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Maternal and Child Survival Program

Supporting Nigeria's Country-Led Scale-up of Chlorhexidine for Newborn Sepsis Prevention

Findings from a Mixed-Methods Case Study

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The Maternal and Child Survival Program (MCSP) is a global, $560 million, 5-year cooperative agreement funded by the United States Agency for International Development (USAID) to introduce and support scale-up of high-impact health interventions among USAID's 25 maternal and child health priority countries, as well as other countries. The Program is focused on ensuring that all women, newborns and children most in need have equitable access to quality health care services to save lives. MCSP supports programming in maternal, newborn and child health, immunization, family planning and reproductive health, nutrition, health systems strengthening, water/sanitation/hygiene, malaria, prevention of mother-to-child transmission of HIV, and pediatric HIV care and treatment.

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Nigeria's Approach to Scaling Up Use of Chlorhexidine

Nigeria's neonatal mortality rate was estimated at 38 per 1,000 live births in 2013, one of the highest in the world.[1] About one-fourth of these deaths were estimated to be due to infections, many of which could be prevented through proper umbilical cord care.[2] Chlorhexidine (CHX) gel is an over-the-counter product that reduces neonatal infection when applied to the umbilical cord stump after delivery and during the first week of life. CHX was first introduced in Nigeria in 2012 through the first meeting of government and nongovernmental stakeholders and the U.S. Agency for International Development's (USAID's) Targeted States High Impact (TSHIP) Project operating in the northern States of Sokoto and Bauchi. The widely disseminated success stories from these two states, including engagement of Nigerian manufacturers for local production, provided local evidence that the Government of Nigeria needed to scale up the use of CHX for umbilical cord care. Country champions for CHX use also helped to disseminate these success stories through PATH's global Chlorhexidine Working Group, which in turn helped to advocate for its countrywide scale-up.

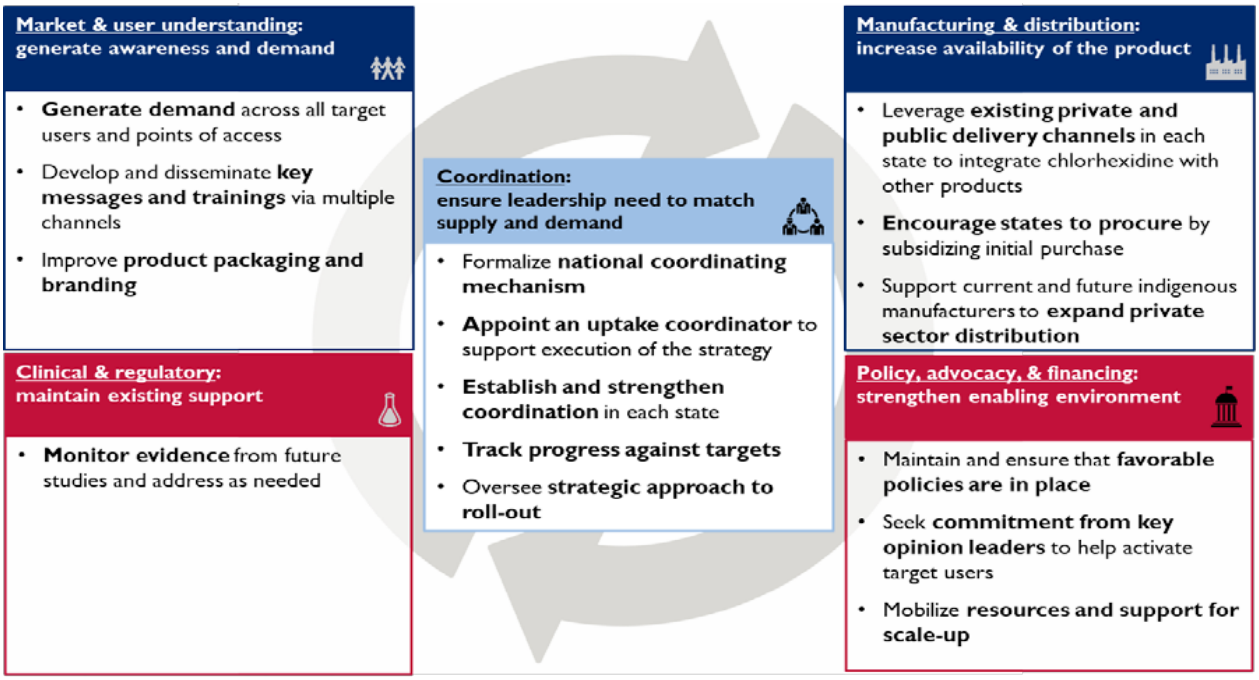
With technical assistance from USAID's Center for Innovation and Impact, Clinton Health Access Initiative (CHAI), USAID/Nigeria, and USAID's global flagship Maternal and Child Survival Program (MCSP), the Federal Ministry of Health (FMoH) developed and finalized the *National Strategy for Scale-Up of Chlorhexidine in Nigeria* in 2016. The strategy outlines interventions, guides programming, and sets a concrete **target of 52% coverage of CHX for all births (facility and community) after the fifth year of scale-up (2021)**, estimated to avert 55,000 neonatal deaths over 5 years. The strategy specifies the use and distribution of 4% CHX gel in 25-gram tubes for daily application to the stump, starting on the first day of life, regardless of the location of delivery. Within Nigeria's decentralized health system, operationalizing this national plan required further action by each of Nigeria's 36 state-level Ministries of Health (MoHs) and Primary Health Care Development Agencies (SPHCDAs), which run public health programs at the public primary and secondary health care facility network as well as oversee private health care providers in the states. In cooperation with the FMoH, MCSP, a five-year global program, supported the Ebonyi and Kogi state governments to provide a systematic approach to CHX scale-up from 2014 to 2018, following the National Strategy, while UNICEF continued to support 10 other states.

The *National Strategy* identifies ways to leverage existing systems, processes, and markets to ensure gains in coverage are sustained over time. It identifies organizations, individuals, and stakeholder groups to facilitate coordination of scale-up efforts across the multi-stakeholder environment to implement specific aspects of the *National Strategy* (Figure 1). The *National Strategy* proposes scale-up indicators at national and state levels, includes cost projections to guide resource mobilization, proposes use of CHX in both facility and home settings, and envisions its distribution through three channel—public facilities, private facilities, and community level.

[1] Akinyemi JO, Bamgboye EA, Ayeni O. 2015. Trends in neonatal mortality in Nigeria and effects of bio-demographic and maternal characteristics. *BMC Pediatrics* 15:36. doi: 10.1186/s12887-015-0349-0

[2] United Nations Children's Fund. 2017. Child mortality estimates: causes of deaths of newborns in Nigeria, 2016. Estimates generated by the World Health Organization and Maternal and Child Epidemiology Estimation Group (MCEE).

Figure 1. Five strategic priority areas for scale-up in Nigeria Federal Ministry of Health's chlorhexidine scale-up strategy[3]

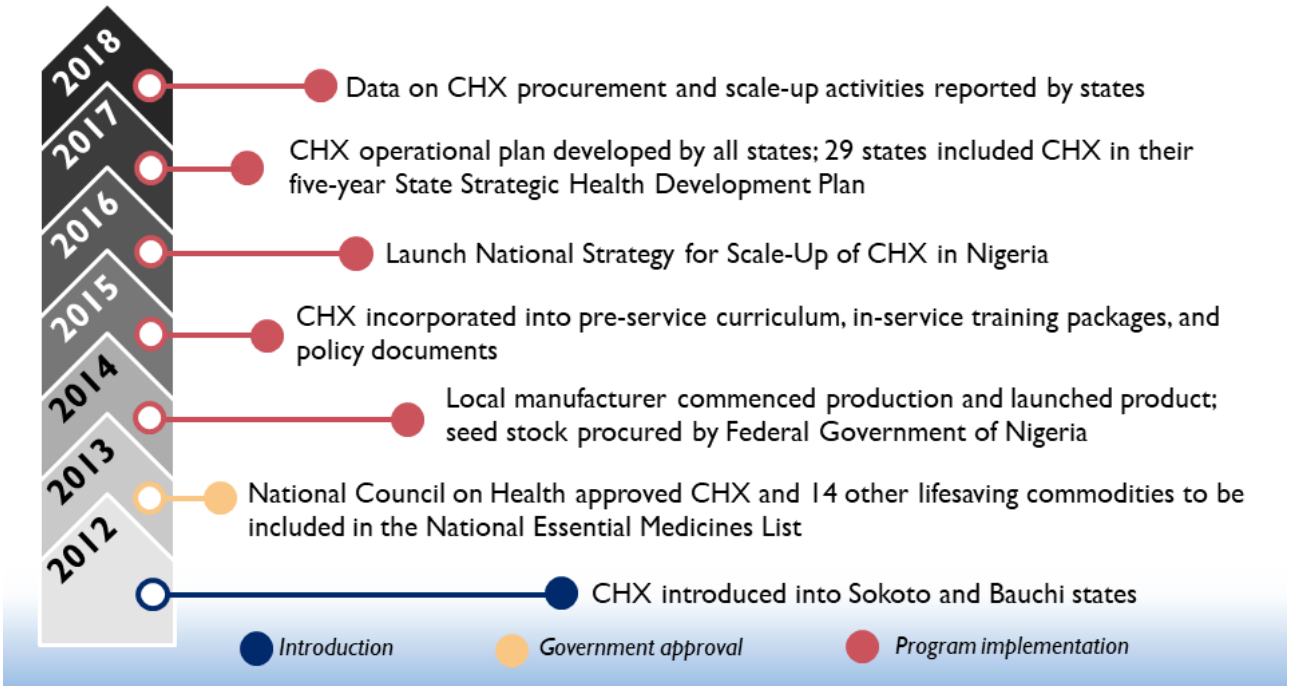


To help implement the strategy, the FMoH partnered with MCSP to secure a full-time scale-up coordinator and foster key partnerships. The FMoH's Family Health Department engaged other departments and agencies, states, implementing partners, donors, professional health associations, manufacturers, and other stakeholder groups on multiple occasions through a series of consultative meetings to build capacity for implementation of the *National Strategy*. By 2017, CHX was incorporated into the national training curriculum of the Essential Newborn Care Course (ENCC) and appended to the national essential medicines list (EML). The FMoH led participation at annual conferences of major professional associations and provided technical assistance to build sustainable financing and distribution through the various channels, including regular engagement with local manufacturers. FMoH created a WhatsApp group in early 2018 as a platform to engage the state reproductive health and maternal child health coordinators for experience sharing among the states, and frequent communication on implementation progress. Within 3 months, more than 780 messages and links were shared, 224 of which were photos. Many of these show engagement of stakeholders at subnational levels with the *National Strategy* (government officials, implementing partners, and key influencers) as well as community members using CHX.

To accelerate the rollout of CHX use, many states incorporated CHX activities into their strategic health development plans and used government funds as well as funds from Saving One Million Lives (SOML) to procure and distribute the product to health facilities, while other states have undertaken advocacy efforts, notably to UNICEF, which supplied CHX to its project states.[4] Figure 2 shows a timeline of key events.

[3] Federal Ministry of Health (FMoH). 2016. From National Strategy for Scale-up of Chlorhexidine in Nigeria. https://www.healthynewbornnetwork.org/hnn-content/uploads/NATIONAL-STRATEGY-FOR-SCALE-UP-OF-CHX-IN-NIGERIA-FINAL-002.pdf

Figure 2. Timeline of key actions



In addition, states have launched advocacy efforts to build champions among gatekeepers and influential figures such as hospital administrators, politicians, and community volunteers. Many states have also undertaken efforts to sensitize end users—including providers, traditional birth attendants, and families—on the importance of proper umbilical cord care using CHX gel. They did this through fora such as trainings on ENCC, family planning, and lifesaving skills, as well promoting it during celebrations such as World Breastfeeding Week, immunization days, and World Prematurity and Pneumonia Days. Since the launch of the *National Strategy*, the FMoH, state departments of health, and private sector identified and implemented plans based on the approaches summarized in Table 1 to overcome known barriers to scale-up.

Table 1. Prioritized approaches to overcome barriers to scale-up of chlorhexidine[4]

Scale-up priority area (from Figure 1)	Barriers	Approaches to overcome scale-up barriers
Market and user understanding	• Low awareness • Competitive alternatives • Socio-cultural practices • Delayed cord separation	• Increase awareness among likely points of sale (for example, drug dispensers, public and private health facilities) of the relative advantage of CHX over alternative methods • Increase awareness among family members of newborns and community structures of the relative advantage of CHX over harmful cord practices
Clinical and regulatory	• Weak regulatory regime	• Monitor safe manufacturing and use of CHX through routine pharmacovigilance systems
Coordination	• Weak coordination at state level • Weak reporting as a result of CHX not being captured in routine	• Coordinate stakeholder efforts to implement the *National Strategy* and state-level strategies • Use of labor and delivery registers in labor wards to capture CHX use in the facility while awaiting integration of a CHX indicator into the NHMIS

[4] FMoH. 2016. From National Strategy for Scale-up of Chlorhexidine in Nigeria. https://www.healthynewbornnetwork.org/hnn-content/uploads/NATIONAL-STRATEGY-FOR-SCALE-UP-OF-CHX-IN-NIGERIA-FINAL-002.pdf

Scale-up priority area (from Figure 1)	Barriers	Approaches to overcome scale-up barriers
	national health management information system (NHMIS) data	
Manufacturing and distribution	• Weak logistics system for maternal, newborn, and child health commodities	• Improve logistics management for maternal, newborn, and child commodities • Support local manufacturers to attain global good manufacturing practice
Policy, advocacy, and financing	• Inadequate funding streams at all levels	• Improve long-term sustainability of financing for CHX gel

Figure 3. Number of states (out of 37) that reported meeting key milestones (January–March 2018)

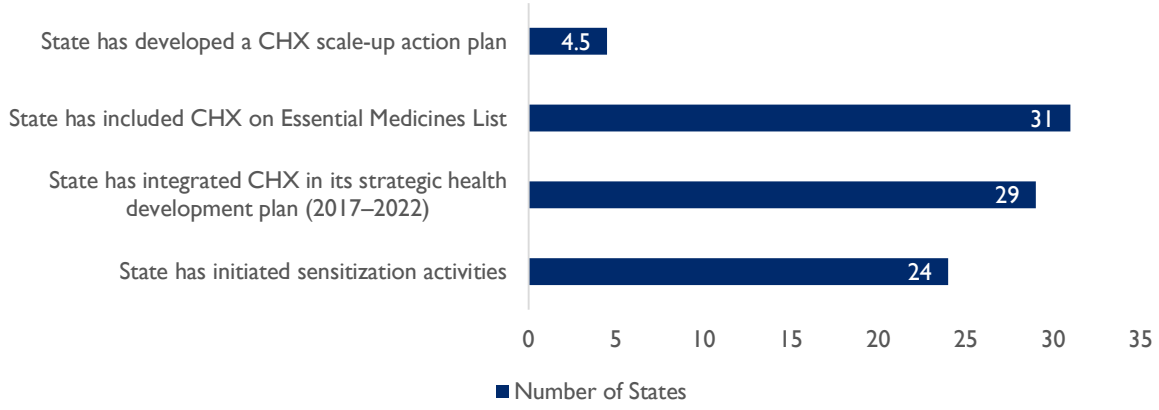


Figure 4. Number of states (out of 37) that reported primary procurement financing source (2017)

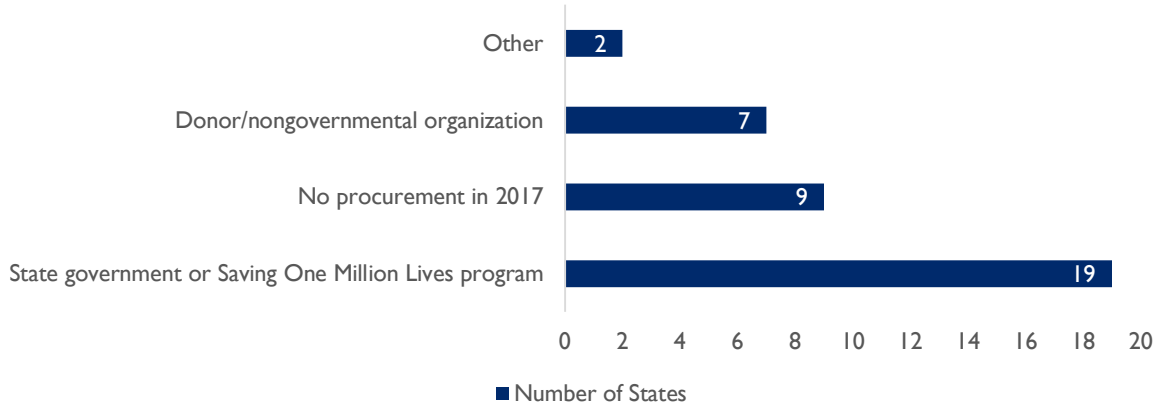


Figure 3 shows how many states reached milestones for developing a plan, including CHX on the State EML, committing public financing, and initiating activities. All states have now developed action plans for inclusion of CHX, usually as part of their strategic health and development plans. Major purchasers, including state governments, development partners, and hospitals, are procuring larger volumes of CHX. In Ebonyi State, in the month following a two-day multi-stakeholder engagement organized by MCSP, 1,200 units of CHX were

procured. Local manufacturers reported distributing 532,008 units of CHX to state governments and local distributors within Nigeria in 2015; 1,536,532 in 2016; and 688,395 in 2017. The high quantity distributed in 2016 was due to a partnership with the Society for Family Health through which 600,000 tubes were procured as "seed stock" to stimulate distribution through the private sector. Figure 4 shows that the majority of states (19 out of 37) relied on state government or SOML as the primary procurement financing source. Local manufacturers (Drugfield Pharmaceuticals, Emzor Pharmaceuticals, Jawa Industries, and Tuyil Pharmaceuticals) report a combined capacity to produce 30 million units per year and have exported 130,000 units to Zambia, Mali, Republic of Benin, Mozambique, Ghana, and Niger Republic. In 2019, the FMoH also integrated CHX indicators into routine reporting systems.

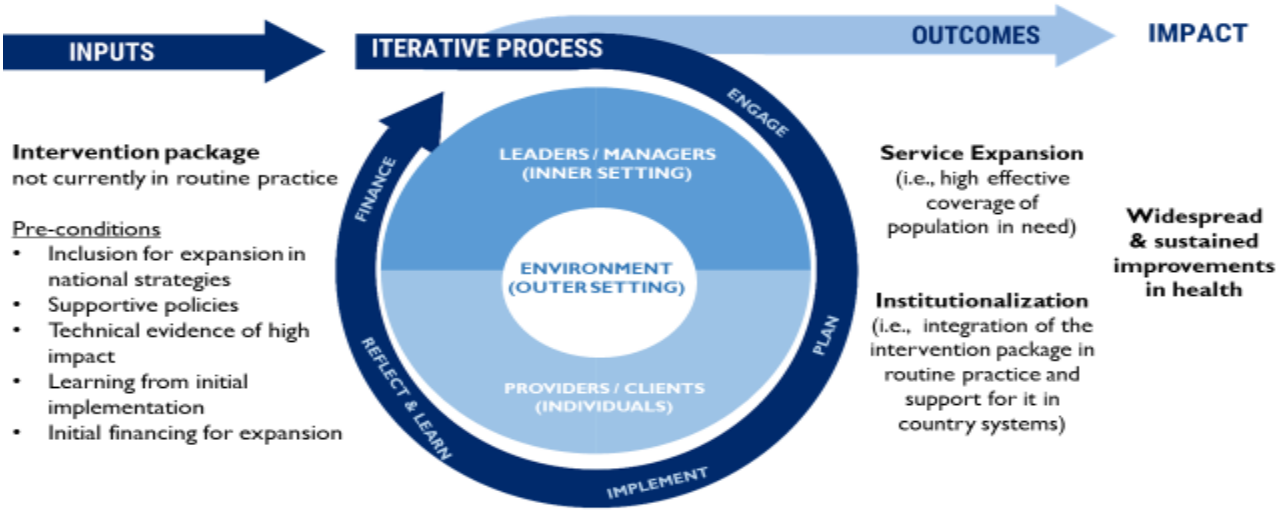
Framework and Methods for Studying Scale-up Outcomes and Processes

MCSP worked with the FMoH to conduct a summative case study to analyze the actions, events, and milestones of various stakeholders in the CHX scale-up effort at the state and national levels. The evaluative framework for this case study adapts key elements of the ExpandNet/World Health Organization (WHO) conceptual framework for implementing a scale-up strategy, and the consolidated framework for implementation research (CFIR)[5] as an evaluative framework for that experience. Figure 5 shows the conceptual framework for the systematic scale-up process in its advanced stages of expansion and full scale-up. The study team looked at the enablers and barriers related to five domains of the CFIR (intervention characteristics, outer setting, inner setting, individuals, and processes), and progress toward achieving high effective coverage (i.e., service expansion) and its institutionalization for sustainability.

- The left side of Figure 5 shows factors related to **intervention characteristics** and pre-conditions that should be in place from earlier piloting stages. These are the elements of scale readiness that affect the intervention's scalability in that context.
- Working from the center of Figure 5 outward, there is the **outer setting** (i.e., "environment") or those conditions outside the implementers' control. In the next circle are the **inner setting** (i.e., leaders and managers) and **individuals** (i.e., providers and clients). These are the people who interact individually and in their organizational setting to supply and consume the intervention package. Finally, the outermost circle shows the components of an iterative cycle of adaptive management that those engaged in the scale-up process engage in: engagement of relevant partners, planning, implementation, reflection and learning, and ongoing financing. These strategies are employed by the government and other stakeholders to support effective scale-up of the intervention and are similar to ExpandNet's "strategic choices."
- On the right of Figure 5 is the desired impact, that is, widespread and sustained improvements in health. To achieve this, the needed outcomes are both service expansion (i.e., high effective coverage of the population in need) and institutionalization of the intervention and its supports in routine systems. ExpandNet calls these vertical and horizontal scale-up.

[5] http://www.cfirguide.org/constructs.html

Figure 5. General framework for driving the "advanced stages" of scale-up



Source: Authors' adaption of the ExpandNet/WHO conceptual framework for implementing a scaling up strategy and the consolidated framework for implementation research

The majority of births in Nigeria occur in the home (59.0% according to Nigeria Demographic and Health Surveys [DHS] 2018), followed by births in public facilities (26.4%), and finally private facilities (13.0%), but there is significant variability by state. Although the National Strategy deals in a general way with the strategies needed for women delivering in each location, this variability by state has necessitated tailoring strategies to focus on the distribution channels for CHX that target women using the most common birth location. To capture the diverse experiences of state-led scale-up processes, key informants were chosen from three states that could illustrate insights about this range of scale-up strategies, tailored to the various situations that correspond to the three distribution channels included in the national plan (see Table 2). These states also span various geopolitical zones of Nigeria:

- Kogi, with MCSP support, has pursued a strategy focused on public facilities, where 51% of its births occur.
- Ogun has pursued a strategy focused on private facilities, where 55% of its births occur. This was private sector driven from onset, and then financed by the state government through the Araya Community Based Health Insurance Scheme.
- Sokoto, with previous support from the USAID-funded Targeted States High Impact Project (TSHIP) project and current UNICEF support, has pursued a strategy focused on distribution in the community, where 88% of births occur in the home.

Table 2. States selected for in-depth study

State	Geopolitical zone	Location of birth*	Nature of partner support for chlorhexidine (CHX)-related activities
Kogi	North-central	Public facility 51% Private facility 25% Home/other 24%	2015–present: Focused on public sector facilities and scale-up management
Ogun	South-west	Public facility 23% Private facility 55% Home/other 22%	2015: Pooled procurement of CHX for private facilities in a social franchising model
Sokoto	North-west	Public facility 12% Private facility <1% Home/other 88%	2012–2015: Focused on community-based distribution of CHX, co-packaged with misoprostol

*Source: National Bureau of Statistics (NBS) and UNICEF. 2018. Multiple Indicator Cluster Survey 2016-17, Survey Findings Report. Abuja, Nigeria: NBS and UNICEF.

This mixed methods case study started with a desk review of FMoH strategies, plans, and policies as well as information on coverage (Multiple Indicator Cluster Survey [MICS], Nigeria DHS 2018, and service statistics from DHIS2). The team then collected complementary qualitative information from key informant interviews as well as completing structured tools (described in detail elsewhere) to assess the strategies used by the FMoH, state governments, and their partners to progress along a scale-up pathway.[6] The study accounted for previous studies in Nigeria related to CHX and was designed to complement, not duplicate, these studies. This report pulls together that information plus the primarily collected information from the study team.

The study team consisted of an experienced qualitative researcher from Nigeria, two individuals from MCSP Nigeria, and one from MCSP headquarters (HQ) familiar with the history of implementation. The team also consulted frequently with key informants at the FMoH as they did their desk review for key information, developed the interview guides, and began to code the interviews. The team did the following:

- For a description and quantification of the inputs and outcome (coverage) shown in Figure 5, reviewed key project and policy documents, the 2016/2107 MICS, and the 2018 Nigeria DHS.
- Used the Management Systems International Scalability Checklist[7] to help identify the key areas of focus concerning scalability and the scale-up environment, to help narrow the focus of the interviews.
- Used the CFIR[8] to develop semi-structured interview guides for key informants to query them about the processes and players in the middle section of Figure 5 (implementers, leaders, and the processes they executed).
- After the interviews, used the MCSP institutionalization checklist to guide a structured discussion among team members and come to a consensus on the level of institutionalization in each of the health system components.

The study team purposively selected key informants. Study resources allowed the team to sample 40 key informants from multiple levels of government as well as organizations from the three states that represent civil society, private providers, professional associations, donors, and implementing partners familiar with the scale-up process. All interviews were transcribed and uploaded to Dedoose. They were coded by two members of the in-country study team and reviewed by the HQ team overseeing all scale case studies. Codes used were a combination of initial codes linked to the CFIR constructs and those that emerged from the data.

Ethical Review

The study team obtained approval on the selection of the three states from the FMoH and the National Health Research Ethics Committee. The Johns Hopkins University Institutional Review Board issued a Non-Human Subjects Research determination and the National Health Research Ethics Committee in Nigeria provided ethical approval to proceed.

Outcomes of the Scale-up Process

Progress on Service Expansion

The 2016/2017 MICS asked respondents about umbilical cord care only for those babies born outside a facility in the 2 years prior to the survey. The MICS estimated that CHX use for home births from 2014–2017 was 3.9%. This offers a baseline for the 2016–2021 national CHX scale-up plan. The overall level of coverage was likely substantially lower than this figure, as there was little to no use of CHX in either public or private facilities at that time. The 2018 Nigeria DHS also asked about CHX, and gave a national-level coverage estimate of 10.9%, which included all births, both at home and in facilities. It is also notable that there was a wide range in coverage by state, as Table 3 shows. Since the 2016–2021 national plan for CHX scale-up set a

[6] The study team engaged in primary data collection for the scalability checklist, environmental assessment, and MCSP institutionalization checklist as well as review of information from all other tools outlined in the Scale Coordinators Guide and Toolkit (MCSP Legacy website: https://www.mcsprogram.org/resources/). References for sources from which these tools were adapted are in the Guide.
[7] Cooley L, Linn J. 2014. Taking Innovations to Scale. Washington, DC: Results for Development Institute. https://www.usaid.gov/sites/default/files/documents/1865/v5web_R4D_MSI-BrookingsSynthPaper0914-3.pdf
[8] https://cfirguide.org/

target of 52% by 2021, states should have reached 40% of this target (i.e., 21%) by the 2018 Nigeria DHS. The five states shown in the top tier in Table 3 exceeded this target; the 10 in the middle tier were at least halfway to the target; and the 22 states in the lower tier were less than halfway to the target. Ogun has the highest level of coverage of any state. Kogi is at 15.5% coverage, and Sokoto is at 3.4% coverage. This report will focus on the implementation issues across these three states. States with differing emphasis on all three types of distribution channels (public, private, and community) are represented in the top tier of performers that are currently exceeding the trajectory in coverage change envisaged in the National Strategy. Therefore, the variability in the level of coverage in these three states is likely not explained by the distribution channel they chose because Ebonyi (which is similar to Kogi in emphasizing public facilities) and Bauchi (which is similar to Sokoto in emphasizing the community) are also among the states that are exceeding the target coverage level set in the national plan.

Table 3. Service expansion: Use of chlorhexidine (CHX) for cord care

	State	% of newborns with CHX applied to cord within 24 hours of birth
>100% target	**Ogun**	**38.7%**
	Oyo	33.1%
	Ekiti	28.6%
	Ebonyi	26.6%
	Bauchi	22.3%
50–100% target	Gombe	18.3%
	Abia	16.1%
	Borno	15.6%
	Kogi	**15.5%**
	Bayelsa	14.3%
	Lagos	13.9%
	Imo	12.8%
	Kaduna	12.3%
	Cross River	12.2%
	Osun	11.1%
<50% target	Katsina	10.1%
	Yobe	9.9%
	Kano	9.2%
	Akwa Ibom	9.0%
	Benue	7.9%
	Niger	7.1%
	Jigawa	7.0%
	Taraba	6.9%
	Nasarawa	6.5%
	Adamawa	6.5%
	Kebbi	6.2%
	Rivers	6.0%
	Plateau	3.9%
	Enugu	3.7%

	State	% of newborns with CHX applied to cord within 24 hours of birth
	FCT-Abuja	3.6%
	Sokoto	**3.4%**
	Delta	2.8%
	Edo	2.4%
	Kwara	2.3%
	Ondo	1.8%
	Anambra	1.2%
	Zamfara	1.0%

Source: Nigeria DHS 2018, Table 9.15, https://dhsprogram.com/pubs/pdf/FR359/FR359.pdf

Progress on Institutionalization

The study team assessed the institutionalization of CHX components within the health system, scoring them retrospectively for 2015 and also for 2018. The institutionalization assessment tool used is described in the Scale Coordinator's Guide on the MCSP Legacy website.[9] Figure 6 shows the consensus of the study team members based on the information from the key informant interviews. A score of zero represents no institutionalization and a four, complete institutionalization (i.e., integration into routine systems such as information systems, training, etc.). The planning and leadership for CHX scale-up component improved the most between 2015 and 2018. This was due to the *National Strategy* being finalized in 2016, as well as the inclusion of CHX in most states' strategic health development plans and the development of CHX action plans. Institutionalization of CHX made strong gains in personnel and policy during the period. Logistics was the only area with no improvement since 2015, which mirrors the experience across most maternal, newborn, and child health (MNCH) commodities. Progress on coordination and finance is also lagging as CHX activities still rely heavily on ad hoc funding and the support of development partners.

Figure 6. Institutionalization of chlorhexidine in health systems: 2015 (before national strategy) and 2018 (time of study)

Enablers and Barriers to Scale-up

The team used a structured checklist[10] to identify potential areas of focus for further investigation in the key informant interviews. The study team assessed the characteristics of the intervention that acted as enablers or barriers to scale up of CHX, using the constructs of the CFIR. If there was not clear evidence that a characteristic was either an enabler or a barrier, it was termed "equivocal." The main findings are described below.

See Table A.1 in the annex for a more complete list of the findings.

[9] https://www.mcsprogram.org/resources/

[10] Cooley L, Linn J. 2014. Taking Innovations to Scale (scalability checklist in Annex 2). Washington, DC: Results for Development Institute. https://www.usaid.gov/sites/default/files/documents/1865/v5web_R4D_MSI-BrookingsSynthPaper0914-3.pdf

Characteristics of the Intervention Affecting Scale-up

Intervention characteristic	Enabler/barrier
Source of intervention	Enabler
Complexity	Enabler
Cost	Enabler
Perception of evidence for intervention	Equivocal
Perception of relative advantage	Equivocal
Design and packaging	Equivocal

Enablers: Local Source of Intervention, Low Complexity, and Low Cost

The fact that there is a national plan to scale up CHX signed by the MoH and that there are multiple private manufacturers of CHX contribute to the perception that the source of the CHX intervention is local—that is, a Nigerian solution to the problem of newborn sepsis prevention, rather than a donor-driven solution imposed by outsiders. This helps with acceptance, especially among opinion leaders.

Key informants commented that CHX gel is more effective and more convenient to use than other traditional practices, especially methylated spirits, since it only requires a single application per day. These informants strongly believe that people are likely to accept it if they understand its purpose and advantages. They expected that health care workers and individuals will accept CHX because it is a simple product, relatively easy to use, and convenient. Multiple stakeholders across the health system and geographic locations shared these viewpoints. For example, a national partner, a partner who is a provider in Ogun State, a representative of a national professional association, and a representative of a professional association in Kogi State all mentioned that CHX is easier to use than methylated spirits because it is applied once a day. A traditional ruler in Sokoto State discussed how effective CHX is, and a manufacturer described its uptake as a "no brainer." A partner in Sokoto said the fact that CHX is simple enough to be delivered by community health volunteers will fast track scale-up.

The cost of CHX across the country varies widely because it depends on the number of middlemen in the supply chain. Views on whether the cost of CHX will encourage or discourage scale-up were mixed, but most respondents, representing a range of professions and geographical locations, characterized CHX as affordable or that users would be willing to pay for it (one national government official, three partner respondents, one donor respondent, two manufacturer respondents, two professional association respondents in Kogi State, one professional association respondent in Sokoto State, one state government official in Sokoto, and one state government official in Ogun).

[CHX] is one of the cheapest things among the things they buy. How much are pampers? Pampers are around 500 Naira, and they buy pampers almost weekly. Why will they not buy one chlorhexidine tube and it will last them that particular child? —Professional Association respondent, Sokoto

A minority of the respondents (5 of 40), however, characterized CHX as too expensive for families to buy, especially compared with methylated spirits. A partner in Abuja summed up these sentiments:

If it is more expensive than the local alternative, I think the poorer family will naturally object, not because they have anything against the product, but because they can't afford it. —Partner respondent, Abuja

Mixed Effects: Evidence for the Intervention, Design Quality and Packaging, Relative Advantage

Informants told the study team that many providers are still not aware of CHX and even when they are, the product is often not available at the facility, and, for home births, there is even less awareness. Mothers and delivery attendants have no knowledge of CHX, and no one has sold it to them. As awareness about CHX

increases, the challenge will be encouraging grandmothers, who often care for newborns during their first week of life, to change their traditional child care habits.

Some felt that an additional difficulty is related to the packaging. On the positive side, CHX can easily be integrated into routine interventions and platforms such as delivery lists, delivery packs, and existing projects and training programs. But on the other side, some providers may resist recommending CHX to patients because they heard about a widely reported story in 2015 of a previous imported formulation of CHX that came in eye dropper-sized bottles. A mother mistook it for eye drops and placed it in the eyes of her newborn, causing blindness. All domestic manufacturers now use a gel formulation of CHX to avoid another mistake like this. In addition, the instructions in the package have been improved for low-literacy child caretakers to clearly show that the gel should only be applied to the umbilical cord. Still, this story has persisted.

Although those interviewed were clearly convinced of the relative advantage of CHX over methylated spirits, many felt that this message has not been universally received or accepted. Key informants from among MCSP staff believe that most of the resistance to using CHX is due to clients and, to some extent, providers being uninformed about how effective and easy to use it is. One aspect of CHX use that concerns many potential users is that it is accurately perceived to delay separation of the umbilical stump. Many parents are motivated to get the stump to separate as quickly as possible, so traditional ceremonies can take place.

Characteristics of Clients and Providers Affecting Scale-up

Client/provider characteristic	Enabler/barrier
Knowledge and beliefs	Equivocal
Self-efficacy (of providers)	Barrier

Much is already known about client beliefs from formative research done through previous efforts. The main findings follow, and Table A.2 in the annex has a more complete list of the findings.

Barriers: Lack of Awareness, Cultural Practices, and Inertia

Currently the most important barrier to use of CHX appears to be lack of awareness. Providers are not aware of CHX or the product is not available at the facility, and, for home births, mothers, grandmothers, and delivery attendants are not aware of CHX and no one has sold it to them.

Traditional cultural practices include putting something on the umbilical cord (either methylated spirits or toothpaste)—not for antisepsis, but rather to hasten cord separation in time for the naming ceremony, which usually occurs on the eighth day after birth. The stump falling off is a religious and cultural priority. Grandmothers, who tend to care for newborns, are unlikely to learn about CHX from the provider after delivery, and less likely to change their habits. They generally want to use the cord care method they used for their own babies. In addition, some providers may not feel comfortable adopting CHX because there is a cultural norm among providers in public facilities that they need to receive direct training on new health practices before adopting them.

Caregivers often believe that CHX will help the umbilical stump fall off quickly and primarily use it for this purpose. Stakeholders have attempted to educate clients that CHX has benefits beyond timing of stump separation, but misinformation is still widespread. Anecdotal evidence shared by key informants suggests that the clash between cultural beliefs and the reality of the benefits of CHX has hindered increased uptake.

> *There will be religious bias towards it. Even when you make them adopt it and you do not pass that communication very well, our culture requires the cord to fall off before the 7th or 8th day of the naming ceremony and it is the major thing women are trying to achieve with the use of a product…our Medical Rep told me that they had to return the carton they bought from [the main store] because the mothers were complaining that it is not helping the cord stump to fall off quickly.*
>
> *—Partner respondent, Abuja*

Although there is some evidence that CHX delays cord separation by a few days on average, communication campaigns about CHX take advantage of this cultural norm of placing something on the cord. A traditional ruler from Sokoto State shared a view that was not technically correct, but demonstrates the cultural importance of umbilical stump separation. This respondent suggested that people were motivated to use CHX because they believed it allowed the umbilical stump to separate sooner: "this chlorhexidine, if you apply it in the cord, maximum of 2 days the cord will drop and the other one will be removed, but if it is traditional harmful one it will take up to a week not healing." Many respondents felt that the widespread cultural practice could be a positive factor for CHX scale-up because CHX is being substituted for another substance. As one donor summed up:

When you visit the field it looks like Chlorhexidine gel is one intervention that is actually accepted. I think the fact that we have a lot of cultures where people must apply something, even the literate ones have to come out of that culture in which people have to apply something on it, you are giving them better alternative and they can see that it is having an impact.
—Donor respondent, Abuja

Characteristics of Implementers (Inner Setting) Affecting Scale-up

Implementer characteristic	Enabler/barrier
Readiness for implementation	Variable by implementer
Structural characteristics	Organizational complexity of public system is a barrier
Implementation climate	Barrier

Key informants identified several characteristics of implementers of CHX-related activities that made CHX scale-up easier or more difficult to scale up. Table A.3 in the annex summarizes these findings. One complication in terms of the analysis is the fact that the consortium for CHX scale is a loose public-private partnership with private manufacturers and public and private distributors, so there is a complex organizational environment with several different implementers—private manufacturers as well as the health facilities and providers in the public or private sector.

Readiness for Implementation

One national partner discussed the fact that manufacturers have a large distribution network for commodities, targeted at private sector facilities and drug shops. However, key informants identified several shortcomings in terms of readiness for widespread distribution of CHX to public facilities, particularly primary health care facilities.

Private drug manufacturers entered the market under the assumption that they would not have to invest a lot of resources in demand-generation because demand would grow naturally after the national government added it to the national EML and several donors signaled that they would buy CHX. Respondents from among the manufacturers said that they have very low profit margins for CHX, thus were resistant to investing in demand-generation activities, but after demand got off to a slow start they have begun investing resources. Due to inefficiencies in the supply chain, units of CHX might go through several middlemen before getting to the final outlet, so the price to consumers is much higher and totally variable by outlet type and geographic location. The government and consumers then blame the manufacturers for setting high prices. In addition, some public sector providers do not accept a market-based system that requires manufacturers to make some profit on each unit to stay solvent. Some people have called for price setting or argue that manufacturers should provide CHX for no profit because they should save newborns in their home country. Manufacturers also seem to understand that this viewpoint exists and have said that they are concerned about marketing the drug for fear that people will think they are being greedy or deceiving.

On the other hand, there is also variability in service readiness on the part of the service providers. The focus on who these providers are is different in each state, based on the distribution channel emphasized. In Sokoto, supply of CHX itself remains an issue. A state government respondent stated that demand for CHX was created during the TSHIP program, but irregular supply of CHX means that those who would use it cannot get it (see

the subsection on supply chain issues). A Sokoto-based respondent from a professional association also brought up the topic of availability when asked how to assure sustainability of gains in CHX coverage:

On the government's part, they should try and equip the facilities with the necessary things that will enable the health providers do their work, because there is no point you are trained, the facility is there; but you become handicap when you don't have tools to work with, it is another big issue. —Professional association respondent, Sokoto

In Kogi, a recent influx in funding for primary health care facilities appears to be enabling CHX scale-up. A Kogi state government respondent noted that recent investments in the health system targeted at primary care facilities have enabled the health system to function better; however, this respondent and a second from Kogi state government also observed that primary health care facilities within Kogi State are currently managed by the State Ministry of Local Government and not by the State MoH, a potential barrier in some but not all states. The Ministry of Local Government struggles to pay salaries, and therefore does not prioritize important inputs to primary care, such as essential medicines.

Because the PHCs are not under one roof they are left to the mercy of the Local Government Authority, the same local government that is finding it difficult to pay salaries. They are paying percentages, so they can't even talk of procuring chlorhexidine gel. —Kogi state government official

In parallel with training of health workers, CHX needs to be available at the last mile. One partner cautioned against training health workers before availability needs are met:

You know when you go to the sick bed of a mother and say you need to access this service, you need to state where. When you tell a woman chlorhexidine is good, [etc.]…, you need to say where it can be gotten from and this has to be a place that is within 5km radius. You need to get it down to door level so that this growing demand can be satisfied. —Partner respondent, Abuja

Barriers: Structural Characteristics and Implementation Climate

A national government respondent identified that high attrition of health workers may affect CHX scale-up. The example provided was related to state officials; however, this problem is seen among government health workers as well.

Because there is high attrition in the states, the person who is DPRS in the next couple of 2 months or so may not be there again. You people are not paying salaries. What are you expecting from workers? —National government respondent, Abuja

In Kogi State, public worker salaries across the health sector were delayed or not paid for an extended time in 2017 and 2018. This situation weakened the health system, and was a major discussion point of respondents from Kogi State. A state government respondent in Kogi State identified a dysfunctional health care delivery system as a potential a barrier to scaling up CHX within a facility:

When the facilities are closed like they are now—I was in the facility where I worked yesterday and the facility was closed—when the pregnant women come to seek antenatal care they do not get them. People have to give birth at home or go private clinics, they are probably where this sensitization or scale-up has not reached so the traditional method come into play. So I believe that we are not [at the community] but with what we have on ground now we need to do a lot of things to build the system. It is not just the moral, the system itself needs strengthening, the hospital system both primary and secondary facilities many of them are in deplorable state. You need to bring them up. —Kogi state government respondent

In addition, uneven distribution of the health workforce is another major concern for scale-up of CHX. A Sokoto state official noted that 70% of the health workers are based in Sokoto local government authority, while only 30% are in the remaining 20 local government authorities in the state.

In some cases, quality improvement or assurance efforts have driven implementation. A professional association respondent in Sokoto State discussed how an organizational culture of supervision within facilities will help CHX be implemented. And an implementer/provider in Ogun State described how they assure adherence to standards of care by newly franchised private providers through trainings and supportive supervision.

Characteristics of the Environment (Outer Setting) Affecting Scale-up

Environment (outer setting) characteristic	Enabler/barrier
Policy and incentives	Enabler
Networking with other agencies ("cosmopolitanism")	Complex public-private partnership
Other: procurement difficulties, short-term programming	Barrier

Here we examine the main findings on the extent to which the external environment is either enabling or not. Table A.4 in the annex has more detail on the findings from key informant interviews.

A Constellation of Enabling Policies

USAID supported a series of engagements for stakeholders at national and subnational levels, and this led to the development of the *National Strategy*. There was consensus across a wide variety of respondents that the *National Strategy for Scale-Up of Chlorhexidine in Nigeria*, launched by the FMoH in 2016, greatly enhanced the enabling environment for scale-up of CHX. Respondents from an implementing partner, a professional association, and an Ogun state government official cited the *National Strategy* as important for enabling local action. The national plan built on a market segmentation analysis done by CHAI and helped systemize thinking about three main channels for distribution (public facilities, private facilities, and community level) that encouraged a whole market approach. This encouraged states to tailor their responses to their system strengths and to focus on the channel most appropriate for the predominant location of births. Furthermore, USAID also encouraged the engagement of the CHX uptake coordinator, who was financed through MCSP and seconded to the FMoH. Over the last several years, she helped identify key areas for action to accelerate the scale-up process, such as inclusion of CHX on state EMLs, inclusion of an indicator for initial application of CHX in the health management information system (HMIS), and inclusion of the questions on umbilical cord care in the 2018 Nigeria DHS to include use of CHX.

There was broad consensus among respondents of all types that the inclusion of CHX on the EML at both federal and state levels has also been critical.[11] When asked about policies surrounding CHX, many respondents mentioned the EML. When asked about key actions that can be taken to increase CHX coverage, several people mentioned including it in the state EML to enable procurement at the state level and/or to enable registered retailers to stock it. One Kogi state government respondent, however, reminded the team that this is necessary but not sufficient action: "[CHX] is in there in the state essential medicine list … but being in the state essential medicine list does not translate to government procurement."

Three respondents from FMoH agencies discussed how various national government policies kick-started local CHX manufacturing. For instance, a Nigerian regulatory body stopped issuing waivers for importing CHX from other countries. The Government of Nigeria (GoN) created a separate, expedited process for registering essential commodities such as CHX; abolished import duties for active pharmaceutical ingredients (raw materials); created a manufacturing guide for CHX; and designated CHX as an over-the-counter drug to improve availability in the private market.

An FMoH respondent discussed how a partner was able to provide manufacturers with the formulation of CHX when it was not initially available. These policies and actions proved successful in encouraging manufacturers to enter the CHX market. In 2014, one manufacturer was producing CHX. As of 2018, five manufacturers can produce CHX.[12]

[11] The EML streamlines various medicines that are deployed in the health care delivery system. It identifies the drugs that should be stocked at each level of the health care system. It guides the procurement of drugs and their use in the public sector, provides drug information to health care providers, and guides reimbursement for drugs under the National Health Insurance Scheme (NHIS).

[12] Despite the new entrants into the market, all three of the manufacturers interviewed were not concerned about increased competition because the potential market for CHX is so large. One manufacturer mentioned that building a production line for CHX gel was a worthwhile investment for the company because now they can use the production line to produce other gel formulations.

A Complex Political Environment Affects CHX Scale-up

The political environment at the state level is complex and dynamic, with considerable autonomy from the national level, which can create difficulties in scaling up a new health intervention such as CHX. State government respondents from all three states discussed how administration changes can disrupt a scale-up effort. For example, a state official in Ogun State mentioned that policies can change when administrations change. A state official in Sokoto discussed how paying community workers under TSHIP did not continue after a new administration came on board, despite good evidence that it was working well. A state official in Kogi was skeptical that state funds would be used for another mass procurement of CHX now that elections (national and state level) were approaching. Other respondents provided insights as to why this might be the case. One respondent discussed how politicians want to invest in things that have tangible value, and preventive health care has benefits that are less tangible and must compete with other initiatives that may have more immediate value.

It has not been sold from a political point of view. This is because health issue is not very easy to sell to the politicians because it is not tangible. … My argument is there is limited funding in the sector, yet some sectors get funded and the reality of the public sector is the money is not enough and you have competing sectors and within a sector you have competing interest for it. Then how do you make it much more sellable from the political angle? —Implementing partner respondent, Abuja

Two state officials in Sokoto identified how MNCH interventions such as CHX are competing for attention with other health priorities. One explained that malaria has a different partner and financing landscape than MNCH and is a lower priority. A state government respondent in Sokoto explained that when TSHIP was starting in the state, it encountered challenges getting the State MoH to prioritize the program. This may be because CHX was not included in the state EML during TSHIP, which demonstrates how having a commodity on the EML can promote scaling up that commodity. A Sokoto state government official described the situation in this way, "I think chlorhexidine and misoprostol have been included into the Essential Drugs List … nobody [will] start arguing 'what is this,' 'where are you getting this;' it has already been approved."

Barriers: Short-Term and Fragmented Donor Agency Support

Other barriers are the temporary nature and uneven distribution of partner support, as well as the ad hoc and inconsistent nature of national coordinating bodies. Partners tend to work with a small number of states during a given project period. For example, MCSP worked with two states, and although UNICEF has presence in all states, it works with six states specifically on MNCH programs. CHAI is in a few states, etc.[13] Most of the poorest states have a partner that supports MNCH in some way, but not necessarily CHX specifically. The nature of this support is completely different from state to state. For example, some partners only support community-based services, whereas other partners only support facility-based services. States with partners can ask them to support CHX if the state considers it a priority. In addition to partner support, all states have a large budget of funding from the World Bank SOML loan (performance for result). Newborn survival is one of the result indicators and some states have decided that using those funds for CHX will help them improve this indicator, but this is a state decision.

Processes **E**mployed to **D**rive **S**cale-up

Scale-up process	Enabler/barrier
Planning	Enabler
Engaging	Equivocal
Financing	Depends on state
Implementation strength	Barrier
Reflecting, evaluating, learning	Barrier

[13] Information from the *National Strategy to Scale up Chlorhexidine*

We present a summary of the findings related to the implementation strategies used to drive CHX scale-up. That is, engaging key stakeholders in the public-private partnership, going through a planning process with them at national and state level; actually implementing these plans as well as financing them (especially from sustainable and domestic sources of funding); and engaging in an active and adaptively managed process (i.e., learning mechanisms). We present the main findings here. Table A.5 in the annex has more complete information from key informants.

Planning

The *National Strategy* is fairly detailed and contains a timeline and cost analysis. However, it is still relatively high level. Although each of the states was represented in the group that developed the plan at the national level, awareness of the plan variably reached lower levels in each state. Respondents generally suggested that state-level action plans were important for scaling up CHX. As one Kogi state respondent explained, "you cannot start anything without having an action plan." An FMoH respondent agreed that state-level planning was important and there was more work to be done to ensure that both planning and institutionalization occurred across all the states. They explained, "all the 37 states developed state plans, but only 31 have been able to integrate it in the state strategic health development plan." Respondents also recommended that action plans for CHX scale-up be developed and costed out. One partner respondent suggested that having a costed action plan that takes an "integrated approach" will make it more likely to be implemented. Another partner respondent proposed that having a costed CHX action plan could be an advocacy tool to help with resource mobilization.

Engagement Is Difficult in a Complex Environment

Within the FMoH, Family Health has been the lead department for the CHX scale up effort and roles have been assigned to other departments based on their mandates. But many of the partner respondents expressed concern about weak coordination at the national level. One discussed how different departments and agencies were coordinating different work streams related to CHX but were not coordinating with each other. Two other partner respondents identified fragmentation and lack of formal structures for addressing issues within the FMoH organizational structure as potential barriers to scaling CHX.

> *The [Federal] Ministry of Health in my professional view needs to be restructured, every department is doing its own thing, activities are too siloed … The kind of restructuring I am talking about is like they have senior management meeting every Wednesday, but this meeting is not happening. Even if it happens it is for [the FMoH department heads] to state what they are doing. So, there is need to deliberately structure the Ministry to foster coordination, and this starts by … making sure that all departments can come together. —Partner respondent, Abuja*

A professional association respondent expressed a similar viewpoint: "I don't understand workings in the Federal Ministry of Health. There so many divisions, you don't know who is answerable for what and what …" A state government official from Sokoto identified how teaching hospitals, which are managed by a department within the FMoH, were not aware of the *National Strategy* and of CHX, and suggested that interdepartmental coordination be strengthened.

In Nigeria's health system, the Core Technical Committee for MNCH is expected to undertake stewardship and coordination of MNCH initiatives. To follow this norm, the Newborn Subcommittee of the Child Health Technical Work Group would play this coordination role. However, multiple respondents described how the ad hoc nature of these committees makes it difficult for them to coordinate effectively. Because there is no devoted domestic financing stream, and no requirement in their terms of reference that meetings happen every quarter, meetings are dependent on partners calling the group together. Thus, the meetings sometimes inappropriately focus on the agenda items of priority to those partners. This dynamic has had a negative spillover effect on coordination of the CHX scale-up initiative. One partner summed it up:

> *When it comes to coordination, there is what they call [the] Core Technical Committee and there they have the subcommittees. I don't feel how often these committees meet. Not only for the newborn care. It is like whenever somebody has something, they call for the committees. You are talking of coordination. There should be regular statutory meeting and there should be extra meeting when there is something but I don't see it. It is like when a partner has something; they say we can sponsor this and then they call*

for the meeting. I don't think that is how it should be done. Because we have to be following on what is happening in the state. I found out that the federal ministry is and am sorry to say this is solely dependent on partners. —Partner respondent, Abuja

Difficulties with Strength of Implementation

The various states have prioritized different distribution channels and, therefore, have distinct issues in implementing their plans. But one issue that has presented a consistent difficulty has been procurement. Nigeria relies heavily on donor funding for procuring CHX. For procurement of commodities, most donors/partners have a rigorous quality assurance process, some of which include an audit by an international body.[14] Two government agency respondents and one partner respondent helped explain the procurement dilemma. The partner is expected to procure a large number of CHX tubes to include in new mother packs (potentially up to 1 million tubes/year), but it requires either WHO prequalification certification or an audit by a third party to procure CHX from a manufacturer. A third-party audit was conducted in 2015 by this partner for Zinc/oral rehydration solution (ORS), amoxicillin DT, and CHX, however manufacturers only passed the audit for Zinc/ORS. The CHX manufacturer explained that they since revised their processes and passed an audit by the United States Pharmacopeia in 2017. This means that the manufacturer currently has prequalification certification for CHX by an international body. However, this partner still cannot procure CHX from this manufacturer for unknown reasons (possibly because the partner's headquarters does not acknowledge prequalification certification by other agencies). This lack of accepted prequalification certification is a barrier because the national government banned CHX imports.[15]

In terms of domestic procurement, the GoN has had a history of not paying manufacturers in a timely manner for other commodities, making some manufacturers wary of doing business with the government. As one respondent explained,

The only problem my managing director has with [the government] is in the procurement. We supplied [the government] about 100 million naira [worth of commodities] since 2013 and they have refused to pay until now … So, we are focusing on the private sector. —Manufacturer representative, Lagos

Reflecting and Evaluating: Hampered by Lack of Solid Data

There has not been a way to track CHX usage, even in public facilities, as the indicator for initial CHX application was only included in the national HMIS in 2019 after the study interviews had concluded. In the absence of a formal HMIS indicator, some states have reported moving forward with having public facilities add a column to a register, such as the labor and delivery register, to report CHX application at birth. Kogi State's scale-up management team (SUMT) is encouraging the state HMIS unit to support this effort and enable the SUMT to use the data for coordination and decision-making. A national government official shared that the government has a DHIS2 web-based reporting system that is highly interactive. Once CHX is tracked through the HMIS, people at the FMoH analyze the data. However, respondents also explained why reporting is not easy. One Sokoto State respondent highlighted issues around lack of capacity and efforts by government workers or facility managers. Another Sokoto State respondent advocated for support to improve logistics information around CHX distribution.

Sometimes people provide data because is part of their duty. They don't even look at it because they have to submit data to the DHIS…but ideally they should use it. Okay, my immunization coverage this month is low compared to last month, what is happening, why? But no director in primary health care will do that they don't do it…because our partners around they only help us to do that. —Sokoto state government official

A partner also reflected that the HMIS will only be able to measure distribution through public facilities. Private health facilities have been mandated to report to the HMIS, but there is an ongoing limitation with

[14] Note that this audit is different from WHO Good Manufacturing Practices (GMP) certification, because CHX gel is not part of the list of commodities that requires GMP certification. This distinction has caused confusion in the past related to procurement of CHX by this donor/partner.

[15] This ban was likely put in place for two reasons: 1) to show that the government responded to the adverse events that occurred in 2015 after a donor imported and distributed CHX solution, and 2) to protect Nigerian manufacturers from outside competition.

data collection from patent and proprietary medicine vendors and pharmacies. For tracking estimations of coverage, it would also be useful for FMoH planners to have access to manufacturers' wholesale data.

Conclusions

Progress on Scale-up: Reaching Those in Need and Institutionalizing Supports for Sustainability

Nigeria is the most populous country in Africa and accounts for a large fraction of the continent's newborn deaths. A quarter of those deaths are due to infections, and scaling up CHX could go a long way toward reducing newborn deaths. The fact that Nigeria developed and began executing its national plan in 2016 was an achievement in itself and a testament to the dedicated efforts of several champions in the FMoH and development partners. Although the country is not now on track to achieve its target of reaching 52% of all newborns by 2021, it has nevertheless made substantial progress. In addition, focusing only on the aggregate national pace of coverage expansion masks the fact that there is a wide range of achievement among the states. In fact, five states are exceeding coverage targets and another 10 are reaching at least half their coverage targets. It is encouraging that some states have tailored the focus of their distribution plans to match the location of the majority of their deliveries (i.e., community, public facilities, or private facilities). The Nigeria DHS 2018 data on coverage by state shows that at least one state focusing its efforts on each of these distribution channels is in the top tier of states exceeding the coverage target set by the national plan. This is encouraging evidence that each of these distribution mechanisms is a potentially viable path to sustained impact at scale.

The progress on institutionalizing the needed supports across public health system components to reach high levels of CHX use at scale gives confidence that the gains have a good chance of being sustainable. Especially notable is the fact that there has been progress on several key fronts: putting an indicator for CHX use in national HMIS as well as the Nigeria DHS, including the product on the national EML, most state EMLs, and to a lesser extent cultivating local sources of funding. Programmatic evidence shows that these aspects of institutionalization often lag even for mature health interventions.

Enablers and Barriers Driving Scale-up

Table 4 summarizes the study findings by CFIR category.

Table 4. Summary of high-level findings from the study, organized by consolidated framework for implementation research categories

Enabler/mixed picture/barrier to effective scale-up	
Intervention characteristics	The product, intervention, and strategy is **locally owned** (i.e., national scale-up plan and local producers of chlorhexidine [CHX]).
	Low complexity of the clinical intervention.
	Cost is modest and within the means of most people and comparable to methylated spirits, its main competitor product for cord care.
	Perception of strength of evidence is mixed, relative to methylated spirits.
	Design and packaging: Well-designed packaging. It has simple instructions and can be included in delivery kits.
Individuals	**Knowledge and beliefs:** There is still a low level of awareness about CHX. It helps that most people believe that something should be put on the cord to speed its separation, but the fact that CHX slightly delays cord separation could be a problem for wider uptake.
	Providers feel they "need to be trained" even for this simple intervention, impeding its uptake.
Implementers (inner setting)	**Readiness for implementation** is high among private sector manufacturers; lower in public sector (especially in terms of stock management).
	Structure of the public sector is complex, with multiple divisions and levels of the hierarchy that need to be involved, making coordination difficult.
Environment (outer setting)	**Policy** at the national level has spurred state action; with advocacy, states have now mainly put needed policy elements in place (i.e., planning, financing, inclusion of CHX on the EML).
	Coordination within the public-private partnership has been challenging, sometimes because public sector employees suspect the motives of those in the private sector.
	Fragmented, inconsistent, and short-term donor-funded programming across states makes concerted action more difficult.
Processes to Drive scale-up	**Plan** at national level is good. It has acted as a template for **planning at state level.**
	Financing has been opportunistic at the state level (e.g., tapping into the Saving One Million Lives Program), but there has been some movement toward firmer local financing.
	Reflection and adaptive management has been impeded by a lack of information. This may be helped by recent inclusion of a CHX indicator in the HMIS. But there is still a need for a stronger review mechanisms in the public sector and inclusion of information on private sector progress.

Intervention Characteristics

The National Strategy for CHX scale-up has called attention to its importance and shown local ownership. Even though development partners have sometimes pushed for procurement from elsewhere, having local manufacturers of the product has increased the sense of local ownership. The low complexity and cost of the intervention are also enablers. However, issues remain around the use of CHX versus traditional methods. Many do not perceive CHX as superior to the widely used methylated spirits. The tangible benefit that many see for any product they place on the umbilical cord is its ability to make the cord separate faster, rather than preventing the rarer occurrence of umbilical or systemic infections. CHX is not clearly superior to spirits in this regard, so behavior change campaigns need to take this into account. Although the packaging is well designed for low-literacy consumers, a previous imported formulation had the consistency and packaging of

eye drops and, in a widely publicized case, was once mistakenly put into a newborn's eyes. This case is still in the public imagination and is likely acting as a brake in terms of accelerating uptake of the product.

Characteristics of Providers, Clients, Managers, and Leaders (Individuals and the Inner Setting)

There is a continued low level of awareness across all segments of the population (policymakers, health providers, national and local authorities, mothers, fathers, and grandmothers) concerning the benefits of CHX, including how easy it is to use. To date, informants feel there had been underutilization of professional associations to inform their members about CHX and drive the shift from methylated spirits. This lack of awareness has resulted in low demand despite its availability. This has significantly contributed to CHX's inability to displace methylated spirits as the predominant substance to use on the umbilical cord. As CHX scale-up continues, beliefs and practices related to cord separation will need to be monitored. If the current situation persists in which there is not a widespread perception that CHX delays cord separation by a few days, which is problematic for the traditional naming ceremony, then messages about CHX can continue to focus on its effectiveness for keeping the newborn healthy. But if growth in the use of CHX does not accelerate, the more difficult task of attempting to shift cultural norms around delaying the naming ceremony may be in order, because CHX does delay cord separation by one or 2 days on average. Nigerian manufacturers have the capacity and infrastructure to quickly produce enough CHX for the entire country and distribute it to states and large facilities. In some areas, access to CHX has been limited because of weak distribution mechanisms due to ineffective coordination between the public and private sectors.

Environment (Outer Setting)

Key informants identified policy-related changes as among the most influential factors promoting scale-up. The GoN provided the necessary leadership to kick-start the implementation of the *National Strategy* and led scale-up efforts related to national activities, but leadership across states has been variable. Including CHX on the EML and designating CHX as an over-the-counter drug were also important GoN activities that supported scale-up. It also helped ensure the availability of locally produced CHX by no longer issuing waivers for importing CHX, creating a manufacturing guide for CHX, and waiving import duties for active pharmaceutical ingredients. On the more problematic side, there is a still need to strengthen networking across public sector agencies, and great efforts have been made by active champions who have sometimes been supported through external programs, but the short-term and fragmented nature of donor-funded programs is also an ongoing issue.

Iterative Processes to Drive Scale

It is difficult to develop effective plans aligned with national strategies in a complex and decentralized organizational environment, but many informants felt that the CHX scale-up planning process had been done well and in a participatory way at the national level. The National Strategy, in turn, has acted as a template to guide planning at the state level. This progression from national to state level did not happen naturally or by chance, however. It took the active advocacy of some dedicated champions for CHX, both within the FMoH and from the TSHIP project among other development partners, to catalyze the development of the National Strategy and then to get states to incorporate CHX within their health and development plans and take the needed steps to ensure implementation readiness. In terms of implementing these plans, however, there have been varying levels of success. In particular, some of the basic elements needed for reflection and adaptive management have been weak. That is, there has not been a reliable stream of routine information to guide decision-making, nor in most states have the established governance platforms had the strength and scope of authority to make management decisions that would be followed by the relevant stakeholders based on data, even if they had existed. Now that an indicator for initial application of CHX is in the HMIS, there is hope of having data for public system decision-making. But this still does not cover the private distribution system or health facilities. Having the information now makes more urgent the need to strengthen the role of the state Child Health Technical Work Groups or some other equivalent body to actively manage the scaling-up process, using this newly available information for decision-making.

Overall Conclusions

CHX application to prevent newborn sepsis has some clear advantages as an intervention to be scaled up, including its simplicity and low cost. Scale-up of this intervention in Nigeria, however, it is not without substantial difficulties. The complex organizational structure of the public health system and the weakness of the public logistics system makes scale-up challenging through the public channel. The National Strategy and supportive policies have clearly been important levers to help facilitate scale-up, not only through the public channel but also at the community level and through private facilities. But levers do not pull themselves. Some well-placed champions have used these levers as they have expended considerable and ongoing efforts to facilitate key state actions, such as placing CHX in state plans, getting it on state EMLs, procuring it, and placing it within state health and development plans, while encouraging states to take advantage of outside financing for MNCH programs. The results of the 2018 Nigeria DHS show the fruits of these planning, policy, and advocacy strategies in mitigating the organization challenges of the public health system. Aggregate national progress is substantial (10.9% national coverage in the 2018 Nigeria DHS, at year 2 of the five-year scale-up strategy). Even more encouraging is the fact that five states are exceeding targets and another 10 are within 50% of their target, as envisaged in the national scale-up strategy. There are also now several "state experiments" that show that relatively rapid progress is possible in scaling up use of CHX, by focusing appropriate energy on any one of the three distribution channels (community, public facility, and private facility) in the National Strategy. The initial scale-up target was noted as extremely ambitious and was based on the Nepal CHX scale-up curve, which is one of the most successful global health product/service scale-ups ever. Nonetheless, Nigeria is making substantial progress against this high standard. With continued effort by well-placed champions, one feels that Nigeria is poised to make even more substantial progress and possibly reach the ambitious target it set in its national plan of 52% coverage by 2021.

Recommendations

After analysis of the finding of the summative study, the study team made the following recommendations to facilitate the further scale-up of CHX.

Recommendations for National Government

The national government has provided the necessary leadership to kick-start the implementation of the National Strategy and led scale-up efforts related to national activities. In line with providing the enabling environment for scale-up, the national government should now:

- Develop a guideline for the standardization of delivery packs to be used across all levels of the health system (community and facility), including in donations.
- Ensure that all pre- and in-service curricula for all cadres of health workers are updated to include the use of CHX, with instructions on correct recording.
- Continue to provide the necessary coordination and support to states to achieve the 2021 goal of 52% utilization of CHX among all newborns. In this regard, it would be helpful to bring together states to analyze and share what has worked well in the five top-tier states (Bauchi, Ebonyi, Ekiti, Ogun, and Oyo) and discuss how these lessons can be applied to improve the performance of other states that are currently experiencing challenges.

Recommendations for State Governments

The decentralized nature of the health system signifies that the onus of nationwide scale-up resides at the state and local government authority levels. States are at different stages of scale-up and need to take several priority actions:

- Adapt/adopt/revise/update and implement policies, guidelines, and strategies such as translating the National Strategy into state actions integrated in health and development plans and annual operational plans, and including CHX in their EML.
- Ensure reliable resource flows, while also giving credibility to locally manufactured CHX through pooled central procurement, and leverage existing distribution channels used for other commodities to reach the last mile.
- Strengthen multi-sectoral/multi-departmental engagement and coordination (private/public/community) with the goal of using data for decision decision-making, taking advantage of the fact that there is now more data available through the HMIS.
- Increase demand for CHX with tailored messages with audience segmentation that emphasizes information on the benefits, potential side effects, and availability of CHX while addressing cultural beliefs about cord separation.

Recommendations for Development Partners

The role that development partners and donors have played to support the scale-up efforts has demonstrated effective partnership that can be strengthened further, especially at the state level, by taking several key actions:

- Support states as they implement or adapt policies and help them develop action plans to scale up CHX. Such plans must include not only supply side but also demand side interventions.
- Build capacity of focal persons to understand their role in line with the National Strategy to ensure documentation and reporting of scale-up efforts: health providers to properly record information, HMIS officers to analyze and present data, and the reproductive health coordinator to share reports with the FMoH.
- Support the in-service training of health workers from all units/wards that are involved with maternal and newborn care. This includes those who work in antenatal care clinics, labor wards, postnatal care wards, special care baby units, and emergency pediatrics units.

Annex: Analysis of Consolidated Framework for Implementation Research Constructs from Key Informant Interviews

Table A.1. Characteristics of the chlorhexidine (CHX) intervention that influence scaling up

	Characteristics that made scaling easier (Enablers)	Characteristics that made scaling harder (Barriers)
Source of intervention	• Evidence from the Targeted States High Impact program pilot (helped spark policy development) • National policy • Local manufacturers	
Complexity	• Intervention simplicity (once daily application) makes it easier than methylated spirits	
Evidence strength and quality	• Key informants across geography and respondent types were convinced of the evidence	• Policymakers cannot observe the benefits of CHX because it is preventive, not curative
Relative advantage	• Key informants across geography and respondent types were convinced of its relative advantage over methylated spirits	• May delay cord separation compared to methylated spirits • Health workers want to see proof of effectiveness, and since sepsis is rare, proof is difficult to show • Continued concern about the story of its use in a newborn's eyes
Design quality and packaging	• Delivery packs and delivery lists exist in all public and private facilities (CHX can be added) • Easy to bundle with essential commodities (e.g., misoprostol)	• There is no standardization to the content of the delivery list or delivery pack • Product name is difficult to pronounce and remember compared to "spirit"
Cost	• Although there was not complete consensus, a number of stakeholders consider CHX affordable and think caregivers* will buy it if they understand the benefits	• CHX is more expensive through some outlets

*Caregivers were defined as anyone who is responsible for caring for a newborn from birth through at least when the umbilical stump separates. In Nigeria, this might be the new mother or the newborn's grandmother (usually the new father's mother, per cultural norms).

Table A.2. Characteristics of individuals that influenced scaling up chlorhexidine (CHX)

	Characteristics that made scaling easier (Enablers)	Characteristics that made scaling harder (Barriers)
Knowledge and beliefs about the intervention	• Cultural practice of putting something on the umbilical cord	• Potential distributors unaware that CHX has over-the-counter status • Health workers uninformed about CHX • Caregivers' desire to use traditional methods (particularly grandmothers in first week of life) • Cultural belief among caregivers that fast stump separation is better • Some providers reluctant to use CHX because some patients put it in a newborn's eyes in 2015
Self-efficacy		• Health workers think they need training in CHX

Table A.3. Inner setting: Characteristics of implementers that influence scaling up chlorhexidine (CHX)

	Characteristics that made scaling easier (Enablers)	Characteristics that made scaling harder (Barriers)
Structural characteristics		• High attrition rates of state government officials • High attrition rates of public health care workers • In some states, the public health centers are managed by the Ministry of Local Government whereas secondary facilities are managed by the State Ministry of Health, causing fragmentation, inconsistent implementation, and increased need for coordination

Networks and communications		• Communication barriers between facility wards
		• Uneven training of health workers contributing to communication barriers within facilities, for example,
		  • Ob-gyn cadre not trained on CHX, but pediatricians and neonatologists trained
		  • Senior staff at health facilities (e.g., doctors who do not attend many deliveries) more likely to receive in-service training

Organizational culture	• In some places, there is an organizational culture of supervision and adherence to standards of care	• Fragmentation and lack of formal reporting and coordination structures within the Federal Ministry of Health
Implementation climate		• Some public worker salary payment delays, affecting motivation
Readiness for implementation	• Manufacturers' readiness to distribute to states and large facilities (via sales reps) • Manufacturers' ability to quickly produce enough CHX for the entire country • Readiness of a national partner to distribute commodities to private sector facilities and pharmacies	• Poor readiness of central medical stores to deliver commodities (in some states) • Uneven distribution of the health care workforce

Table A.4. Outer setting: Environmental characteristics that influence scaling up chlorhexidine (CHX)

	Characteristics that made scaling easier (Enablers)	Characteristics that made scaling harder (Barriers)
Patient needs and resources	• Mandates/priorities of several national partners and donors align with CHX scale-up initiative	• CHX competes for prioritization with other high-priority health areas, such as malaria • Not all states have partner support for reproductive, maternal, newborn, child, and adolescent health and nutrition • Partner support is temporary • State logistics management coordination units are often bypassed by programs that procure and distribute essential commodities
Networking ("cosmopolitanism")	• Professional associations have wide outreach potential	• Norms require coordination meetings be face-to-face, and provide food, beverages, and stipends • Coordination bodies at national, state, and local levels do not have clear terms of references and tend to operate in an ad hoc manner • National Council on Health does not include state-level program managers, hampering implementation at state level

External policies and incentives	• National Strategy to scale up CHX
	• CHX on national and most state essential medicines lists
	• Policies or partner support to encourage domestic CHX manufacturing, including:
	  • Government of Nigeria (GoN) body ceased issuing waivers for importing CHX
	  • GoN created an expedited process for registering essential commodities
	  • GoN waived import duties for active pharmaceutical ingredients
	  • GoN created a manufacturing guide for CHX
	  • GoN designated CHX as an over-the-counter drug
	  • Partner provided domestic manufacturers formulation of CHX (it was not initially available in the public domain)
		• Procurement barrier for a large donor/partner
		• Dynamic political environment often disrupts health sector programs
		• States independently determine whether to adopt national strategies
		• History of government purchasers not paying manufacturers in a timely manner

Table A.5. Processes to drive the scale-up effort

	Characteristics that made scaling easier (Enablers)	Characteristics that made scaling harder (Barriers)
Engaging/ coordinating	• Senior officials demonstrate ownership over chlorhexidine (CHX) scale-up • Multi-stakeholder engagement of national partners, donors, professional associations, and manufacturers • Engagement between major purchasers and manufacturers	• Ad hoc CHX coordination at the national level • Unsuccessful coordination between national government and state officials • Lack of coordination within some states • Some professional associations not engaged • Disagreement among key stakeholders as to who should coordinate CHX scale-up activities
Planning	• The *National Strategy,* in place since 2016, provides guidance on implementation strategies • Many states included CHX scale-up in their state strategic health development plans	
Financing	• Saving One Million Lives projects in some states decided to use funds to procure CHX or to improve health management information system reporting • Pooled CHX procurements in some states • Drug procurements by partners in some states	• Lack of sufficient government funding for health care overall, and particularly reproductive, maternal, newborn, child, and adolescent health and nutrition • Temporary partner support • Lack of existing mechanisms for pooled drug procurements in many states • Lack of general funding for central medical stores to distribute maternal, newborn, and child health commodities
Implementing	• CHX incorporated into Essential Newborn Care (ENC) training package • The Federal Ministry of Health promoted local manufacturing • Manufacturers conducted some demand-generation activities through sales representatives	• Lack of widespread pre-service training or in-service step-down trainings • Some types of providers do not receive ENC training package (trained birth attendants, ob-gyns, general medical practitioners, private sector providers) • Professional associations did little to disseminate information about CHX to members • Lack of public sector distribution caused widespread stock-outs of CHX in many facilities • Private community-based distributors did not stock CHX • Lack of demand-generation by government and private actors
Reflecting and evaluating	• The 2018 Nigeria Demographic and Health Surveys included a question on CHX application	• CHX indicators are not tracked through the health management information system • Lack of implementation research and use of information for active management