions and funding opportunities as appropriate.

4.3 Resource Planning

Activities related to scale-up of Chlorhexidine require considerable human and financial resources given the number and diversity of states, as well as the number of activities involved. The necessary resources are to be sourced throughout all levels of the government, as well as donors and development partners.

To catalyze scale-up of Chlorhexidine, financial resources are of particular import in the initial stages of implementing the strategy. As the cost of procuring Chlorhexidine is low, it is highly advised that these costs are absorbed by existing state government budgets to demonstrate government commitment to donors and development partners.

A summary of necessary financial resources are:

- **Government funds** at three levels:
  - Funds at the federal-level to conduct advocacy visits at the state-level (e.g., to SMoHs, development partners) and to aid in disseminating and ensuring utilization of training materials

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[90] Could include procurement of Chlorhexidine by development partners on behalf of the SMoH.
[91] Stakeholder interviews, Sep. – Nov. 2015.

- o Funds at the state-level to procure and distribute Chlorhexidine
- o Continued funds at the local-level to maintain LGAs, WDCs, and other coordinating structures
- **Donor funds** to catalyze scale-up and support implementation activities in 36 states and the FCT
- **Development partner funds** to catalyze scale-up and support implementation activities in 36 states and the FCT

Human resource needs are similarly distributed, though concentrate on efforts involving development partners. A summary of necessary human resources are:

- **Government staff** at three levels:
  - o Leadership at the Federal Ministry of Health to coordinate, advocate to states, lead scale-up activities, and oversee monitoring and evaluation
  - o Leadership and engagement at the State Ministries of Health and State Primary Health Care Development Boards to support Chlorhexidine scale-up, generate demand, and coordinate activities within states
  - o Local leaders to advocate and solicit buy-in for uptake and distribution of Chlorhexidine to the last mile
- **Donor staff** to support national and state-level coordination, aid in state-level implementation, and strengthen existing delivery channels
- **Development partners** at the federal, state, and local level to aid in carrying out activities on-the-ground and integrating Chlorhexidine into existing programs

Given the resources involved in implementing the scale-up of Chlorhexidine, a phased approach to scale-up can encourage quick-wins, offer certain states and development partners additional time to mobilize financial and human resources, and enable the sharing of learning and dissemination of best practices.

4.4 Phasing of Chlorhexidine Scale-up by State

In an effort to effectively manage resources, states are grouped into three phases. Each phase looks to balance states across the six geopolitical zones to promote regional leadership and enable successful models to spread via a "neighbor" demonstration effect. The phased approach to scale-up of Chlorhexidine begins in states with existing partner- or state-led programming related to Chlorhexidine or similar products and then uses two criteria (need, feasibility) to select states from each zone for subsequent phases.

Though the National Strategy and Implementation Plan enumerates phases for scale-up of Chlorhexidine, each state is encouraged to develop a scale-up strategy with interventions tailored as needed and procure/distribute Chlorhexidine as soon as possible. Phases exist only to guide initial FMoH advocacy efforts to secure state buy-in. **Any state with the desire or ability to develop its own strategy and implementation plan should initiate when ready and liaise with the FMoH and uptake coordinator.**

As cited previously, there are two criteria used to determine phasing: need and feasibility. A summary of the approach is as follows:

Figure 19: Methodology to determine phasing of Chlorhexidine across states[92]

Approach for phase 1: select states from each of the six regions with existing partner- and state-led programming related to CHX	Approach for phases 2-3: use two criteria to place states from each of the six regions into each phase

Previous or ongoing partner- or state-led programming related to CHX:

- SMoH procurement of CHX
- BMGF
- CHAI
- JSI
- Marie Stopes
- MCSP
- UNFPA
- UNICEF

DFID, Norad, and USAID have also supported development partners (e.g., CHAI, MCSP, TSHIP)

	Description	Rationale
1. Need	• Burden of neonatal mortality attributable to infection, as measured by annual total of neonatal deaths per state	• CHX has greatest potential demand and impact in states with a high burden of neonatal mortality
2. Feasibility	• Ease of scaling CHX in a given state, as measured by a.) ongoing CHX activities and b.) political interest and will[1]	• States with supportive governments and CHX programs underway will provide early feedback on the scale-up plan as well as "quick wins" to maintain momentum for national efforts

Note: (1) Feasibility was measured by assessing current political will for CHX in the state, as demonstrated by a.) completing CHX advocacy visit, b.) visiting Sokoto via study tour, c.) procuring CHX, and d.) extent of SMoH involvement in CHX activities to date (if applicable).

Need and feasibility were then plotted to visualize state-level phasing.

Figure 20: Plot of need vs. feasibility by state for Chlorhexidine scale-up[93]
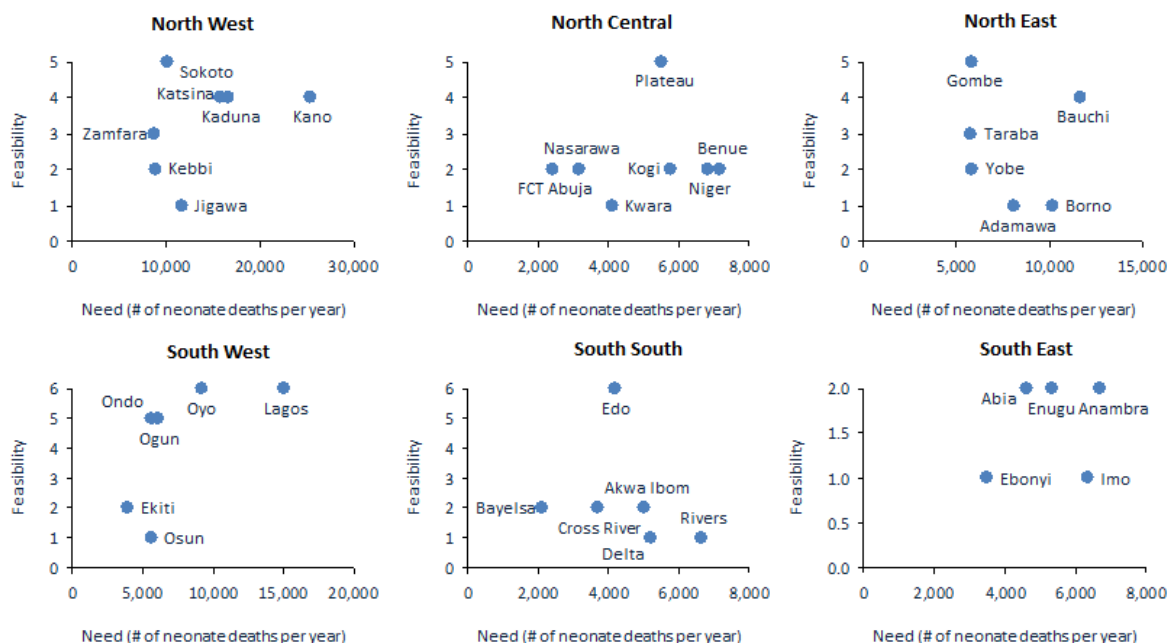
Phase 1 states were prioritized based on significant need – and collectively account for ~55% of the national neonatal mortality burden – as well as strength of active programming and political will related

to Chlorhexidine.[94] Each phase 1 state benefits from the presence of SMoHs and/or development partners already involved in Chlorhexidine programming, increasing the feasibility of scale-up. Phase 1 states with such programming create a strong starting point for CHX scale-up, provide early feedback on the scale-up plan, and ultimately yield "quick wins" to maintain momentum for national efforts. **Scale-up efforts in phase 1 states are to begin immediately.**

Figure 21: Phase 1 states by region and existing partner organization

State	Region	Partner
Kaduna	NW	CHAI, SCI
Kano	NW	CHAI
Katsina	NW	CHAI
Kebbi	NW	UNICEF
Sokoto	NW	Previously USAID/JSI/TSHIP
Kogi	NC	MCSP
Kwara	NC	UNICEF
Plateau	NC	UNFPA, JSI
Adamawa	NE	UNICEF[95]
Bauchi	NE	Previously USAID/JSI/TSHIP
Gombe	NE	UNFPA, JSI; BMGF
Lagos	SW	State-led, with support from CHAI
Ogun	SW	State-led with support from AHME Project
Cross River[96]	SS	CHAI, Saving Mothers Giving Life
Rivers[97]	SS	CHAI
Ebonyi	SE	MCSP

Subsquent phasing was again based on need (number of neonate deaths per year) and feasibility (measured by any ongoing Chlorhexidine activities and political interest and will) within each region.[98]

Figure 22: Phase 2 states by region

State	Region
Zamfara	NW
Abuja FCT	NC
Benue	NC
Niger	NC
Borno	NE
Ondo	SW
Oyo	SW
Delta	SS
Edo	SS
Anambra	SE
Imo	SE

Figure 23: Phase 3 states by region

State	Region
Jigawa	NW
Nasarawa	NC
Taraba	NE
Yobe	NE
Ekiti	SW
Osun	SW
Akwa Ibom	SS
Bayelsa	SS
Abia	SE
Enugu	SE

[94] NDHS ___ Nov. 2015.
[95] Given the misuse of CHX solution in the Northeast, it is recommended that UNICEF start scale-up as soon as possible in all affected states.
[96] There are no states in the South South region with programming directly related to CHX; therefore, Phase 1 selects South South states where CHAI is working on Zinc/ORS scale-up efforts given that the synergies provide a strong starting point for the scale of CHX.
[97] There are no states in the South South region with programming directly related to CHX; therefore, Phase 1 selects South South states where CHAI is working on zinc/ORS scale-up efforts given that the synergies provide a strong starting point for the scale of CHX.
[98] Feasibility was measured by assessing current political will for CHX in the state, as demonstrated by a.) completing CHX advocacy visit, b.) visiting Sokoto via study tour, c.) procuring CHX, and d.) extent of SMoH involvement in CHX activities to date (if applicable).

Proposed phasing above is intended to guide initial FMoH advocacy efforts to secure state buy-in. It can be updated based on events in each state (e.g., a state expresses an interest and willingness to initiate scale-up of Chlorhexidine). As a result, each state is encouraged to develop a scale-up strategy with interventions tailored as needed and procure/distribute Chlorhexidine as soon as feasible.

CHAPTER 5: CHLORHEXIDINE SCALE UP MONITORING & EVALUATION PLAN

5.1 Background Information

Monitoring and evaluation (M&E) is an essential component of any intervention, project, or program as it forms the learning and management tool for planning, implementation, and evaluation. It will provide information about implementation of the outlined activities (as described in Section 2) and generate data about Chlorhexidine use to improve current and future program planning, implementation, and decision-making, as well as identifying areas of improvement for the desired outcome (Chlorhexidine uptake of 52% after the fifth year of national scale-up). The monitoring and evaluation plan will provide a national framework that will be used to measure and track progress towards national scale-up of Chlorhexidine for umbilical cord care in Nigeria. Over ten M&E frameworks were reviewed for the development of this M&E plan.[99] This plan organizes the numerous M&E activities that must take place in order for chlorhexidine scale up to be truly successful by organizing plans for data collection, analysis, use, and data quality.

M&E is a continuous process that will occur throughout the life of the intervention. It will be conducted at every stage of implementation, with data collected, analyzed and used on a continuous basis to inform future programming. It is an iterative process requiring close coordination between FMoH, SMoHs, development partners, and the uptake coordinator. To track progress over time, dashboards will be grounded in a theory of change with intended outputs, outcomes, and impact for scale-up of Chlorhexidine. M&E will be integrated into existing electronic harvesting of data from platforms, such as NDHS and HMIS. In line with the strategy, the indicators for the M&E plan will also be across four of the five core components of scale-up, all except coordination:

- Market & user
- Manufacturing & distribution
- Clinical & regulatory
- Policy, advocacy, & financing

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[99] Health Communication Capacity Collaborative, Demand Generation I-Kit for Underutilized, Life Saving Commodities; Chlorhexidine Navi Care Program, Monitoring Data Presentation; Nigeria Chlorhexidine Market Support Project, JSI / SCI; Count every newborn, BMC Pregnancy and Childbirth; A report of at-scale distribution of chlorhexidine digluconate, PLOS ONE; Bangladesh value chain analysis, Duke; CHX Outcome Forms, TSHIP; Plan for Monitoring & Evaluation, SHOPS Nigeria Private Sector Zinc Program; Performance Indicators for Diarrhea & Pneumonia Treatment, CHAI; CHX Indicators for Pakistan, JSI

5.2 M&E Framework

Figure 24: M&E Result-Based Framework for CHX National Scale-up

CHX National Scale up - Result Based Framework

Impact	Goal : To reduce Neonatal Mortality Rate (NMR) by increasing national uptake of Chlorhexidine gel to 52% by fifth year of strategy implementation				Assumptions
	Market & user	Manufacturing & distribution	Clinical & regulatory	Policy, advocacy, & financing	
Outcome	**Target users correctly apply CHX** 1.0 % of newborns (live births) that received first application of CHX gel to the umbilical cord at birth (home and facility births) 1.1 % 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 1.2 % of health providers who recommended the use of CHX gel 1.3 % of skilled birth attendants having comprehensive knowledge and correct skills on CHX gel use and application	**CHX is available to all target users** 1.4 % of health facilities that provide maternity services with CHX gel stock-out in the last 3 months 1.5 % 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** 1.6 % of health facilities that have copies of updated national protocols (STG, SOPs, Standing order) 1.7 No. of published in-country studies on CHX.	**Policies, KOLs, and financing increase use of CHX** 1.8 No. of states with budget line for CHX gel 1.9 No. of states with at least one development partner supporting CHX scale-up 1.10 CHX gel incorporated in published national EML (Y/N) 1.11 CHX gel incorporated in published national STG (Y/N) 1.12 No. of states with CHX gel on state EML 1.13 No. of states that procured and distributed CHX gel	Government ownership and coordination at all levels of implementation National, State and Local Government cooperation and support is assured Diverse stakeholders involvement and support is solicited at all levels and implementation phases Community entry, sensitization and mobilization is done in a segmented manner to address the different sociocultural preferences Policy makers will commit more resources to newborn health Chlorhexidine is integrated into existing newborn health interventions and programs
Output	**Providers are trained to use CHX correctly** 2.0 No. of people trained on use and application CHX gel **CHX is widely promoted** 2.1 No. of community mobilization activities held to promote CHX gel use 2.2 No. of slots for CHX gel adverts aired	**Production and distribution of CHX is sufficient to meet demand** 2.3 No. of CHX gel tubes produced 2.4 No. of CHX gel tubes distributed			

5.3 Indicator List

The indicators in the M&E plan are directly derived from the result framework. Indicators provide M&E information that is crucial for decision-making at every level and stage of program implementation. The indicator definitions, sources of data, and reporting frequency for each indicator are highlighted in the in the *indicator matrix.*

Goal: To reduce Neonatal Mortality Rate (NMR) by increasing national uptake of Chlorhexidine gel to 52% by the fifth year of strategy implementation.

Outcome Indicators

Market & User: Target users correctly apply CHX gel
- Outcome 1.0: % of newborns (live births) that received first application of CHX gel to the umbilical cord at birth (home and facility births)
- Outcome 1.1: % of women with a live birth in the last two/five years who reported applying no substance other than CHX gel to the umbilical cord.
- Outcome 1.2: % of health providers who would recommend the use of CHX gel
- Outcome 1.3: % of skilled birth attendants having comprehensive knowledge and correct skills on CHX gel use and application

Manufacturing & Distribution: CHX gel is available to all target users
- Outcome 1.4: % of health facilities that provide maternity services with CHX gel stock-out in the last three months
- Outcome 1.5: % of PCN registered retail outlets (PPMVs and community/private pharmacists) with CHX gel stock-out in the last three months

Clinical & Regulatory: CHX gel use follows latest clinical evidence and regulatory guidelines
- Outcome 1.6: % of health facilities that have copies of updated national protocols (STG, SOPs, Standing order)
- Outcome 1.7: Number of published in-country studies on CHX

Policy, Advocacy, & Financing: Policies, key opinion leaders, and financing increase use of CHX (enabling environment in place)
- Outcome 1.8: No. of states with budget line for CHX gel
- Outcome 1.9: No. of states with at least one development partner supporting CHX gel scale-up
- Outcome 1.10: CHX gel incorporated in published national EML (Y/N)
- Outcome 1.11: CHX gel incorporated in published national STG (Y/N)
- Outcome 1.12: No. of states with CHX gel on state EML
- Outcome 1.13: No. of states that procured and distributed CHX gel

Output Indicators

Market & User: Providers are trained to use CHX correctly
- Output 2.0: Number of people trained on the use and application of CHX gel

Market & User: CHX is widely promoted
- Output 2.1: No. of community mobilization activities held to promote CHX gel use
- Output 2.2: No. of slots for CHX gel adverts aired

Manufacturing & Distribution: Production and distribution of CHX is sufficient to meet demand
- Output 2.3: No. of CHX gel tubes produced
- Output 2.4: No. of CHX gel tubes distributed

5.4 Data Management Plan

The National Health Management Information System (NHMIS) consists of tally sheets (registers) with associated summary forms, Management Information System (MIS) matrix forms, and sentinel surveillance form registers for occupational/environmental and communicable diseases as routine sources of data from facilities. These are complemented by community-based activity forms and non-routine sources of data, such as specialized surveys, baseline surveys, and health surveys such as the National Demographic Health Survey (NDHS). NHMIS is used by all public sector facilities and its adoption among private sector facilities is emerging (bearing in mind the National Health Act that mandates it use). The NHMIS collects information on all diseases and services, including neonatal services. To track achievement of the scale-up plan, the use of routine data from the NHMIS is key to the data management plan of the strategy document.

The Data Management Plan for Chlorhexidine scale-up contains routine and non-routine monitoring and evaluation tools, outlines how data and reports are managed at all levels – including data collection, storage, processing, and analysis. It also describes the infrastructure and facilities available for data management, including any software or electronic systems being used.

Pending the review of the NHMIS registers and other data tools, data collection, and reporting forms should be developed to monitor the use of CHX. In developing the tools, consensus should be built among all stakeholders at different levels of health systems. Using the experience from current CHX program implementers, some of the tools developed capture information specific to chlorhexidine use:
- Was Chlorhexidine applied at birth (home and facility births)? – Yes/No
- What is the condition of the baby at birth, one week, and one month? – Alive/Dead
- Any side effect from use of Chlorhexidine – Redness/Skin rashes/Discharge/Swelling? – Yes/No
- Number of women that received Chlorhexidine at 4th ANC visit
- Number of women that received Chlorhexidine from CHEW or TBA
- Have you heard of Chlorhexidine gel before? – Yes/No; What is it used for?
- How did you first hear about its use? – TBA/Health Facility/Others
- How did you get it? – TBA/CHEW/Health Facility/Others

The FMoH, with support from the uptake coordinator, will harness some of the data currently available on chlorhexidine for cord care as a form of baseline assessment. Program or project planning to scale-up chlorhexidine should have a baseline assessment prior to commencement of such a program or project.

5.4.1 Data Collection Process

Use of chlorhexidine gel at birth is proposed to be included in the Labour and Delivery Register of the HMIS and Monthly Summary Form at Health Facility and Community. Routine data for chlorhexidine gel application will be collected and reported from service delivery points using the aforementioned registers and other admission registers. At the end of each month, information relating to all newborns that received the first dose of Chlorhexidine gel at birth will be aggregated and transferred to the monthly summary form at the facility level. This will then be submitted to the LGA M&E focal person who will review the data to check for completeness before the data is entered into the DHIS2 platform. The state M&E officer will then review the data submitted through the DHIS2 for quality before sending to the national domain. Chlorhexidine use at community level will be captured by the community level service providers using community level NHMIS Monthly Summary Forms (NHMIS-MSF) and submitted in the same pattern.

The RH/MCH coordinator, who will be reporting on the state dashboard for Chlorhexidine, will receive aggregated data from the state M&E officer and other implementing partners supporting Chlorhexidine scale-up and implementation in the state- and the community- HMIS monthly summary forms and Integrated Supportive Supervisory (ISS) checklist. The dashboard will be filled and submitted on a quarterly basis to FMoH. See Figure 25.

Nigeria currently has three local manufacturers with NAFDAC registration for production of Chlorhexidine gel. The manufacturers will, on a monthly basis, fill and submit the supplier distribution form to the uptake coordinator. The form will capture information on Chlorhexidine produced and distributed by the different manufacturers. See Figure 26.

5.4.2 Data Collection and Reporting Tools

Monitoring tools include both routine and non-routine data and other subsequent tools that will be developed. The tools will be integrated into existing electronic data platforms, such as HMIS/DHIS 2 – especially for routine data.

Routine Data Tools
- NHMIS Labour and Delivery Register
- Admission registers in newborn units
- Logistic Management Information System (LMIS)
- ISS checklist
- Supplier distribution form

Non-Routine Data Source
Periodic data on Chlorhexidine will be captured through other sources, including surveys and specialized studies amongst which are:
- National Demographic Health Survey (NDHS)
- Multiple Indicator Cluster Survey (MICS)
- Standardized Monitoring and Assessment of Relief and Transition (SMART) Survey
- Service Delivery Indicator (SDI) Survey

- FMoH Training register
- Chlorhexidine need assessment form
- FMoH partner mapping report
- Distribution report from manufacturers
- Program report from implementing partners
- Operations research report

Regardless of the vehicles for data collection, core metrics for CHX utilization (both at the national- and state-level), as well as the frequency of data collection, must be standardized and collected in a systematic fashion. These indicators should align with the national dashboards for any program implementer.

5.4.3 Data Flow and Reporting System

Records from the routine data collection tools must be verified and signed off by both the LGA and State M&E focal person before the onward submission to the National M&E. All data collection tools will be printed in duplicate, one copy for the state level and the other for the focal person at the LGA. Data from already existing data sources will be analyzed to elicit information when required. See below for the flow chart.

For non-routine data sources, data will be analyzed by the uptake coordinator and shared with FMOH and other stakeholders for validation and subsequent dissemination and use.

Figure 25: Routine data flow and reporting system

HMIS branch of the M&E division	**Federal**
State HMIS Unit Officer	**State** → **RH/MCH Coordinator**
M&E or HMIS Officer	**LGA**
Designated Health Records Officer/Service Provider	**Health Facility**
CHEWS/CORPS	**Community**
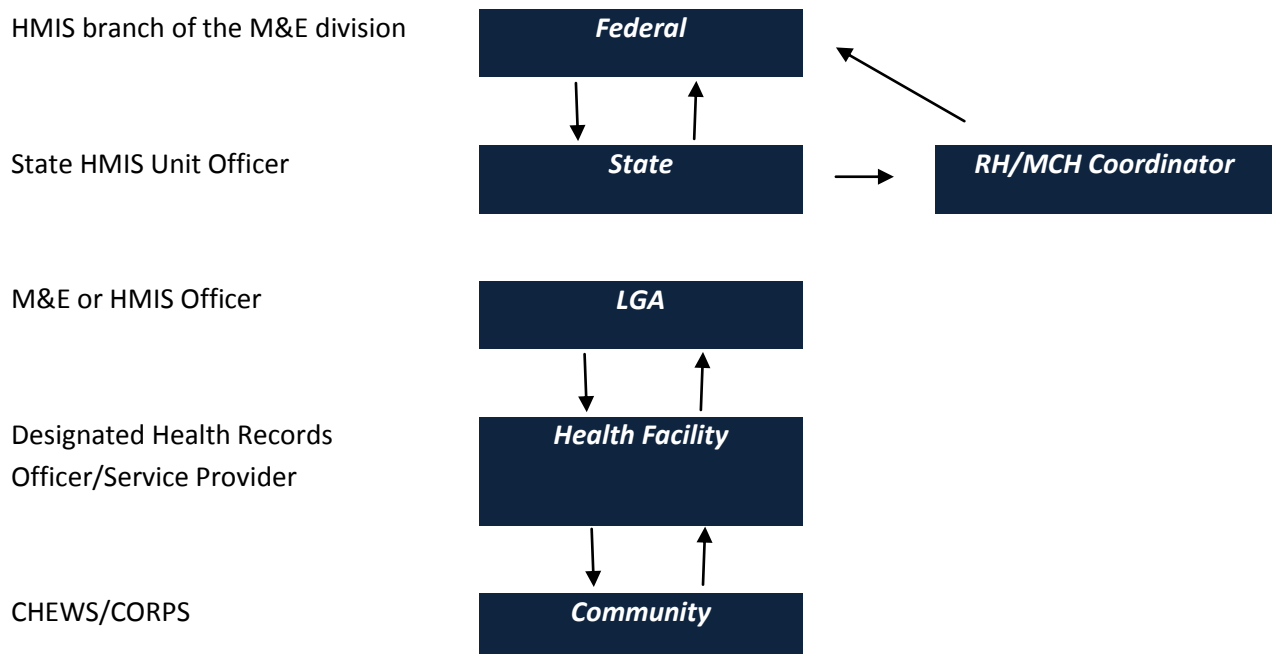
Figure 26: Supplier form flow chart
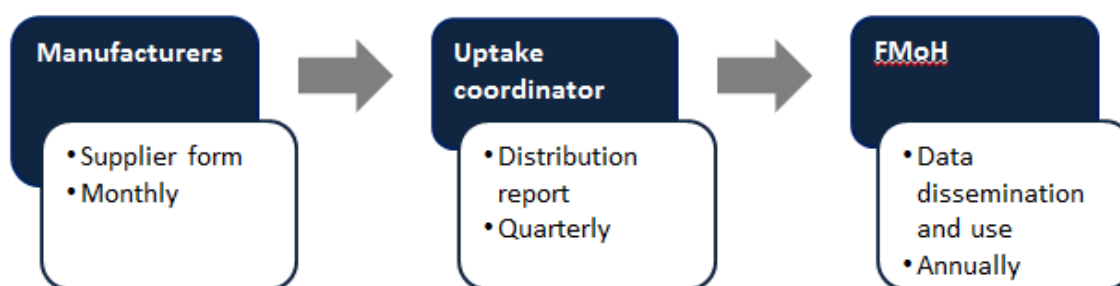
5.4.4 Data Storage

Information on Chlorhexidine gel usage captured on NHMIS register and other data sources will be stored in line with national policy using the District Health Information System (DHIS2). All facility-based information systems feed into the DHIS2. It is a database adaptive to different levels such as LGA, state, and national. The DHIS2 empowers health workers at facilities and all levels to use information to improve health services. Data elements used in DHIS2 could be routine data (submitted routinely, whether annually, monthly, or quarterly); survey or audit data (collected infrequently, but reflecting the situation at the time of data collection); and semi-permanent data that do not change frequently (typically census data). Data elements are grouped as data sets, and a data set is equivalent to a reporting form. All information on the DHIS2 platform is archived on the server managed by Health Information System Programme (HISP) Nigeria. This is supervised by the HMIS branch of the M&E Division, Department of Health Planning Research and Statistics (DHPRS) at Federal Ministry of Health.

5.4.5 Training Database

The training register will be maintained to capture information on health workers that have been trained on the use and application of CHX. Examples of training that incorporate the use of Chlorhexidine include:

- Essential Newborn Care Course (ENCC)
- IMCI/cIMCI
- BEmONC (LSS, mLSS, eLSS)
- iCCM

The trainings will be conducted in keeping with the guidelines outlined in the different training curriculum for the aforementioned trainings. The training register will be filled by implementing partners and MDAs conducting these trainings and shared with the FMoH on a monthly basis. The FMoH, with support from the uptake coordinator, will analyze the training register and produce a training report on a quarterly basis. The training register and report will be backed up in an excel training database.

5.4.6 Data Processing and Analysis

Data processing and analysis will be in the form of an indicator performance tracking dashboard. This dashboard will be used at national and state levels to monitor, analyze and report the progress of chlorhexidine utilization. The dashboards are grounded in a theory of change with intended outputs, outcomes, and impact for scale-up of Chlorhexidine. The dashboards are subject to review as implementation progresses.

At national level, the table will compare the different states' progress against each other. This will help in identifying areas of need and developing action points that will address the challenges responsible for poor performance of the indicators.

Figure 27a: National Dashboard 1 – *This tracks major national-level metrics over time*

	Year 1	Year 2	Year 3	Year 4	Year 5
NMR					
% of newborns (live births) that received first application of CHX at birth (disaggregrated by home and facility births)					
No. of CHX tubes distributed (disaggregated by public and private channel)					
% of health facilities that provide maternity services with CHX stock-out in the last 3 months					
No. of CHX tubes produced monthly (disaggregrated by manufacturers)					
No. of states with budget line for CHX					
No. of states with at least one development partner supporting CHX scale-up					
No. of states with CHX on state EML					
No. of states that procured and distributed CHX					

Figure 27b: National Dashboard 2 - *This tracks major metrics disaggregated by state to allow for comparison of relative performance of states*

	NMR	% of newborns that received first application of CHX at birth	Quantity of CHX tubes procured	% of health facilities with CHX stock-out in the last 3 months	Budget line for CHX (Y/N)	Development partner supporting CHX scale-up (Y/N)	CHX On state EML (Y/N)	Procured and distributed CHX (Y/N)
State 1								
State 2								
State 3								
State 4								
….								
State 33								
State 34								
State 35								
State 36								

Figure 28: State Dashboard - *The state dashboard tracks more granular data to identify Chlorhexidine-related levers*

	Year 1	Year 2	Year 3	Year 4	Year 5

NMR					
% of newborns (live births) that received first application of CHX at birth (disaggregated by home and facility deliveries)					
% of women with a live birth in the last two/five years who reported applying no substance other than CHX gel to the umbilical cord					
% of health providers who recommend the use of CHX (disaggregated by type of health provider)					
No. of people trained on use & application of CHX (disaggregated by health workers and non-health workers)					
% of skilled birth attendants having comprehensive knowledge and correct skills of CHX					
No. of community mobilization activities held to promote CHX (disaggregated by type of community mobilization)					
No. of slots for CHX adverts aired					
No. of CHX tubes distributed (disaggregated by public and private channel)					
% of health facilities providing maternity services with CHX stock-out in the last 3 months					

% of PCN registered retail outlets (PPMVs and community pharmacists) with CHX stock-out in the last 3 months				
% of health facilities that have copies of updated national protocols (STG, SOPs, Standing order)				
Budget line for CHX (Y/N)				
No. of development partners supporting CHX scale-up				
CHX on state EML (Y/N)				
CHX procured by state (Y/N) and quantity procured				
Implementation plan for CHX scale-up developed (Y/N)				

The uptake coordinator is to analyze national-level data to understand national aggregates, trends, and relative performance of states, disseminate information to stakeholders as well as recommend program refinements to the FMoH based on analyses. At state-level, the RH coordinator and development partner focal point will play this role. The uptake coordinator is to recommend updates to metrics and dashboards based on program evolution.

5.5 Evaluation, Research and Special Studies

To monitor progress of the National Strategy and Implementation Plan for Scale-up of CHX, more frequent data collection than that of the NDHS is needed. Survey instruments to capture and collect CHX data will be incorporated into various current and planned programs, including DHIS, MICS, SMART surveys, and Saving One Million Lives. However, CHX-specific surveys, focus group discussions, and in-depth interviews can be initiated as necessary or applicable.

5.5.1 Special study will focus on operations research

Conduct operations research on the effectiveness of Chlorhexidine against methylated spirits, timing of cord dropping, effectiveness of prolonging use of Chlorhexidine until three days after the cord falls, use of Chlorhexidine in preterm births, and identifying neonatal sepsis due cord infection. This will enable for improved decision-making and efficiency with future Chlorhexidine implementation programming.

5.5.2 National- and State-Level Needs Assessment

Conduct an initial needs assessment to identify the current service provision related to CHX available across the country. The result will be used to tailor strategies for state-level implementation, including forecasting and quantification, modalities for distribution and logistics management, supporting implementing partners, as well as compliance of service providers to use of CHX. A facility-level needs assessment will be conducted in the six geo-political zones. Health facilities will be randomly selected based on MNCH service provision at all levels of health facilities – the sample frame will be taken from the national directorate of health facilities in Nigeria which contains all the names, locations, and type of services provided.

5.5.3 Process Evaluation

This process will focus on knowing if the strategy for the provision of services is being followed as stated in the national document. It will be conducted along with the supportive supervision using a checklist to measure activities related to CHX provision. The result from this process will be used to re-strategize or redesign the program interventions and activities where necessary.

5.6 Data Dissemination and Use Strategy

Data produced from the M&E system will inform improvements in program planning, policy making, budgeting, and resource allocation. Dissemination meetings will be held at all levels – federal, state, LGA, and community – during which data relating to specific output and outcome indicators will be shared and discussed. Data sharing during such disseminations will be used to make informed decisions using a participatory approach. Lessons learned and success stories will be documented for learning agendas and program brief and serve as a guide to other countries planning to scale-up the use of Chlorhexidine.

5.6.1 Data Dissemination Methods

The information generated through the monitoring and evaluation of the project will be disseminated through the followings:
- National/state workshops/conferences
- MNCH Core Technical Committee meeting (national and state)
- Health professional association meetings
- Stakeholder meetings
- Community mobilization
- Campaigns and media outreaches
- Advocacy to community and state leaders and civil society

5.6.2 Information Products

The following information products are expected from implementing states:
- Baseline and endline reports
- Needs assessment and process evaluation reports
- State dashboard
- Case studies/surveys
- Success stories/press release

5.6.3 Target Audience/Data Users
- Policy makers/key opinion leaders (including community leaders)
- FMoH/NPHCDA/NAFDAC
- SMoH/SPHCDA
- Development partners
- Health professional associations
- Media
- Community-based organizations
- Civil society organizations

5.7 Data Quality Assurance and Validation Plan

Internal Routine Data Quality Assessment (RDQA) system will be incorporated into the M&E system using existing Routine Data Quality Assessment tools. Data quality assessment will be conducted on a quarterly basis and use the same tools to assess the underlying data management and reporting system for selected standard indicators. RDQA capacity of M&E and HMIS staff at both state and local governments will be further developed. In addition, efforts will be made to ensure that data verification/correction forms are an integral part of integrated routine supervision. The data being collected and submitted either through forms or through electronic systems by the service providers and other levels will be subjected to the following quality checks:

- Reliability: This will ensure that all service providers are using the same data tracking and reporting formats in generating reports
- Validity: This will be done through training to ensure that service providers have the same understanding on different indicators that they are tracking and reporting
- Integrity: This will check whether what was recorded was actually correct
- Precision: Efforts will be made to ensure that the data are exact and measure what they are supposed to measure
- Timeliness: Strategies will be designed to ensure that up-to-date information is readily available to support decisions at different levels of the program implementation

Target Indicator Definitions and Reporting Guidelines

The timeline for data collection, reporting indicators, and persons responsible have been clearly outlined and defined in the below indicator matrix.

5.8 Indicator Matrix

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

5	Number of CHX gel tubes distributed	Total number of CHX tubes distributed *Unit of Measurement:* Number	Output	Distribution report from manufacturers, State LMIS, development partner	Report review	National State	Private sector Public sector	Quarterly
6	Percentage of health facilities that provide maternity services with CHX stock out in the last 3 months	*Numerator:* Number of health facilities that provide maternity services with CHX stock out in the last 3 months *Denominator:* Total number of health facilities that provide maternity services *Unit of measurement :* Percentage	Outcome	HMIS Monthly Summary Form	Report review	National	State Level of Facility	Quarterly
7	*Percentage of PCN registered retail outlets (PPMV and community/private pharmacies) with CHX stock-out in the last 3 months	*Numerator:* No of PCN registered retail outlets (PPMV and community/private pharmacies) with CHX stock-out in the last 3 months *Denominator:* Total number of PCN registered retail outlets (PPMV and community/private pharmacies)	Outcome	Survey	Interview	Programs Projects	State LGAs	Annual
8	Percentage of health facilities that have copies of updated national protocols (STG, SOPs, Standing order)	*Numerator:* Number of health facilities that have copies of updated national protocols on day of assessment *Denominator:* Total number of health facilities assessed *Unit of measurement :* Percentage	Outcome	ISS checklist	Interview	National	State LGAs Level of Facilities	Quarterly Biannually
9	Number of published in-country studies on CHX	Total number of published in-country studies on use, application, and distribution of CHX *Unit of Measurement:* Number	Outcome	Report on in-country publication	Publication review	National		Annual

10	Number of states with budget line for CHX gel	Total number of states with budget line for CHX *Unit of Measurement:* Number	Outcome	State budget report	Budget review	State	State	Annual
11	Number of states with at least one development partner supporting CHX scale up	Total number of states with at least one development partner supporting CHX scale up *Unit of Measurement:* Number	Outcome	Partner mapping report, State Dashboard	Report review	National	State	Quarterly
12	Number of people trained on the use and application of CHX gel	Total number of persons trained on the use of CHX. *Unit of measurement:* Number	Output	Training report	Report review	National	Cadre – Health/non Health workers State IPs	Monthly
13	Number of community mobilization activities held to promote CHX use	Total number of community mobilization activities held to promote CHX use *Unit of Measurement:* Number	Output	Report	State Dashboard	State	State LGA Type of activities	Quarterly
14	Number of slots for CHX adverts aired	Total number of slots for CHX adverts aired *Unit of measurement:* Number	Output	Media report	Report review	National State	State Implementing Partners Type of advert	Monthly Quarterly
15	Number of CHX gel tubes produced	Total number of CHX tubes produced *Unit of measurement:* Number	Output	Supplier Form	Report review	National	Manufacturers	Monthly Quarterly
16	CHX incorporated in published national EML	Is CHX incorporated into published national EML *Unit of measurement:* Yes/No	Outcome	Published National EML	EML review	National		Periodic review
17	CHX incorporated in published national STG	Is CHX incorporated into published national STG *Unit of measurement:* Yes/No	Outcome	Published National STG	STG review	National		Periodic review
18	Number of states with CHX on state	Total number of states with CHX on state EML	Outcome	Published State EML	EML review	State	State	Periodic review

	EML	Unit of measurement: Number							
19	Number of states that procured and distributed CHX	Total number of states that procured CHX Unit of measurement: Number	Outcome	State DRF report, Supplier Distribution Form, State LMIS	Report review	State	State	Annual

*Indicator not trackable at national level but can be adopted by development partners working with PPMVs and Community Pharmacist

ANNEX A: DETAILED COSTING

National-level costs

Scale-up component	Budget Item	Frequency of cost	Estimated cost (US $)	Rationale & assumptions
Market & user	Product design costs (e.g. branding, messaging)	One-time	25,000	Based on estimate from a design firm working in global development
	Update and disseminate training materials by FMoH	One-time	9,000-11,000	Assumption that task can be completed in 6 months by technical staff ($20k/year)
	Disseminate CHX training materials by professional associations	One-time	9,000-11,000	Assumption that task can be completed in 6 months by technical staff ($20k/year)
Manufacturing & distribution	Brand PPMVs that regularly stock CHX (>90%) with "seal of approval" for neonatal health	Annual	9,000-11,000	Assumption that task can be completed in 6 months by technical staff ($20k/year)
	Technical assistance to manufacturers (expand private sector delivery channels)	One-time	105,000	Costs from SHOPS ORS/Zinc is $35,000 per pharmaceutical company supported – assumes technical assistance is provided to three manufacturers

Policy, advocacy, & financing	EML and STG updates	One-time	140,000 – 180,000	Amount cited in FDS workplan
	FMoH/CHX representative travel to advocacy visits at SMoHs, hospitals, profession associations, and relevant professional association conferences	Annual	26,000-34,000	Assumption that half the states will be visited per year and 5-8 conferences will be attended (includes conference booth registration)
Coordination	Uptake coordinator	Annual	50,000 – 70,000	Assumption that salary for FTE is $60k/year
	Host coordination meetings (bi-monthly for the first year, quarterly thereafter)	Annual	900-1,000 per meeting	Assumption that majority of funding for meetings will be sourced from existing Newborn Sub-Committee. Also assumes that in first year, one meeting will be in-person and one meeting will be via phone per month
	Conduct M&E activities (collect, analyze, and share data from states)	Annual	9,000-11,000	Assumption that task can be completed in 6 months by technical staff ($20k/year)

Over the five-year period, the total projected costs at the national level are $900,000, of which nearly 50% is incurred during the first year of scale-up.

These costs are predominantly driven by the following one-time activities:

- **Market & user –** Improving communication for Chlorhexidine to drive demand and updating/disseminating training materials are the only national-level demand generation activities costed.
- **Manufacturing & distribution –** Technical assistance to three manufacturers is the only one-time national-level manufacturing & distribution activities costed.
- **Policy, advocacy, & financing -** Finalizing and disseminating the national EML and Standard Treatment Guidelines (STG) represent the entirety of one-time policy and advocacy costs.

The following costs are more evenly distributed over all five years.

- **Manufacturing & distribution –** Incentivizing PPMVs that regularly stock Chlorhexidine with a 'seal of approval' is annually costed.
- **Policy, advocacy, & financing –** Advocacy visits to SMoHs, hospitals, and professional associations/conferences are distributed across all five years.
- **Coordination –** The national coordination meetings along with the salary and travel costs incurred by the uptake coordinator are spread relatively evenly across the scale-up time period. In total, greater than 40% of costs fall under coordination, highlighting this as the primary responsibility for national-level actors.

State-level costs

Scale-up component	Budget Item	Frequency of cost	Estimated cost (US $)	Rationale & Assumptions
Market & user	Radio adverts, cost per year	Decreasing annually*	18,000 – 22,000	Costs from CHAI & SHOPS radio campaigns for ORS/Zinc and SFH estimates for a CHX program. For CHAI, assumption that 60% of total costs ($50k) would be recurring annually. For SHOPs, assumption that 60% of community mobilization went to radio adverts

	Print adverts, cost per year	Decreasing annually*	9,000-11,000	Based on costs for CHAI ORS/Zinc activities
	Training (clinical mentoring)	Decreasing annually*	25,000-30,000	Costs from CHAI ORS/Zinc and SFH's estimates for a CHX program. Cost estimates of $30 per head from CHAI and SFH costs for clinical training in each state; assumption that 1,000 clinicians required training
	Training (community-based)	Decreasing annually*	80,000-100,000	Average of costs from CHAI ORS/Zinc, TSHIP, and SFH's estimates regarding a CHX program. Annual costs for CHAI are $40k per year. JSI/TSHIP costs were halved because training accounted for 80% of all expenses, which is unlikely in other states.
	Training for PPMVs	Decreasing annually*	35,000-45,000	Average of total costs for CHAI & SHOPS ORS/Zinc, assumed even distribution across three years
	Detailing for PPMVs	Decreasing annually*	9,000-11,000	Total costs for CHAI ORS/Zinc activities, assumed even distribution across three years
	Wholesale activation	For first two years only	7,000-8,000	Assumes 4-6 weeks of a full-time employee (FTE) making equivalent to $60k each year
Manufacturing & distribution	Price of CHX	Volume-based	0.50 – 1	Price listed on Health Newborn Network is $0.58 - stakeholder interviews indicate wholesale cost of roughly NGN150 or an

				ex-factory cost of roughly NGN70 per seven-day application.
	Shipping cost of CHX (from manufacturer to state/zonal warehouse)	Volume-based	5% of commodity cost	Assumption based on estimate from a Nigeria supply chain expert
	Costs of shipping CHX tube to state warehouse	Volume-based	0.05-0.15	Direct Delivery and Information Capture (USAID | DELIVER) cost by both volume and dollar amount is $0.07; Review & Resupply (USAID | DELIVER) costs were deemed prohibitive
Policy, advocacy, & financing	EML updating costs	One-time	3,000-5,000	1/37 (total number of states and the FCT) of national cost to update EML and STG
	Replacing alternative cord care products on mama kit/delivery lists with CHX	One-time	3,000-5,000	1/37 (total number of states and the FCT) of national cost to update EML and STG
	Advocacy and coordination travel budgets	Decreasing annually*	9,000-11,000	Assumption of ~50 intra-state visits/trips in the first year with average cost of $200
Coordination	National coordination meeting attendance	Annual	200-500 per meeting	Assumption to cover travel costs and per diem for two days
	M&E activities	Annual	55,000 –	SHOPS ORS/Zinc costs per survey is

			65,000	$57,500

Decreasing annually – The level of funding for these activities will decrease across the five years outlined in the blueprint. The amount in years 2-5 of scale-up for that state is based on a percentage of year 1 funding as follows: year 1=100%, year 2=80%, year 3=50%, year 4=25%, and year 5=10%.

Total costs will vary by state based both on the total number of deliveries and the state-specific strategy and implementation plan. In most states, demand generation, training, and monitoring & evaluation activities account for the majority of expenses. This is due both to initially high costs involved in these activities, as well as the relatively low costs to procure Chlorhexidine.

Costs predominantly incurred within the first two years are driven by:

- **Market & user –** Entails demand generation activities (e.g., radio and print campaigns), PPMV detailing and trainings of community-based care takers, clinicians, and PPMVs. In the first two years of scale-up, a state is likely to use 60% of their total scale-up costs on demand generation and training activities.
- **Coordination –** Entails monitoring & evaluation and attendance at coordinating meetings. In the first two years of scale-up, a state is likely to use 20% of their total scale-up costs on coordination.
- **Policy, advocacy & financing –** Costs associated with in-person advocacy visits to hospitals, local leaders and conferences quickly decrease after the first two years. These costs should not exceed 5-10% of total scale-up costs across the five years.

Except for the cost of procuring Chlorhexidine, all costs will decrease over time.

- **Manufacturing & distribution –** Following the potential for an initial catalytic grant from development partners to procure Chlorhexidine, states are increasingly responsible for the procurement CHX stock. Even with this increase in cost, though, the total costs of procurement and distribution should remain around 10% of total costs of scale-up.

ANNEX B: ANALYSIS TEMPLATE TO GUIDE STATE-LEVEL STRATEGY AND IMPLEMENTATION PLAN

	Conduct analysis on CHX point of service in state using NDHS data on place of delivery		

	Non-facility – unassisted or family ___%	Non-facility – assisted ___%	Facility ___% public ___% private
Determine predominant point(s) of service for CHX in the state in order to identify most important target users for CHX			
Identify key points of access and prioritize training activities at these points of access to increase awareness	Private pharmacy/PPMV Public pharmacy (e.g. PHC) Public or private outreach	Private pharmacy/PPMV Public pharmacy (e.g. PHC) Public or private outreach	Public facility Private facility Private pharmacy/PPMV
Formalize coordination system to oversee execution of state-level interventions	MNCH committee? → Health CTC? → Other?	MNCH committee? → Health CTC? → Other?	MNCH committee? → Health CTC? → Other?
Based on points of service and access, identify procurement and distribution	Last-mile MNCH system? → Last-mile FP system? → Private? Other?	Last-mile MNCH system? → Last-mile FP system? → Private? Other?	Direct to hospital Direct to government via state medical warehouse
Identify KOLs for advocacy efforts to secure buy-in and use these gatekeepers to generate demand for CHX amongst target users	Community leaders, including WDC chairman; Community members, including men, husbands, women's groups, and other mothers; health care workers	Facility health providers Community leaders, including WDC chairman Leaders within professional associations Other CHWs, VHWs, TBAs, MBAs, etc.	Facility directors Leaders within professional organizations
Select channels for population-level demand generation activities and tailor messaging to attract key targets users	Radio and/or TV PPMV & pharmacy signs and job aids	PHC, PPMV, & pharmacy signs and job aids CHW trainings, meetings, materials Radio and/or TV	Provider trainings, meetings, materials Facility signs and job aids
Secure financing / budget needed to enable all scale-up activities	State budget National Health Act World Bank loans Donors	State budget National Health Act World Bank loans Donors	Facility budgets, State budget National Health Act World Bank loans; Donors

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⬇ *Yes, proceed to next step*   ⬇ *No, consider other options*

ANNEX C: ACTIVITY AND COSTING TEMPLATE TO GUIDE STATE-LEVEL STRATEGY AND IMPLEMENTATION PLAN

Activity	Is activity needed in state?	If yes, what is the estimated cost?	If yes, who is responsible?	If yes, what is the approach?
PPMV training	___ Yes ___ No			
Pharmacists training	___ Yes ___ No			
Direct to consumer promotion to target users and gatekeepers	___ Yes ___ No			
Radio promotion	___ Yes ___ No			
TV promotion	___ Yes ___ No			
SMS promotion	___ Yes ___ No			
Print promotion	___ Yes ___ No			
Support for private sector procurement	___ Yes ___ No			
Support for state procurement	___ Yes ___ No			
Community distribution system	___ Yes ___ No			
Public facility training	___ Yes ___ No			
Private facility training	___ Yes ___ No			
Community-based training	___ Yes ___ No			
State coordination	___ Yes ___ No			

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