



# Scaling up Chlorhexidine For Reduction of Neonatal Mortality in Madagascar:

*A Costed Plan*



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Robin Houston  
ElianeRamiandrisson  
Alain Patrick Diop

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## Acronyms and Abbreviations

AC	Agent communautaire
ANC	Antenatal care
BCC	Behavior change communication
BCG	Immunization for tuberculosis
CHW	Community health worker
CHX	7.1% chlorhexidine digluconate (delivering 4% chlorhexidine) for umbilical cord care
CSB	Centre de Santé de Base
DAMM	Direction de l'Agence du Médicament de Madagascar
DHS	Demographic and Health Survey
DPMLT	Direction de la Pharmacie, des Laboratoires et de la Médecine Traditionnelle
EMIL	Essential Medicines List
FP	Family planning
FANOME	Fandraisana Anjara NO Mba Entiko
GMP	Good Manufacturing Practice
IMCI	Integrated management of childhood illness
JSI	John Snow, Inc.
LLIN	Long lasting insecticide treated net
MAFEHA	Malagasy Healthy Families
MCHIP	Maternal and Child Health Integrated Program
MNCH	Maternal Neonatal and Child Health
MNP	Micronutrient powder
MOH	Ministry of Health
MTOT	Master training of trainers
MVU	Mobile video unit
PA	Point d'approvisionnement communautaire
PATH	Program for Appropriate Technology in Health
PhaGCom	Community pharmacy
PhaGDis	Wholesale pharmacy
PSI	Population Services International
SALAMA	Centrale d'Achats de Médicaments Essentiels et de Matériel Médical de Madagascar
SIG	Système d' Information de gestion
SONU	Soins Obstétricaux et Néonatals d'Urgence
STI	Sexually transmitted infection
TWG	Technical working group (for chlorhexidine)
UN USP	United Nations United States Pharmacopeia Convention

## **Executive Summary**

Most countries have had steady reduction in under-5 mortality. However, many countries, including Madagascar, have experienced smaller reductions in neonatal mortality. The causes of neonatal mortality have been well documented, with birth asphyxia, prematurity and infection the greatest contributors. Recent studies have demonstrated that early application of 7.1% Chlorhexidine Digluconate (CHX) to the umbilical cord significantly reduces mortality. Thus, in settings with poor hygiene at birth, this simple intervention can help prevent sepsis and cord infections, and avert preventable deaths.

In Madagascar, child mortality remains high despite some improvements over the last decade. Neonatal mortality also declined, but currently represents 33% of all under-5 deaths. A contributing factor is the high rate of home deliveries (65%). Although there are no data on the proportion of infections linked to cord care, current traditional practices contribute to increase the risk of sepsis and umbilical infection.

A Madagascar technical working group that includes the Ministry of Health, JSI/Mahefa, JHPIEGO/MCHIP, PSI/M and UNICEF developed a protocol to introduce CHX for umbilical cord care as a pilot program in the district of Mahabo in western Madagascar. With funding from USAID and PATH, the pilot program was officially launched in September 2013. It will be formally evaluated in July 2014. However, in order to reach the 2015 objectives of mortality rates reduction and given the interests on CHX at global level, a costed scale-up plan needed to be developed. The document would serve as an advocacy tool for use with the MOH and potential donors.

The vision for this scale-up plan is:

*"To achieve 80% coverage nationally for application of CHX immediately after birth for all deliveries using the most efficient, cost-effective and sustainable approach to ensure maximum impact on neonatal mortality."*

To achieve the vision described above, the plan includes three key objectives with strategies that define specific activities designed to achieve each objective:

1. Establish CHX as the standard for cord care
2. Ensure that CHX is available
3. Ensure that CHX is used by health facility staff, ACs, and mothers for cord care management for all neonates

### **Ensuring that CHX is established as the standard for cord care**

The plan will be used for advocacy at all levels—both to facilitate rapid inclusion in Government MNCH policies, and also to define and coordinate donor support.

The introduction of CHX as the new standard of umbilical cord care may not require an extensive revision of all MNCH policies, strategies and other documents - which may take a lot of time. Whenever a revision is planned, it represents an opportunity for CHX to be included. Nonetheless, the plan recommends holding policy development workshops that will spur the process. Once the MOH has established CHX as the new standard of umbilical cord care, it needs to be disseminated to all levels beyond a simple ministerial note. To that end, the plan recommends dissemination meetings at national and regional levels.

A prerequisite to scaling-up is the registration of CHX and ensuring that the exact formulation and dosage for CHX used for cordcare is included in the list of commodities routinely procured by the CSBs

### **Ensuring that CHX is available**

In order to maximize availability, while fitting into the existing successful systems for commodity procurement and distribution, the plan recommends procurement and distribution through two channels—the existing Government essential drug system, and the social marketing approach. These two systems combined should allow for universal availability, particularly for mothers in remote areas who may also be the most vulnerable. Both systems are based on users' fees, thus it is recommended to establish a price and a system to address both affordability and sustainability of procurement/resupply.

Commodity needs were calculated based on expected pregnancies and were estimated at 2,147,200 CHX tubes for the 3-years scale-up plan . The amount needed for each system were estimated to be 40% through the public sector and 60% for the social marketing system—based on current estimates of facility use for delivery

### **Ensuring that CHX is used by health facility staff, ACs, and mothers for cord care management for all neonates**

The scale-up involves a training of all health facility staff and at least 2ACs per fokontany . A standard cascade training model is recommended with the integration of a CHX training module into existing MNCH/IMCI activities or refresher trainings at all levels,

In order to ensure the highest level of awareness and to create an informed demand among mothers, female family members and health care workers, the plan also envisions an integrated social marketing BCC approach using the same communication materials developed for the pilot.

Monitoring progress with scaling up can be done through commodity outflow and records of neonates for which CHX is used. Those data can be provided by the existing MOH SIG provided CHX is included . However, these will not provide an accurate measure of actual use or true coverage which can only be assessed through a survey. Thus, the plan includes a population-based survey of regions having completed CHX introduction after Year 1 of scaling up. After that, CHX should be included in any national survey that covers a range of MNCH interventions such as theDHS or UNICEF MICS survey or other existing survey.

It will take time for Government policy and strategy to change and to generate adequate funding for national implementation. Thus, the plan envisions a phased-in approach, anticipating 3 years to achieve national implementation coverage. The budget for a 3-years scaling up was estimated at 3.125.841 USD. The plan estimates that 1/3 of regions will be introducing CHX in Year 1, however it will depend on the Government and implementing partner planning and budget schedules. For this reason, no specific regions were identified for each year of the scale-up plan. However, it is likely that partners will prefer to introduce CHX in regions where they have ongoing activities into which to integrate this new intervention.

The scale-up plan will be successful if there is a shared commitment to the vision, with all stakeholders committed to their role. It calls for donor coordination and advocacy on the part of the Government to secure funding to supplement the Government's contribution for scaling up. Thus, it is recommended that the MOH/DSMER lead the process of scale up and oversee program implementation as appropriate.

## **Introduction**

Most countries have had steady reduction in under-5 mortality. However, many countries, including Madagascar, have experienced smaller reductions in neonatal mortality. The causes of neonatal mortality have been well documented, with birth asphyxia, prematurity and infection the greatest contributors (ref 1). There is currently a renewed global interest in reducing neonatal mortality by strengthening systems and interventions to address these causes.

Chlorhexidine has been widely used as a hospital antiseptic. Recently, a series of controlled studies have demonstrated that early application of 7.1% Chlorhexidine Digluconate (CHX) to the cord reduces mortality—by as much as 23%. (ref 2,3,4,5) These studies have generated global and national interest in introducing this simple intervention where neonatal mortality remains high. Recognizing that for many countries, ensuring hygienic delivery practices and a clean home environment is difficult, the greatest benefit will come from ensuring that CHX is the standard of care for cord care. (ref 6) The WHO guidelines recommend clean and dry umbilical cord care (ref 7); however, in settings with high risk of bacterial infection, use of an antiseptic such as chlorhexidine is acceptable. And as of July 2013, the WHO Model List of Essential Medicines for Children (EMLc) now includes 7.1% Chlorhexidine digluconate (delivering 4% chlorhexidine) for umbilical cord care.

A Global Technical Working Group consisting of key technical experts and implementing partners convenes regularly to review progress with establishing CHX as a key intervention in countries with persistently high neonatal mortality. The Working Group assists with issues such as product specifications, procurement, assessment of local production capacity, and tracking policy development. Several countries have completed initial work, and are exploring the mechanisms for expanding CHX use.

Having introduced the CHX 7.1% gel in a pilot district in 2013, Madagascar is one of the earliest countries to be developing a full scale-up plan and the policies and strategies to support it. With such a plan, the Government can work with implementing partners to address one of the leading causes of neonatal mortality.

## **Context**

### **Current situation**

In Madagascar, child mortality remains high despite some improvements over the last decade. According to the last Demographic and Health Survey (2008/9), overall under-five mortality decreased from 159/1000 live births in 1997 to 72/1000 live births in 2008 (ref 8). During this same time period, neonatal mortality also declined, but currently represents 33% of all under-5 deaths.

Per 1000 live births

	DHS 97	DHS 2003/4	DHS 2008/9
Under 5 mortality	159	94	72
Infant Mortality	96	58	48
Neonatal mortality	40	32	24

A contributing factor to high neonatal mortality is the high rate of home deliveries: only 35% of deliveries are done at a health facility and only 44% of all births are assisted by a skilled birth attendant. In addition, despite a high rate of ANC (86%), only 49 % of women actually complete the recommended 4 consultations and 35% did not receive any postnatal care.(ref 8).

Traditional practices are still predominant with regard to cord care, especially for home deliveries. Other substances are used alongside alcohol and it is a common practice to put a bandage on the freshly cut cord. (ref 9). These practices likely increase the risk of sepsis and umbilical infection. Although there are no data on the proportion of infections linked to cord care, it is estimated that the proportion of deaths caused by infections (including sepsis) is 27%. (ref 10)

### **Existing MNCH policy**

There is currently no specific neonatal health policy. However, the National Child Health Policy (2005), the National Reproductive Health Policy (2000) and the National Community Health Policy all includes references on neonatal care .

A Roadmap for Maternal and Neonatal Mortality Reduction (2005-2015) was developed in 2004 with the objective to reduce maternal mortality from 469 to 127 per 100,000 live births and neonatal mortality from 32 to 17 per 1000 live births. (ref 11) The main strategies are increasing access to quality maternal and neonatal care at health facility level and strengthening capacities for better management at community and household level.

Current key interventions related to MNH by the MOH and its partners are: family planning, safe motherhood, malaria prevention during pregnancy, breastfeeding, micronutrient (iron folate) supplementation, Emergency Obstetrical and Neonatal Care (known as SONU) and Essential Newborn Care, and community-based IMCI (Integrated Management of Childhood Illness). Regarding umbilical cord care, the MOH recommends the application of WHO dry cord care procedures in the guidelines for newborn essential care (Ref 12).

### **History and current status of chlorhexidine pilot**

A technical working group that includes the Ministry of Health, JSI/Mahefa, JPIEGO/MCHIP, PSI/M and UNICEF developed in early 2013 a protocol for the introduction of chlorhexidine (CHX) for umbilical cord care as a pilot program in the district of Mahabo in western Madagascar. Mahabo is one of MAHEFA's program districts,

where it is already training and supporting community health workers (CHWs) to manage childhood illness and to provide health services such as family planning.

The pilot intervention has a phased approach, with phase I (4months) consisting of formative research to assess cord care practices, acceptability and feasibility of introducing CHX and to develop CHX brandname and logo; and phase II (12 months) as operational research with the introduction and free distribution<sup>1</sup> of CHX by health workers during ANC visits and by community health workers (CHWs) during home visits. Main targets are pregnant women in their 3rd trimester of pregnancy, with secondary targets for communication including health providers such as midwives and other female family members

To date, with funding from Jhpiego/MCHIP, PSI/M completed the formative research and developed a CHX product brand under the name *AroFoitra*<sup>2</sup>. The CHX product with the *AroFoitra* brandname and packaging (cf annex 3) were imported by JSI/Mahefa from Lomus Pharmaceuticals Pvt. Ltd. (known as Lomus) in Nepal.

The TWG developed a communication plan and key messages for the intended target groups. Communication materials such as radio spots, Mobile Video Unit spots, counseling cards for CHWs and health staff, posters and flyers were developed and pre-tested. JHPIEGO and JSI/Mahefa developed the training curricula on neonatal health, cord care practices and use of CHX for the health workers and CHWs. JSI/Mahefa ordered 300 dolls to assist in CHW training and product demonstration with target audiences.

The official launch of Phase II of the pilot program was done in September 2013 in presence of implementing partners and local authorities. The training of health workers has been completed and *AroFoitra* is already being distributed by health facilities throughout the district. The training of CHWs has been initiated and is still ongoing.

### **Need for rapid scale-up**

An evaluation of the pilot is planned for July 2014. Since, the CHX product efficacy and safety has already been established in other countries, the pilot will only be evaluated for coverage, acceptability and best practices with regard to communication and training and distribution channel.

However, in order to reach the 2015 mortality objectives and given the interests and support for CHX at global level, the MOH and its partners are already preparing for a scale-up. The current status of the pilot already provides sufficient information regarding the model and main issues in implementation and scale-up.

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<sup>1</sup> The protocol for the pilot intervention was developed by the TWG based on the Nepal model following a visit in that country of representatives from MOH and key partners.

<sup>2</sup> *Arofoitra* means "protects the umbilic"

## Strategic approach to achieve scale

### Vision

The vision for this scale-up plan is:

*"To achieve 80% coverage nationally for application of CHX immediately after birth for all deliveries using the most efficient, cost-effective and sustainable approach to ensure maximum impact on neonatal mortality."*

To achieve this vision, the plan will be used for advocacy at all levels—both to facilitate rapid inclusion in Government MNCH policies, and also to define and coordinate donor support.

CHX must fit into the broader Government maternal, neonatal and child health strategy, and thus must be synergistic with the broader vision for those strategies, including supporting institutional deliveries. There is an immediate need for donor support, but the plan envisions inclusion of CHX for cord care as an integral part of the long-term Government strategy for reducing neonatal mortality.

The plan includes activities designed to maximize availability, while fitting into the existing successful systems for commodity procurement and distribution. Hence, the plan includes procurement and distribution through two channels—the existing Government essential drug system, and the successful social marketing approach being used of a number of essential drugs. These two systems combined should allow for the greatest likelihood of universal availability, particularly for mothers in more remote areas who may also be the most vulnerable.

The plan includes a cascade training model that involves training of all health facility staff and ACs ; and orientation of community leaders, future mothers and female family members by the ACs . With the current high home delivery rate, high coverage can only be achieved by including community-based services done by ACs, who will also recommend facility delivery. The plan recognizes the inefficiency of 'vertical' training, and anticipates integration of a CHX training module into existing training at all levels. Thus, CHX can be included with MNCH training, IMCI training, or refresher training for any element of MNCH care.

The plan also envisions an integrated social marketing BCC approach to ensure the highest level of awareness among mothers, female family members and health care workers. With Madagascar's successful social marketing of a number of critical health(FP/RH and IMCI) commodities, CHX can be added as one of the 'menu' items for preventive and curative commodities needed along the continuum of care. With this approach, opportunities for messaging integration will be sought, while ensuring the simplicity of the CHX messages for mothers. In addition, a variety of materials will be used to ensure that health workers, ACs

and mothers understand the importance of CHX and the value in applying CHX for all newborns—as a critical part of routine cord care.

Program implementation must achieve sustained high coverage. The plan includes recommendations on inclusion of a limited number of indicators that are amenable to inclusion in the HMIS (known as SIG) as revision of that system occurs. In addition, the plan recommends inclusion of logistics outflow documentation through both the Government logistics management system and the existing commodity monitoring done for social marketing. However, given the known limitations of these systems, and the lack of assurance that these will provide adequate information on actual use, the plan includes funding for a population-based survey following year 1 of scaling up, and funding for a portion of a national survey at the end of year 3. These would provide the Government with more accurate estimates of coverage based on mothers' stated application, and would avoid a situation of achieving national scale-up only to find low coverage.

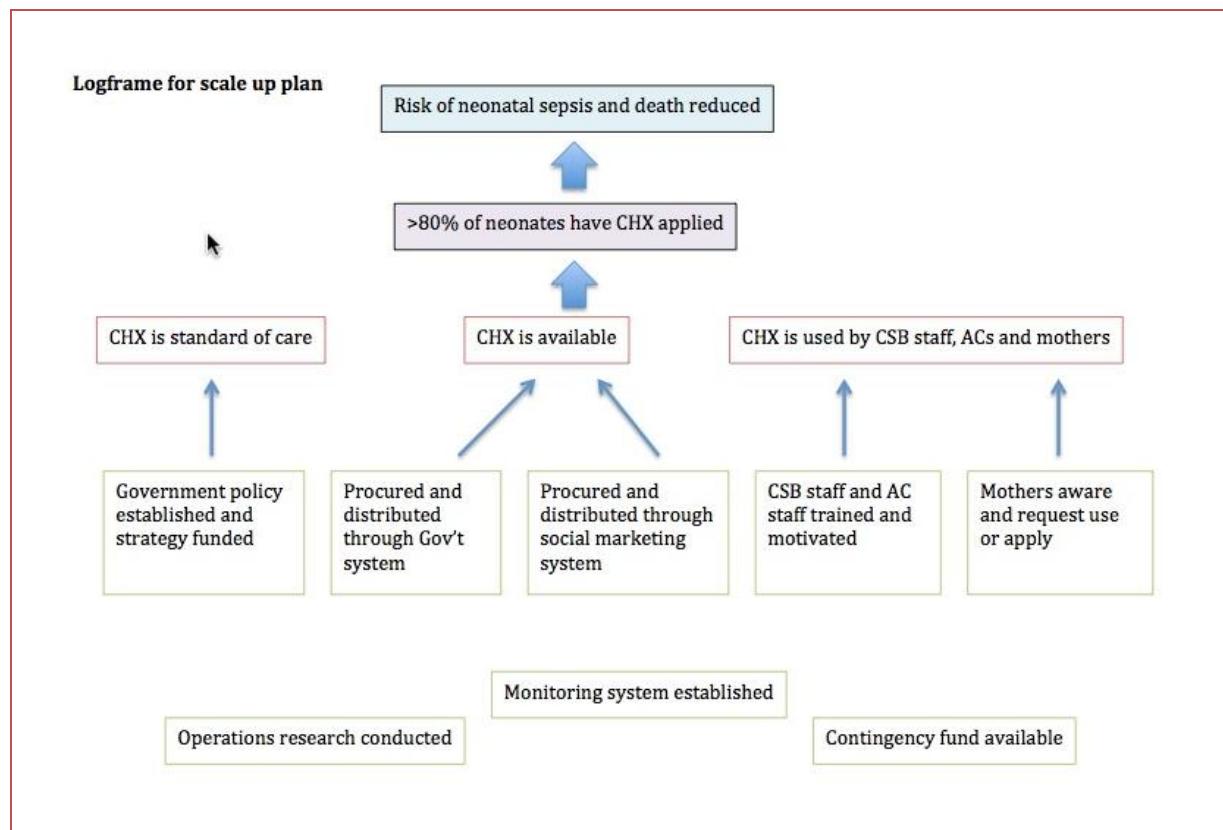
It will take time for Government policy and strategy to change and to generate adequate funding for national implementation. Thus, the plan envisions a phased-in approach, anticipating 3 years to achieve national implementation coverage. The specific details of this phasing-up will require further discussion between the Government, donors and implementing partners to allow integration with the different annual planning schedules. Thus it is not feasible for the plan to recommend specific regions for each year of the scale-up plan. For this reason (and recognizing that there are significant cost differences for each region), the plan only provides an estimate by year based on an average cost per region. Due to the urgency of inclusion of CHX in several policy documents now undergoing revision, the plan has included a detailed Year 1 workplan.

### **Activity goals for scale up plan**

To achieve the vision described above, the plan includes three key objectives:

1. Establish CHX as the standard for cord care
2. Ensure that CHX is available
3. Ensure that CHX is used by health facility staff, ACs, and mothers for cord care management for all neonates

Each objective includes strategies that define specific activities designed to achieve each objective. These fit within the logical framework below:



Based on this logframe, a proposed workplan for Year 1 along with estimated costs for each activity are included in Annex 1. While the indicators and timeline for Year 1 are suggested, the Technical Working Group has the responsibility of refining these based on further discussions with all partners. Since successful implementation of the plan will require strong collaboration and coordination among partners, it is important to have agreement on responsibilities and measures of progress.

The activity goals are designed to reflect the successful implementation of this scale-up plan. As CHX is incorporated into Government MNCH strategies, social marketing strategies and related systems, long term goals and measures of progress will need to be included in these plans. As with other MNCH interventions, overall progress will be measured by coverage—in this case application of CHX for all neonates—monitored by routine systems, and assessed by periodic population-based measures. The implementation of the plan will be successful, with the greatest contribution to reduction in mortality, if high coverage is achieved.

Details on the various strategies and activities are included in the sections below.

## Key Strategies

### Advocacy and Policy Evolution

#### *History of CHX policy development and discussion*

Regarding umbilical cord care, the MOH recommends the application of WHO dry cord care procedures (ref 12). However, the majority of health staff still uses a liquid alcohol formulation for cord care at facilities (ref 9). The plan assumes that the introduction of 7.1% CHX as the new standard of umbilical cord care may not require an extensive revision of all MNCH policies, strategies and other documents - which may take a lot of time. Whenever a revision is planned, it represents an opportunity for CHX to be included. Nonetheless, the plan recommends holding policy development workshops that will spur the process. Once the MOH has established CHX as the new standard of umbilical cord care, it needs to be disseminated to all levels beyond a simple ministerial note. To that end, the plan recommends dissemination meetings at national and regional levels.

Before the pilot start-up, the TWG sought approval from the MOH and the research was approved by the Ethical Review Board, which was granted. A temporary authorization was also obtained from the National Drug Enforcement Agency (DAMM) to be able to import CHX as a gel formulation from Lomus, Nepal for the pilot project. In order for partners to order CHX for the scale up, product registration is a prerequisite. The process for the “Autorisation de mise sur le marché” (AMM) will take 4-6 months. The plan assumes that this process will be completed successfully before scale-up plan is initiated.

In addition, in order for the Government to procure CHX (usually through SALAMA) for the public sector, the product must be on the national Essential Medicine List (EML). According to the feasibility study conducted in May 2013 (ref 13), chlorhexidine is already included on the national EML, but without a specific formulation. The product currently used in health facilities is chlorhexidine 20% in liquid preparation—a different formulation than the proposed 7.1% w/v gel formulation. To ensure that CSBs order the right product, it will be important that the exact formulation and dosage for CHX used for cordcare is included in the list of commodities routinely procured by the CSBs. That process needs to be clarified with the DPL/DAMM. This is also an opportunity to clarify the list of medicines that CHWs can manage and store.

A CHX technical working group was established in 2012 that includes the Ministry of Health, JSI/Mahefa, Jhpiego/MCHIP, PSI/M, USAID and UNICEF. Those partners collaborated for the pilot project in Mahabo. For the scale-up, it may be important to include in key discussions other partners from donor organizations and technical agencies.

Finally, the implementation of the national scale up plan will require a focal point who is responsible for coordinating all activities. Ideally, this focal point would be a senior staff at the MOH/DSEMR to ensure cooperation and coordination among partners and key stakeholders. However, since the tasks are likely to require a person full-time for the first

year, and it is advisable to recruit a consultant who will work under the direction of the MOH/DSEMR. In year 2, the responsibility of coordinating the scale-up should be fully taken by the DSEMR. To that end, the plan includes a budget line for this activity.

#### *Recommended activities for scale up*

##### Advocacy

- Identify a national focal point who will ensure the coordination of the scale up process. (*The focal point should be the DSEMR and it is the department's responsibility to designate this person within their department.*)
- Recruit a CHX consultant to support the scale-up process and who will work closely with this department and under the leadership of the DSEMR.
- Organize an advocacy workshop in order to raise awareness about umbilical cord infections and CHX – this will be an opportunity to present the pilot and to invite a renowned scientific on CHX.
- Organize an advocacy meeting for donors/partners to raise funds for the scale-up
- Organize a national event to launch the scale-up of CHX distribution in order to raise awareness about umbilical cord infections and the availability of CHX

##### Policy development

- Ensure the registration of CHX (7.1% w/v digluconate gel) to obtain the AMM
- Ensure that CHX (7.1% w/v digluconate gel) formulation is part of the national list of medicines/commodities procured by CSBs.
- Conduct a workshop to develop the policy recommendations on CHX to ensure that CHX is introduced as a standard for umbilical cordcare in all MNCH policies, strategies and documents
- Establish and disseminate a MOH note/circular on CHX for cordcare
- Conduct policy dissemination meetings on CHX policy at central and regional level for health personnel from public and private sector and related associations
- Revise EmONC protocols, guidelines for health facilities and training curricula (including preservice training) to include CHX for cordcare
- Use pilot findings to refine CHX policy, and or scale-up implementation strategies and activities as needed
- Work with DSEMR/DDS/DAM/DPL to establish the national legal framework for CHWs to procure and manage medicines for community-based services

#### **Commodity Procurement**

Commodities must be available if coverage goals are to be achieved. Hence establishing an efficient method for procuring CHX is critical. In discussions with different stakeholders, there are a variety of options for both procurement and distribution.

Chlorhexidine comes in a variety of preparations, and is currently available as a 20% solution for antisepsis. The preparation needed for cord care is a 7.1% w/v chlorhexidine digluconate, which can be either a liquid or gel preparation. Both have the same

effectiveness although scientific evidence shows that the gel adheres rapidly on the skin. A client preference study done in Madagascar showed a strong preference for the gel preparation, which is being used in several countries. [ref 9]

While procurement from a local producer is optimal, a technical review of the capacity for production in Madagascar was completed in 2013, and concluded that local manufacture is currently not possible. [ref 13] Furthermore, with the preference for a gel preparation, there is currently a single manufacturer (Lomus-Nepal), which supplied single application tubes for the pilot in Mahabo. This manufacturer has been assessed by an international team and found to have good manufacturing practices. [ref 14] The company currently supplies CHX for several other countries. Alternative suppliers may be emerging from other countries, including India and China. The Lomus preparation has an estimated shelf life of 3 years.

Health commodities are currently procured in several ways. First, the Government procures through a contracting process with the parastatal organization SALAMA, which completes tender, places the order, stores the commodity, and either supplies based on regional or district orders, or distributes to district centers. Second, several implementing partners manage a social marketing scheme involving a number of commodities distributed through a series of regional warehouses, depots, and points of sale. This procurement is done separately and managed independently. Some partners, including UNICEF, may also procure through other mechanisms—such as the UNICEF Copenhagen procurement office.

The plan recognizes the importance of ensuring commodity availability for CHX and related materials. Thus, the plan recommends taking advantage of both mechanisms for procurement—through the Government system, and through the social marketing mechanism. For both systems, procurement for the moment is likely to be from Lomus, which can supply adequate quantities of the preferred single application gel preparation. However, SALAMA's regulations about sole sourcing may delay procurement for the public sector. It may be advisable that for the first year of scale up, partners procure directly CHX for both public sector and social marketing distribution.

One further consideration is whether a multi-application liquid preparation for use at facilities may be less expensive. Many facilities currently use a liquid alcohol preparation for cord care. Should cost for a liquid CHX preparation be substantially less, it may be worth considering. However, there are disadvantages to considering a second formulation. First, this may generate some confusion among clients—who may be exposed through community efforts to the gel preparation, but then see a different preparation at facilities. Similarly, having two preparations may complicate training and BCC efforts, and create difficulty with monitoring of commodity outflow. This plan assumes that the potential cost savings are outweighed by the additional complexity—and thus recommends a single preparation. However, the plan includes operations research on this topic.

The plan calculates commodity needs based on the Government annual report estimate of expected pregnancies (recognizing that some pregnancies will not result in a live birth).

The plan assumes a coverage goal of 80%, and includes a 10% overage to cover damaged commodities and other system losses. The plan estimates the amount needed for each system to be 40% through the public sector and 60% for the social marketing system—based on current estimates of facility use for delivery. The plan estimates an annual need, with the first year anticipating program implementation using both systems in a third of the country (about 8 regions), with the entire country covered by year 3. However, the number of regions per year may change depending on the readiness of partners to scale up in their intervention areas.

Ideally, commodity procurement will be done in an integrated fashion with other commodities for both Government procurement and procurement for the social marketing system—with CHX included as one of the commodities managed.

#### *Recommended Activities for scale up*

- Ensure the registration of CHX (7.1% w/v digluconate gel) to obtain the AMM
- Ensure that CHX (7.1% w/v digluconate gel) formulation is part of the national list of medicines/commodities procured by CSBs.
- Mobilize funds to procure a single formulation for cord care: 7.1% w/v chlorhexidine digluconate gel for single application
- Procure CHX as one of the Government's essential drugs through the existing system of procurement facilitated by SALAMA—to provide an estimated 40% of need
- Procure CHX as one of several commodities managed through a social marketing approach—to provide an estimated 60% of need

## **Distribution system**

### *Model for pilot*

Following the Nepal model, the pilot is based on a free distribution of CHX through two channels: health facilities and community health workers (CHWs). Pregnant women who attend the health center for their ANC visits are provided information and *AroFoitra* (CHX) during their 3rd trimester of pregnancy.

The CHWs who are already supported by the MAHEFA program on c-IMCI, FP interventions and counselling for birth preparedness also provide pregnant women with information and CHX during home visits. However, they encourage women to deliver at the health center where CHX is also available.

### *Rationale for a model different than the current pilot*

There is a consensus among partners that a free distribution model may not sustainable for a scale-up at national level. Madagascar has a long history of user fees for drugs in the public sector called the FANOME system and people currently pay for alcohol, gaze and other items used for cord care. There is also a dynamic social marketing system offering a

large range of child health products at low (subsidized) cost to the consumer and which is officially recognized as part of the National Policy for Community Health (Ref 15). Thus, the recommended distribution strategy for CHX scale up is to take advantage of both existing systems which are considered as complementary.

#### *Public sector distribution: SALAMA and FANOME system*

The distribution of essential drugs in the public sector relies on SALAMA, the central procurement agency of the MOH. SALAMA is an autonomous non-profit organization and finance its activities from the resources generated by the sales of drugs. SALAMA is in charge of procuring, storing and distributing drugs and health products up to the district level (to the PhaGDis- wholesale pharmacy) and to hospitals. In general, SALAMA delivers ordered drugs on a quarterly basis to the PhaGDis. The health center PhaGComs (community-run pharmacies) are responsible for collecting their supplies from the PhaGDis and ensuring their transportation to the CSB. Both the PhaGDis and the PhaGCom receive a margin on the sales of drugs to finance their activities. Because of the crisis, this margin has now been reduced from 35% to 15% for both, which is apparently not sufficient to cover their actual costs. ACs are also able to get commodities from the CSB they are attached to.

Using SALAMA for the scale up of CHX will ensure the sustainability of the program as it is building on an existing system, and the user-fee system allow to cover some costs.

However, weaknesses of this system include a rigid ordering and delivery system, irregular supply of drugs and stockouts at the CSBs, and the low attendance rate in the CSBs.

Although there is no evidence that users' fees may influence coverage, it is recommended to set price very low for CHX . In addition, a system should be put in place to manage the revenues from CHX and ensure the sustainability of procurement/resupply after the 3-years scale up.

Strengths	Weaknesses	Opportunities	Threats
Sustainability - Building on existing system - Cost recovery	Rigid ordering system: now every 2 months with quarterly delivery  Low attendance in health facilities  Irregular supply at CSBs	Strengthening of Health System	User fees may influence coverage

#### *Social marketing: private sector and community-based distribution*

Since 1999, PSI/M has social marketed a large range of health products that are available at low cost to the consumer. Products include condoms, contraceptives, STI Kits, long-lasting insecticide-treated nets, home based water treatment solution, a prepackaged treatment kit for malaria, a prepackaged kit for the treatment of pneumonia, a combined zinc/ORS kit for the treatment of diarrhoea and a recently introduced micronutrient powder (MNP).

Socially marketed health products are distributed throughout Madagascar through three channels - commercial, pharmaceutical, and community-based. The nationwide network includes 317 authorized wholesalers and 14,000 retailers, 13 pharmaceutical wholesalers, 220 pharmacies and 2000 licensed retail shops ("dépôts de medicaments") and about 15,000 ACs who have been trained in the social marketing system and who are supported by local NGOs. This social marketing system delivers products mainly to wholesalers, but ensures that all vendors are always supplied through a pull/push system. To ensure that ACs are regularly supplied with products, PSI/M has developed a network of community-based private wholesalers (also called PA) located at the commune level. ACs are directly linked to those supply points, which purchase products from PSI/M distribution from regional warehouses. For some products (contraceptives, MNPs), CHWs have also the choice to resupply from CSBs. A study on willingness to pay demonstrated that clients are willing to pay for valued commodities [ref 9]. It is recommended that the price is the same as in the public sector. Usually, sales revenues in the social marketing approach are considered as program income and are utilized for product procurement or program activities depending on donors.

This established nationwide distribution system (using the private sector and NGOs) is the greatest strength of social marketing and definitely contributes to increasing the availability of essential health products in the country. According to a 2006 TRAC study, 63% of the treated malaria bednets (LLINs) owned by households were from the private sector and social marketing system. [ref 16] However, the coverage of community-based distribution currently does not fully cover all regions, and the system relies on NGOs for AC support in the use of the social marketing system.

Strengths	Weaknesses	Opportunities	Threats
Health commodities distribution by ACs defined by the National Community Health Policy	Uneven distribution of community activities	Synergy with other community-based health activities	Price may influence coverage
Nationwide distribution presence	C-IMCI activities by ACs delayed by validation process in pilot region	Willingness to pay among target groups	
Partnership with private sector	Reliance on NGO partners/donors for AC training and support	Pricing products motivates ACs and incites use (quality image)	
Network of trained ACs distributing products for FP and C-IMCI			
Push/Pull system ensuring availability of stock -thus, very few stock outs			

### *Rationale for dual system*

Since only a fraction of pregnant women actually delivers at health facilities, it is important that CHX is available through other channels in order to reach those who deliver at home. A distribution system using both public sector and social marketing (private sector and community-based) is likely to achieve equitable access and maximum coverage.

### *Recommended Activities for scale up*

- Establish distribution of CHX through both Government and social marketing channels starting in year 1
- Develop a price structure for both systems. The structure should include attractive margins for the various distribution levels and the price should be the same at the consumer level to avoid competition between the channels.
- Organize a workshop with partners to validate price structure (and eventually other elements of distribution system)
- Identify priority regions and districts for each year /phase
- Conduct an assessment of the price and affordability of CHX after Year 1 of scale up
- Work with the MOH to develop the legal framework for supply points and ACs to distribute and store health commodities.

#### Public sector

- Develop a system for the management of revenues generated by CHX distribution in the public sector
- Determine the allocation of CHX by districts following the prioritization established by the MOH/TWG.
- Ensure the storage and transportation of the products to district level
- Ensure the storage at district level and transportation to CSBs

#### Social Marketing

- Ensure the storage and transportation of the products to regional warehouses
- Determine the startup stock for ACs based on experience from the pilot
- Deliver and resupply CHX to wholesalers and retail outlets in the pharmaceutical sector, and to community supply points according to demand, in the regions or districts identified for prioritization

### **Training and Capacity Building**

Chlorhexidine for cord care is a new intervention, which has only been introduced in one pilot district. To achieve high coverage, all health workers must be aware of this intervention, and understand CHX application. In addition, mothers, community leaders, private practitioners all must be aware of this change in cord care.

The plan envisions a standard cascade training approach, but with CHX introduced into existing training or refresher training rather than as a stand-alone vertical training. The basic elements of CHX training are relatively simple, and there are basically no significant safety issues of concern. Thus, based on the lessons learned and best practices from the pilot, a short module on CHX can be easily added to IMCI or MNCH training at all levels.

The plan includes a master training—to generate a small core group of master trainers. These master trainers will assist with other MNCH/IMCI training by introducing the CHX element at the district level—thus creating a cadre of trained district staff who can include the CHX in upcoming CSB staff and AC trainings.

All health workers and ACs will in this way be trained in application of CHX. It is critical to ensure good quality training at the AC level—since the majority of deliveries occur at home, and the AC is most likely to interact with mothers. CSB staff and ACs together can orient community leaders, private practitioners and mothers. These educational efforts will be complemented by the social marketing and BCC efforts outlined in the plan.

The plan recognizes that for some districts, with little support, the current activity level of ACs is very limited, and thus there may not be the capacity for the community component of CHX introduction. For such districts, coverage could be severely limited by this gap. Thus, the plan includes some contingency funds to cover extra efforts to build capacity of ACs and supportive NGOs for these districts.

The pilot being undertaken in Mahabo district provides valuable experience with regard to training and training materials. The pilot has developed and tested training materials for use at all levels, including pictorial guides. The pilot training has included a doll—for use in demonstrating how to apply CHX. This doll can be used for all training levels. Ideally, the doll would be available to ACs for use in demonstrations to mothers. Some modification of the doll may be needed to reduce the cost for the AC level—as this is a costly element of the training and not applicable for other MNCH activities.

For the longer term, CHX for cord care will need to be included in all related health curricula. However, revisions for educational curricula are beyond the scope of this plan, and it is anticipated that any upcoming revisions in school curricula will be based on current Government policy—and thus with a policy endorsing CHX, this change will be included.

#### *Recommended Activities for scale up*

- Adapt training materials used in pilot for use at scale
- Establish a cadre of master trainers through a MTOT
- Include CHX with all MNCH/IMCI and related training as a module for cascade training to the community level

## **Social Marketing and Behavior Change Communication**

### *Review of Social Marketing approaches for other commodities*

For all socially marketed products, activities evolve around the marketing mix or the four Ps (product, price, place, and promotion). The product is usually branded with a Malagasy name and logo that appeal to target groups and around which a brand strategy is developed. For the CHX pilot, the brand name *Aro foitra*<sup>3</sup> and a logo were developed and pretested. Branding increases product awareness and recognition.

To promote behavior change and create an informed demand, generic and branded communication campaigns are conducted. Multiple media/communication channels are used to maximize message retention and comprehension: radio, TV, mobile video units, printed materials(flyers, posters), and interpersonal communication through ACs and/or health staff. Finally, all points of sale (including health facilities) would have branded materials to allow consumers to identify that the product is available there.

The same marketing approach was used for the CHX pilot, for which many communication materials have already been developed, including radio spots, Mobile Video Unit (MVU) spots, posters and flyers. Counseling cards were also developed to help ACs and/or health staff conduct their communication activities. In addition, 300 dolls were purchased to assist with AC training and product demonstration with mothers. Most of these materials can be used for the scale-up. However, some may need update and or modification, including finding a way to reduce costs for the doll.

### *Interplay between social marketing and BCC—brief discussion for Madagascar context*

For the pilot, a detailed communication plan was developed to reach the different intended target groups. Essentially, the main messages for pregnant women are to deliver at a health facility and to use CHX to reduce health risks for their baby. Those messages are now being delivered across all channels, including the ACs and health center staff for whom trainings included a communication component with the key messages and communication techniques. Further coordination of communication activities will be needed among partners in the case of an integrated approach with other MNCH activities for the scale up.

For the phased scale up, the coordination of distribution and communication activities will be very important to ensure that promotion is done when the product is available in a given area. Since there is a limited number of MVU teams, it would be important for example to coordinate with local partners (local NGOs, CHWs, health staff) to support their activities in priority areas.

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<sup>3</sup> The brandname *Arofoitra* was registered by PSI at OMAPI (office of intellectual property)

### *Recommended activities for scale up*

- Mass media
  - Produce and pre-test 2 new radio spots (to be switched with existing ones) and adapt in dialects as necessary
  - Broadcast radio spots on national and local radios
- Print media and educational materials
  - Print 6,000 posters per year for 3500 CSBs and 2,500 points of sale (poster has already been developed for the pilot)
  - Print about 2 million pamphlets over 3 years to be distributed to pregnant women (pamphlet has already been developed for the pilot)
- Interpersonal communication
  - Develop and pretest a 30min video on maternal, neonatal health and use of CHX for umbilical cord care to be broadcasted during Mobile Video Units (MVU) sessions, to complement the existing video spot.
  - Conduct regular MVU sessions in areas identified as priorities with local partners (local NGOs, CHWs, health staff)
  - Print jobaids to be distributed to health facilities staff and ACs (counseling card and curriculum have already been developed and updated for the pilot)

### **Monitoring and Evaluation**

The long-term vision for scaling-up CHX, is that this intervention becomes part of the standard of care, and thus incorporated in health services at all levels, by all pathways. Thus, CHX should be available in pharmacies and licensed retail shops (dépôts de médicaments), Government facilities, and from ACs. This “all avenues, all partners, all opportunities” approach should be helpful in achieving high national level coverage.

The plan calls for monitoring progress with scaling up in several ways. First, as a commodity, the ‘outflow’ or distribution of CHX should be monitored in the same way as other commodities. Thus, CHX should be included in the Government’s logistics management information system as a routine commodity. Similarly, the outflow through the social marketing system should record the CHX distributed to regional warehouses, and the quantities ordered and distributed to peripheral supply points. Commodity outflow through these two systems will provide an estimate of gross availability—as a reflection of use.

Second, CHX will be included as an intervention to be routinely recorded in the Government health system. Ideally, provision of CHX to mothers coming to facilities should be recorded in patient registers, and thus included in the existing HMIS reporting system or SIG. However, modification of the SIG for a single intervention is not realistic. For the immediate situation, a separate recording form to record provision of CHX to mothers will be needed, with the anticipation that with the next revision of SIG, CHX will be included. Similarly, ACs should record the CHX they distribute to mothers on their storage sheet and

neonates register—so this can be added into the overall CHX provision through the health system. Commodity provision through the health system will provide an estimate of client use.

However, there are known limitations to both of these recording systems—and neither will provide an accurate measure of actual use, or true coverage. Actual use can be assessed for facility deliveries and postnatal visits, but with most deliveries done at home and the low postnatal visits rate among population, overall coverage can only be assessed by surveying mothers.

There is currently no experience with a level of actual use that can be achieved through the plan's proposed approach. Thus, there is a need to assess actual use as the plan progresses to allow for improvements that will insure optimal coverage. Without such an assessment, scaling up could be completed only to find low true coverage—that is, that few mothers were actually using CHX.

The plan recommends reducing this risk by including a population-based survey of regions having completed the introduction following Year 1 of introduction. While such a survey is costly, it is justified on the basis of needing to understand whether introduction is resulting in use by the majority of mothers (including its use by facility workers for mothers delivering in facilities). Ideally such a survey would serve multiple purposes for the broader MNCH services. Following national level scale-up (Year 3), it would be useful to include CHX in a national survey that covers a range of MNCH interventions. This could be through a DHS or UNICEF MIC survey or other existing survey.

### **Proposed monitoring structure**

<b>Indicator</b>	<b>Numerator</b>	<b>Denominator</b>	<b>Source</b>
% of recorded live births at facilities with CHX applied	# CHX recorded as applied by CSB staff	# live births recorded	CSB register
% of expected pregnancies receiving CHX	# CHX distributed by AC to pregnant women	# expected pregnancies	AC register and monthly reports to CSBs
% of expected pregnancies for whom CHX available	# CHX distributed (through SM and Gov't distribution)	# expected pregnancies	Government LMIS and SM records
% of recently delivered women stating use of CHX for newborn cordcare at last delivery	# recently delivered women stating use (stratified by those using within 1 hour of delivery)	# recently delivered women in sample	End of Year 1 survey
% of recently delivered women stating use of CHX for newborn cordcare at last delivery	# recently delivered women stating use	# recently delivered women in sample	Periodic DHS, MICs or other national survey after national scale up

In preparation for the pilot, a number of qualitative studies were completed, including assessment of cord care practices, and acceptability of CHX. In July 2014, after one year of introduction, the pilot will also be assessed to evaluate the effectiveness of the distribution channels in achieving CHX access to and coverage. It may be useful to assess client perspectives on the introduction of CHX with regard to program implementation. The plan includes a qualitative assessment end of Year 1 to help understand program implementation issues, potential constraints to use, and overall perspectives among mothers on the introduction of CHX.

As an additional aspect of monitoring, there is a clear need for supportive supervision for the introduction of a new intervention. Recognizing that supervision is often weak, the plan includes supervisory activities both from the central level to districts, and from districts level to CSBs or commune levels. Ideally, supervisory visits would be integrated visits—covering a wide range of MNCH issues.

As an additional element of supervision, the plan includes a ‘follow-up after training’ activity designed to both assess the effectiveness of training, but also to provide data on changing behaviors. This model has been used successfully in other countries, and involves a small team visiting a district within 3 months after training is completed. The team visits a selection of CSBs, ACs and communities, and using a tool designed around the training elements, assesses changes related to that training. This helps uncover areas of weakness in training, behaviors that are particularly difficult to change, and gaps in program performance.

#### *Recommended Activities for scale up*

- As an interim measure, include recording of CHX used for deliveries at CSB, for attended births and distributed by ACs as part of SIG reporting, with the expectation that SIG revisions will include CHX
- Include recording of CHX distribution to district centers as a component of the logistics management system
- Include recording and reporting of CHX distribution to pharmaceutical wholesalers and points of supply and a record of sales to pharmacies as a component of the existing social marketing system
- Complete an assessment following Year 1 that includes a population-based coverage survey and qualitative client survey in regions having completed CHX introduction
- Include CHX as part of routine supervision to CSB and ACs
- Include a follow-up after training activity to assess training effectiveness and data quality on changing behaviors.

## Contingency Funding

The plan has budgeted for several activities that may require special attention. These are categorized as contingency funds—since they may not be needed. However, for each, allocation of funds could be critical to the overall scale-up effort.

The plan recognizes that there may be significant variations in the overall implementation capacity between districts. This may be particularly true for community-based activities—which in part depend on the motivation and activeness of the AC, and on the activity of local partner NGOs. Districts with limited community-based implementation capacity may also be the districts with the highest home delivery rates—thus making them the most vulnerable districts with regard to achieving adequate CHX coverage. Thus the plan includes some contingency funding to provide extra support to improve community-based services and the capacity of ACs and local NGOs for a selection of districts.

Adverse events have not been reported for CHX. However, several other programs have suffered setbacks due to an association between the intervention, and a perceived adverse event—even when the adverse event is not shown to be associated with the intervention. This association may create a perception among mothers or the broader community, which may then be expressed as concern about the intervention. Identification and management of such events are included as part of the Government's drug safety surveillance system. To complement this, the plan includes a small budget for management of such an event. Management may include having a recognized expert assess the event, and then help calm the community as well as ensuring an adequate educational response in the media to ensure that the population does not lose confidence in the intervention.

### *Recommended Activities for scale up*

- Starting in year 2 of scale-up, develop a special capacity building approach for districts with limitations in AC and NGO capacity to ensure adequate community-based CHX distribution and use
- Establish a procedure for mounting a rapid response for any adverse event

## Operations Research

Introduction of CHX is likely to generate implementation questions, and questions related to efficiency. Since it is anticipated that CHX will become a routine part of MNCH service delivery, operations research that can improve long-term sustainability and reduce costs is a good investment. Thus, the plan has included some additional budget to cover some anticipated research activities.

As CHX is adopted by more countries, it is likely that there will be improvements in the preparations available, and potentially significant reductions in cost. While the current preference is for a single dose gel preparation, a cheaper multi-dose dispenser for facilities may represent a significant savings. One operations research project could explore the cost and use of an alternative formulation in facilities—assessing ease of use, wastage and client

perceptions in light of continued gel use at the community level. The plan includes a small budget for such research.

A second operations research question relates to determination of coverage. Currently, coverage assessment depends on an interpretation of distribution, or a population-based survey of recently delivered mothers—with the latter providing the best coverage estimate. Often population-based estimates do not disaggregate data below the regional level—thus making it difficult for districts to know what coverage they have achieved. This difficulty with coverage assessment applies to many MNCH interventions—and thus alternative robust methods would have broad applicability.

To address this gap, some alternative coverage assessment methods may be useful. One method involved capitalizing on the high immunization coverage many countries have achieved—particularly for BCG. In Madagascar, the 2009 DHS reported a BCG coverage of 83%. This means that the vast majority of mothers bring their child to a facility for BCG, and a sample of those women will be reasonably representative of the whole population of recently delivered women. Administering a carefully developed questionnaire to these women could be a mechanism to ascertain coverage for an intervention such as CHX (as well as for other MNCH interventions requiring maternal behavior change). The plan includes a small budget for exploring this new method in 1 region.

#### *Recommended Activities for scale up*

- Complete operations research on alternative formulations of CHX, including a multi-dose liquid formulation for use at health facilities--reviewing cost, client perceptions and potential barriers to optimal use
- Research alternative coverage assessment methods including a sentinel surveillance system using questionnaires administered to recently delivered women bring infants for BCG immunization

### **Phased scaling-up**

CHX for cord care is a relatively simple intervention, and should be easily accepted as a component of the broader MNCH/IMCI program. Since introduction of CHX lends itself to easy integration with other programs (integration of training, , integration of commodities distribution, integration of social marketing and BCC, integration of supervision and monitoring), the plan anticipates that it should be possible to achieve national scale within 3 years.

With limitations in Government and implementing partner planning and budget schedules, the plan recommends phased introduction of CHX, covering for example 1/3 of regions (8 regions ) in the first year, and 7 regions in each of the following years. Ideally, phasing would be done based on specific criteria—choosing the regions of greatest need—for example, highest neonatal mortality—first. With that regard the “audit des décès maternels” implemented with UNFPA could be used to estimate neonatal mortality figures

by regions. Nonetheless, the selection (and number) of regions for each year of the scale-up will more likely be based on current Government and donor plans, and will depend on the readiness of partners to scale up in their intervention areas.

Several implementing partners currently work in selected regions only. USAID and UNICEF, for example, have selected regions for support of focused MNCH activities. Thus it is likely that partners will prefer to introduce CHX in regions where they have ongoing activities into which to integrate this new intervention. Thus, the plan has not recommended specific regions for a phased in approach—but rather anticipates expanding regional coverage on an annual basis, based on Government/partner discussions.

For each year, it is anticipated that the series of activities included in the plan will be implemented for the selected regions for the year. In Year 1, much of the advocacy work will be completed—laying the ground work for establishing CHX as the new standard of care, and gaining commitment from donors to support its introduction. For selected regions, procurement will need to be promptly undertaken, so distribution is completed prior to the completion of training. In Year 2, new regions will be included, but ongoing activities will need to be continued in Year 1 regions. Ongoing activities are assumed to be routine—with training completed, and monitoring and supervision integrated into existing systems. Thus, the plan has not included a budget for these ongoing routine activities—though it does include a budget for commodity procurement and distribution for all districts for each of the 3 years.

## **Role and responsibilities**

The scale-up plan will be successful if there is a shared commitment to the vision, with all stakeholders committed to their role. The following roles are anticipated:

### *MOH*

The MOH/DSMER should lead the process of scale up and oversee program implementation as appropriate. Their responsibilities in the scale up process include:

- Facilitating the registration of the gel formulation and inclusion among the drugs procured and distributed through the Government system
- Setting up and leading a national coordinating committee including stakeholders , donors and key partners
- Ensuring that CHX for cord care is introduced as a standard in all MNCH policies, strategies and documents disseminated at all levels
- Facilitating the procurement of CHX with regard to administrative procedures and customs clearance
- Mobilizing resources for the scale-up
- Facilitating the participation of health staff and the use of public health infrastructure for program implementation

- Facilitating the development of a framework for PA and AC to detain medicines

#### *Donors/Partners organization*

The role of donors and partners organizations is to provide financial and technical contributions towards the scale-up as well as:

- Sitting on the coordinating committee
- Conducting supervision visits as appropriate
- Mobilizing resources for the scale-up, including identifying new funding opportunities and presenting lessons from Madagascar in international fora
- Sharing data available to monitor the recommended CHX indicators

#### *TWG*

The TWG was the initiator of the CHX introduction in Madagascar. It may incorporate other key partners and then transform itself in a coordinating committee that will oversee the scale up process under the leadership of the MOH. However, the MOH may appreciate having a small core group that can meet upon demand and provide technical recommendations.

#### *Resources mobilization strategy*

The current plan calls for donor coordination and advocacy on the part of the Government to secure funding to supplement the Government's contribution for scaling up. Donors are likely to have different interests and capacity for committing funds, and this process will need coordination. Given the global interest in CHX and international agency mobilization of funds, this approach is reasonable.

There are, however, alternative methods which may be useful to explore. There may be grant funds available that could cover the bulk of the scale-up budget (for example the USAID/Gates Grand Challenge grants). Such a mechanism has been used in other countries, and could be attempted in Madagascar.

## **Assumptions and Risks**

The scale-up plan makes some assumptions with regard to the expectations for implementation. These include:

- Government policy is modified to include CHX as the new standard of care for all newborns born at home or in facilities—thus permitting the initiation of scaling-up
- 7.1% w/v chlorhexidine digluconate is registered before initiation of scale-up
- 7.1% w/v chlorhexidine digluconate is accepted as one of the essential commodities that the Government procures and distributes
- 7.1% w/v chlorhexidine digluconate is accepted in the menu of commodities managed through the existing social marketing system

- Once included within the Government's MNCH strategy, CHX is accepted as a commodity to be monitored through the existing SIG and LMIS and thus included with upcoming modifications
- There is a consensus among Government and implementing partners on CHX having a small (subsidized) client cost—thus allowing it to fit within existing systems
- Funding is available from Government and donor support

There are a number of risks that could threaten the implementation of this scale-up plan. Political instability could threaten the systems needed to initiate the scale up, making implementation impossible. Funding may not be available from the Government or donors, or may be inadequate to cover the entire country. In spite of preliminary study results, mothers may decide not to use CHX, or some adverse event or other influences may create concern among mothers that could reduce coverage. Limitations in supervision, staff motivation, AC capacity and educational efforts may prevent achievement of optimal coverage. The price of CHX could potentially be an impediment to achieving optimal coverage, particularly among the most vulnerable families. These and other risks could impair coverage, and thus reduce the impact on mortality.

## Annex 1: Summary Budget

Objectives, Strategies and Activities	3-years Budget in USD
<b>Objective 1: Establish CHX as the standard for cord care</b>	<b>48 615</b>
<b>Strategy 1.1:</b> Establish policy and secure funding for implementation of scale-up plan	48 615
<b>Objective 2: Ensure that CHX is available</b>	<b>1 103 923</b>
<b>Strategy 2.1:</b> Procure and distribute CHX through Government essential drug logistics system	427 628
<b>Strategy 2.2:</b> Procure and distribute CHX through existing social marketing system	676 295
<b>Objective 3: Ensure that CHX is used by CSB staff, ACs and mothers</b>	<b>1 973 304</b>
<b>Strategy 3.1:</b> Integrate CHX into all MNCH related training	1 104 798
<b>Strategy 3.2:</b> Include CHX in social marketing approach, and initiate a comprehensive BCC strategy	396 500
<b>Strategy 3.3:</b> Include CHX in SIG and Logistics monitoring, and in periodic coverage assessments	410 724
<b>Strategy 3.4:</b> Reduce capacity gaps in vulnerable districts and manage emergency needs	29 842
<b>Strategy 3.5:</b> Complete operations research to increase implementation efficiency	31 440
<b>TOTAL GLOBAL BUDGET</b>	<b>3 125 841</b>

## Annex 2 : Workplan and Budget for Year 1

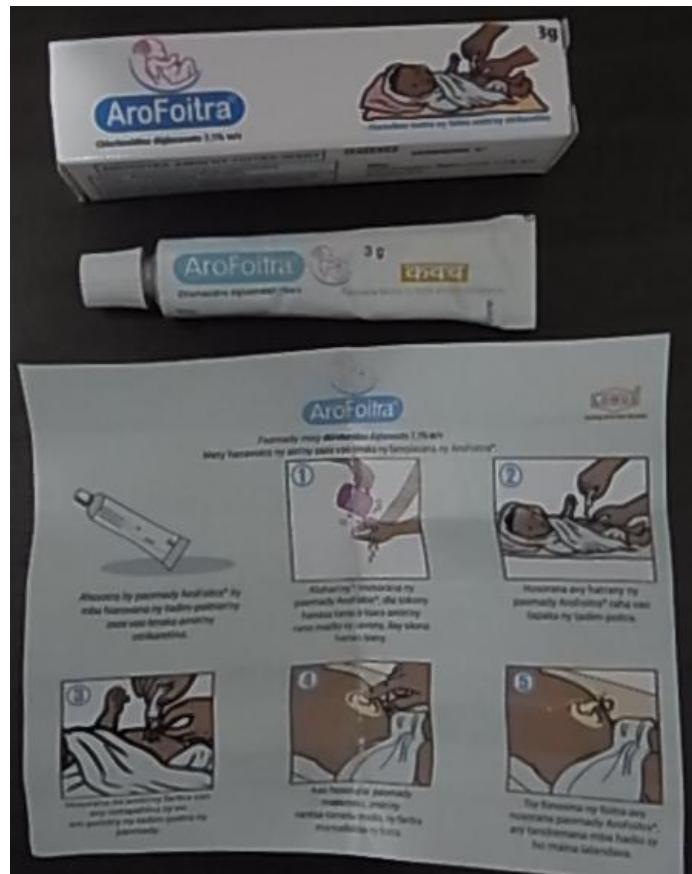
<b>Objectives, Strategies and Activities</b>	<b>Measures of progress</b>	<b>Timeline-Year 1</b>				<b>Budget USD</b>	
		Qtr 1	Qtr 2	Qtr 3	Qtr 4		
<b>Objective 1: Establish CHX as the standard for cord care</b>						<b>36 799</b>	
Strategy 1.1: Establish policy and secure funding for implementation of scale-up plan							
1.1.1: CHX scale-up coordinator	Coordinator hired	✓				10 659	
1.1.2: Policy development workshops	Policy established	✓				8 475	
1.1.3: Workshop to secure and coordinate donor funding	Funding for Year 1 secured	✓				913	
1.1.4: National policy dissemination event	Event completed		✓			10 000	
1.1.5: Regional dissemination event	Events completed in 8 regions		✓	✓	✓	6 752	
<b>Objective 2: Ensure that CHX is available</b>						<b>194 502</b>	
Strategy 2.1: Procure and distribute CHX through Government essential drug logistics system							
2.1.1: CHX 7.1% w/v registered	Registration completed	✓				-	
2.1.2: CHX 7.1% included in essential drug commodity list for procurement through SALAMA	CHX included	✓				-	
2.1.3: CHX procured and distributed for Year 1 need for Government system distribution	143,147 tubes procured and distributed (for 40% of need for 8 regions for Year 1 implementation)		✓	✓	✓	81 271	

<b>Strategy 2.2:</b> Procure and distribute CHX through existing social marketing system						
2.2.1: CHX included in menu of commodities procured and distributed through social marketing system	CHX included	✓				-
2.2.2: CHX procured and distributed for Year 1 need for social marketing system distribution	214,720 tubes procured and distributed (for 60% of need for 8 regions for Year 1 )		✓	✓	✓	112 501
2.2.3: CHX pricing workshops	Workshop completed	✓			✓	1 095
<b>Objective 3: Ensure that CHX is used by CSB staff, ACs and mothers</b>						<b>729 685</b>
<b>Strategy 3.1:</b> Integrate CHX into all MNCH related training and included with pvt.sector orientation						
3.1.1: Pilot materials adapted for scaling up	Final training materials developed	✓	✓			-
3.1.2: MTOT	MTOT completed—8 master trainers available		✓			407
3.1.3: Integrated TOT	Integrated TOT completed—4/district for 8 regions=163 trainers available		✓	✓		16 367
3.1.4: Integrated training for all health workers completed in final 8 regions	Integrated training completed—3 person/CSB for 8 regions=4700 CSB staff trained			✓	✓	121 717
3.1.5: Integrated AC training	Integrated AC training completed—2/fokotany for 8 regions=12,700 AC trained				✓	268 042
<b>Strategy 3.2:</b> Include CHX in social marketing approach, and initiate a comprehensive BCC strategy						
3.2.1: National radio spot messages	Spots developed and broadcast		✓	✓	✓	9 300
3.2.2: Local radio spot messages	Local spots developed and broadcast in 8 regions		✓	✓	✓	22 500

3.2.3: Posters	Posters printed and distributed to 8 regions		✓	✓	✓	9 493
3.2.4: Mother's educational pamphlet	Pamphlets printed and distributed to 8 regions		✓	✓	✓	36 606
3.2.5: Mobile video units	Video developed and mobile units mobilized in 8 regions		✓	✓	✓	35 470
<b>Strategy 3.3:</b> Include CHX in SIG and Logistics monitoring, and in periodic coverage assessments						
3.3.1 Pilot forms adapted for interim use within HMIS or SIG	Forms available in 8 regions	✓				16 300
3.3.2 CHX added to Government logistics recording system	Forms available in 8 regions	✓				32 600
3.3.3 CHX added to social marketing commodity outflow monitoring system	Forms available for use in 8 regions	✓				100
3.3.4: Population-based coverage survey	Survey completed (representative by region for 8 regions—end of Year 1)				✓	100 000
3.3.5: Qualitative client survey	Qualitative survey completed				✓	12 000
3.3.6: Supervision	Supportive supervisory system established in 8 regions			✓	✓	7 172
3.3.7: Follow-up after training	Follow-up after training completed in 8 regions within 3 months of completion of AC training				✓	40 727
<b>Strategy 3.4:</b> Reduce capacity gaps in vulnerable districts and manage emergency needs						
3.4.1: Special program for AC capacity building	Address AC capacity needs in 10% of districts in 8 regions					(year 2)
3.4.2: Special program for local NGO capacity development	Address NGO capacity needs in 10% of districts in 8 regions					(year 2)

3.4.3: Contingency fund in event of perceived adverse event	Fund available	✓					614
<b>Strategy 3.5:</b> Complete operations research to increase implementation efficiency							
3.5.1 Alternative CHX formulations for CSB use (e.g. liquid multi-dose dispenser)	Research completed						(year 2)
3.5.2 Alternative methods for coverage assessment	Research completed						(year 2)
<b>TOTAL YEAR 1 BUDGET</b>							<b>961 351</b>

### **Annex 3 : Sample of product with brandname and packaging**



## Annex 3 : Sample of training and BCC materials



**Ny AroFoitra**

- Ranompanafody mamonoo mikroba karazany maro
- Mahombay sady azo antoka
- Mora ampiasaina
- Alaina mandritra ny fisaoana fahaeftira eny amin'ny Tobimpahasalamana na eny amin'ny Mpamentana ara-pahasalamana
- Tsy mila fampiasana bandy sy akoala intsy

**Ireo dingana tsy malintsy atao miaoloha ny fanoesorana ny AroFoitra**

Saôna madio amioiny rano sy savony ny tanana

**Ahiflikika amioiny rivolta mba ho maïna**

**HAFATRA SAMIHAFIA**

Arahmasao ny Reny teraka sy ny Zaza menava :

- Fampinonoin-Ifery avy hatrany soritiriny falateahana ka anatin'ny adiny iray farafahatarany.
- Fampinonoin-Ifery tsy misy fangorony hateraminy ny fahsenin-boley.
- Fampiasana Chlorhexidine (AroFoitra) eo amintiry foitra.
- Fametrahanana ny Zaza eo anilaminy reniny mandrakarina mba hitacomana ny hafanany Zaza sy ny manodidina azy.
- Fampandranana ny Zaza menava (mitaika) afaka 6 ora ka tandremana tsy ho lera ny foitry
- Fikalanana ny fahadivonainy tadiim-poitra sy ny vatanin'ny Zaza.
- Entia eny amin'ny Tobimpahasalamana akaly indindra ny Reny sy ny Zaza afaka 3 endro raha sendra teka tany an-trano.
- Fampirishana ny fanoavana valksiriny (BCG sy Polio O ho an'ny Zaza vao teraka).
- Fanoesana kopiaranya Zaza.
- Faneraha-maso matetika ny Reny terabao sy ny Zaza menava sao misy fambara loza ny andro voalohany ny mandritra ny heminandro.
- Fanentana ny Reny mampiasana Fandindrana Filtrahana.
- Fahadivonainy vatanin'ny Reny tera-bao.
- Famantana ny Reny momba ny sakalony ny Reny mampinono.
- Fikalanana ny fahadivonainy Reny tera-bao.

**Ireo fambara loza hita eo amioiny foitra ratsy fikarakarana :**

Foitra manontolo :

- Mena sy mivonto ny foitra sy ny manodidina azy.
- Mamoka fofta mambio sy mandrakosa, misy nana.
- Mibontsina sy henjana ny kibo.

**Hafta ho an'ny Mpamentana ara-pahasalamana :**

- Manco fenoianana ny veihavy bevohoaka eo amioiny fanta fadiiany.
- Marso fenantana amioiny fofta momba ny AroFoitra araka ny fisy tadiid AroFoitra sy ny fiaovom-pantenana (Vengvampy Arahan-Dink).
- Maka ny fanekeviny Reny bevoheka rehy latohary ny fenantana.
- Mizara pomady AroFoitra amioiny ireo manalhy.
- Mameno ireo rejista eo mpelatana araka ny asa atao.
- Mandela tatitra ara-potome ny asa vita.
- Manotika ireo fivoina diañka rohetra.

**Job aid for AC**

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