

Guide to implementing 7.1% chlorhexidine digluconate for umbilical cord care

GET READY



PLAN



EXECUTE



Three phases to ensure sustainable implementation

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The Chlorhexidine Working Group (CWG) is an international collaboration of organizations committed to advancing the use of 7.1% chlorhexidine digluconate (delivering 4% chlorhexidine) for umbilical cord care through advocacy and technical assistance. PATH serves as the Secretariat of the CWG.



Introduction



Photo: PATH / Evelyn Hockstein

Each year, 3 million newborns die globally, and infection is the cause of at least 15% of their deaths.¹ Poor hygiene and lack of antisepsis at birth, as well as during the first week of life, increase the risk of deadly but preventable infections. Ensuring optimal cord care at birth and during the first week of life (including use of chlorhexidine) is a crucial strategy to prevent life-threatening sepsis and cord infections, and avert preventable neonatal deaths.

Chlorhexidine digluconate is a broad spectrum antiseptic with over 40 years of widespread use. It is available in a range of concentrations and for a variety of applications, but its specific use for umbilical cord care was tested in three clinical trials in Nepal, Bangladesh, and Pakistan, in the form of 7.1% chlorhexidine digluconate (hereinafter referred to as chlorhexidine). The results of these trials showed there was a 23% reduction in neonatal mortality, if chlorhexidine use began on the first day of life. Given these promising results, in 2013 the World Health Organization (WHO) added chlorhexidine to its Model List of Essential Medicines for Children² and in 2014 WHO issued a new guideline on umbilical cord care³, which included a formal recommendation on the use of chlorhexidine.

Interest in chlorhexidine has been mounting. As of 2016, the intervention is being implemented in eleven countries and the Chlorhexidine Working Group (CWG)—a consortium of international organizations working to advance the use of chlorhexidine through advocacy and technical assistance—is in contact with policymakers in over 15 other countries who have expressed interest in introducing this product. The CWG has been generating interest from manufacturers and providing technical assistance to them

so they will be able to produce good quality chlorhexidine. Four local manufacturers have already started producing chlorhexidine gel or solution and a few other local manufacturers are expected to start producing chlorhexidine in the near future. The progress of chlorhexidine implementation and scale-up can be tracked on the Chlorhexidine Working Group's Global Scale-Up Tracker on the Healthy Newborn Network.

This guidance document, "Guide to implementing 7.1% chlorhexidine digluconate for umbilical cord care" was developed to help policy makers, program managers, and donors facilitate the introduction of chlorhexidine into existing essential newborn care services in low- and middle-income countries. It is based on the experiences of the CWG partners in introducing chlorhexidine use as part of essential newborn care in various countries. It consists of three phases: **Get Ready**, **Plan**, and **Execute**. Each of the three phases, in turn, is composed of activities

that facilitate introduction and scale-up. Phases do not necessarily occur in a sequential manner. Some activities/components across the phases will occur simultaneously, while others are dependent upon the results of activities from a previous phase. Each section includes a list of helpful documents that could be used to effectively conduct activities or address issues. These documents can be found on the Health Newborn Network website (<http://www.healthynewbornnetwork.org/issue/chlorhexidine-for-umbilical-cord-care/>).

We acknowledge that each country/program faces unique situations. Although the CWG developed this guidance such that it will apply to a wide range of contexts, ministries of health (MOH) and other program implementers may need to adapt to this guidance better fit their local needs. Nevertheless, we hope that this guidance will aid chlorhexidine introduction and scale-up which will lead to sustainable delivery at high coverage.



PHASE 1

Get Ready



Successful introduction and scale-up requires the coordinated effort of various key stakeholders, including divisions within MOHs that are responsible for community health and supply chain management, health workers, professional organizations, civil society, donors and partners that provide technical and supply chain management support, as well as manufacturers and distributors in both the public and private sectors. Therefore, the introduction of chlorhexidine use typically starts by engaging these various key stakeholders and gaining their consensus regarding whether and how to implement this intervention. During the “Get Ready” phase, the following four major activities should be undertaken.



Gaining consensus through a stakeholder consultation process

In order to engage and coordinate key stakeholders, it can be helpful to convene a meeting. At such a meeting, stakeholders should review existing clinical and operational evidence, policies, and clinical guidelines at the global and country levels and then discuss whether introducing chlorhexidine use could help contribute to reducing neonatal mortality in the country. The CWG Technical Brief and summary PowerPoint provide an easy way for key stakeholders to become familiar with the technical details of global chlorhexidine implementation. Country-level policies and guidelines to be reviewed should include:

- National essential medicines list
- National newborn and maternal health strategy documents
- Guidelines for:
 - Essential newborn care
 - Birth-preparedness package
 - Emergency obstetric and newborn care
 - Community maternal and newborn health programming
 - Community health workers' roles and responsibilities
 - Post-natal care home visit

Outcomes of the initial stakeholder meeting(s) could be:

1. consensus and commitment gained among stakeholders to introduce use of chlorhexidine to reduce neonatal mortality for this purpose,
2. identification of gaps in evidence needed for implementation,
3. next steps, roles, and responsibilities defined for each stakeholder/organization, and/or
4. establishment of an on-going coordination mechanism such as a technical working group.

It is especially important to establish an ongoing mechanism to coordinate efforts among various stakeholders. Some MOHs may already have technical working groups with a mandate to discuss newborn health strategies and interventions. Such technical working groups could serve as the coordination mechanism for introducing the use of chlorhexidine for cord care. If no appropriate technical working group already exists, creating a new one is an alternative. The technical working group and the coordination effort should both be led by the MOH, which can provide continuous oversight and will have ownership of the implementation plan that will later be created.

HELPFUL DOCUMENTS

- CWG Technical Brief (available in English, French, and Portuguese)
- CWG Chlorhexidine Products and Uses in Healthcare (available in English, French, and Portuguese)
- UN Commission on Life-Saving Commodities for Women and Children Policy/Advocacy Toolkit
- CWG Chlorhexidine Overview PowerPoint
- Results of randomized controlled trials in Nepal⁴, Bangladesh⁵, and Pakistan⁶, and a meta-analysis⁷.
- Chlorhexidine Gel Versus Aqueous for Preventive Use on Umbilical Stump: A Randomized Non-inferiority Trial⁸
- Safety and Impact of Chlorhexidine Antisepsis Interventions for Improving Neonatal Health in Developing Countries⁹

Generating evidence to support introduction and planning

In countries where the CWG has been working, the governmental authorities have decided that no additional evidence on clinical efficacy is needed to justify the use of chlorhexidine for cord care in those countries. This is because (1) the results of the clinical trials in Nepal, Bangladesh and Pakistan were so strong, and (2) the WHO already recommends chlorhexidine use and lists it in its essential medicine list.

However, formative or market research may assist MOHs and other implementers to further understand the market/users and develop an effective strategy/plan for introducing the use of chlorhexidine into their existing essential newborn care services and programs. In addition, some countries have used the results from formative or market research to select product characteristics—the application regimen (single day or multiple day application), dosage form (gel or liquid), design and language used for packaging and instruction for use, and pricing—that can facilitate proper product use and uptake.

When initiating formative or market research, the first step should be to develop a set of research questions addressing a range of factors that may be relevant, depending on context, including:

- Current cord care practices, understanding about causes of cord care infection and neonatal sepsis, and treatment practices.
- Target users, influencers, and decision makers, and their profiles.
- Acceptability of chlorhexidine to end-users/service providers, as well as understanding any relevant motivations/barriers to uptake.
- Communication avenues that will effectively reach target users and communication messages that will encourage them to change their behavior to using chlorhexidine.

- Selection of chlorhexidine product attributes (e.g., dosage form [gel vs. liquid], primary container, etc.) that will appeal to users and service providers and will ensure proper product use, given the profiles of the target users and also taking into account other products already on the market.
- Distribution channels to reach target users.
- Appropriate price point which is driven by target users' willingness to pay for chlorhexidine and pricing of products that they use as a reference.

HELPFUL DOCUMENTS

- Ethiopia formative research¹⁰
- Madagascar formative research
- Kenya and Nigeria market research results
- Mali formative research

ACTIVITY 3

Aligning policies and guidelines

While reviewing existing policies and guidelines for the use of chlorhexidine for cord care, key stakeholders should be requested to determine: (1) the best location for its use (facilities and/or home), (2) the preferred administration regimen (single day use or multiple day use), and (3) the most appropriate dosage form (gel or liquid). As previously mentioned, some countries have decided to conduct market or formative research and generate evidence related to these questions. Policy makers and key stakeholders should keep in mind that location of use, application regimen, and dosage form must all be acceptable to service providers and care givers in order to achieve a high rate of coverage for chlorhexidine. It is also important to select a dosage form and a container for chlorhexidine that will distinguish it from other chlorhexidine products that are already on the market for other purposes and other products commonly used for newborns. It is critical that chlorhexidine be clearly distinguished from these other products to prevent potential misuse. The CWG's country guidance and supplementary country guidance documents address issues that policy makers and key stakeholders will need to consider in making appropriate decisions.

In addition, key stakeholders will need to make their best effort to develop coherent policies and guidelines for the use of chlorhexidine for cord care. For example, cord care instructions might be included in various guidelines such as essential newborn care, birth preparedness, and emergency obstetric and newborn care guidelines. In such cases, each guideline should state use of chlorhexidine in the same manner.



Photo: PATH / Doune Porter

HELPFUL DOCUMENTS

- CWG Country Guidance
- CWG Supplementary Country Guidance

Disseminating policy and guidelines

Once policy and guidelines are updated, it is important to disseminate them to other government agencies such as the national regulatory authority and government and private sector procurement agencies. This will help facilitate the regulatory approval for chlorhexidine and updating of procurement lists to include chlorhexidine for cord care. In addition, in countries where the political system is devolved, the responsibility for introduction and delivery of chlorhexidine for cord care may reside with the government at the sub-national level. In such circumstances, it may therefore be critical to disseminate updated policy and guidelines to the governments at the sub-national level and obtain their buy-in as early as possible, as this will assist in planning for the national scale-up of chlorhexidine.

PHASE 2 Plan



Once consensus has been gained among key stakeholders, any needed additional evidence has been generated, and policies and guidelines have been updated, the next phase is to plan for introduction.

Countries could choose to introduce the use of chlorhexidine in a phased manner by starting to:

- 1) use chlorhexidine in a small number of districts/states/counties and then expanding use to additional geographical regions over time,
- 2) use chlorhexidine at facilities and then expanding its use to the community level over time or vice versa, or
- 3) distribute chlorhexidine only in the public sector and then expanding the distribution channels over time to private sectors channels, such as pharmacies. The most appropriate strategy will depend on context.





In any event, the introduction of chlorhexidine use for cord care should be made with further scale-up in mind. In this regard, a national scale-up strategy should be developed as early as possible. While donors and partners may initially support introduction of chlorhexidine, they will gradually phase out as the programs start running successfully. Therefore, sustainability plans, including long-term indicators for success, should be built into the national scale-up strategy, which will then be transferred to an implementation plan by identifying priority action items and determining a timeline and responsible actors for each action item.

To be useful, implementation plans should be living documents, revised and updated as the use of chlorhexidine for cord care expands. Guidance documents and scale-up frameworks developed by various organizations for chlorhexidine or other similar interventions could provide a process and define essential activities that must be undertaken to develop practical scale-up strategies and plans. National scale-up strategies and implementation plans already developed by some countries for chlorhexidine could provide good examples for others. Each country might have its own internal diversity with regard to health needs, health care infrastructure, and access to health care. It is important that a national scale-up strategy and implementation plan address this within-country diversity. The following five components warrant attention. It is critically important to coordinate activities to address these components and the various stakeholders involved. As mentioned in the first section (Get Ready, Activity 1), the coordination effort should be led by the MOH. The MOH can provide leadership and governance in this phase and has ownership of the implementation plan. Some MOHs may already have technical working groups with a mandate to discuss newborn health strategies and interventions. Such technical working groups could serve as the coordination mechanism in this phase.

Demand generation

It is critically important to understand the target users and then define a strategy to educate the target users on proper use of chlorhexidine and generate their demand for the product. Market research may be quite useful for identifying the target users and effective strategy to generate their demand.

Expectant women may be a logical target market segment, however, other female family members, relatives, and husbands often influence them in regard to decisions about their babies' health, including cord care. Likewise, community members/leaders, traditional birth attendants (TBAs), and health care professionals also frequently influence them. Therefore, understanding who the target market segment and users are and how they interact with influencers when making their decisions about the use of chlorhexidine will help in developing an effective demand generation strategy and behavior change communication materials to generate product demand.

In addition, it will be important to ensure that health workers are informed on the rationale for use and motivated to use the product. In some settings, many births are attended by TBAs. In such cases, they may be an important target for demand creation.

In many settings, substances other than chlorhexidine are often used for cord care. It is therefore important to determine:

1. what substances are most commonly used,
2. why such substances are used,
3. where they are obtained,

4. when they are obtained,
5. how much they cost,
6. how they are used, and
7. what factors would most likely contribute to shifting to the use of chlorhexidine.

This information can be effectively used to develop a demand generation strategy and appropriate communication materials and mediums. For example, the "I-Kit" is a step-by-step guide to developing communication strategies to increase demand for priority commodities such as chlorhexidine. In addition, "Driving Demand for Chlorhexidine", which was developed by Center for Accelerating Innovation and Impact at USAID, include practical ideas to develop demand generation materials.

HELPFUL DOCUMENTS

- Demand Generation Implementation Kit (I-Kit) for Underutilized, Life-Saving Commodities
- Madagascar flyers and poster for AroFoitra (Malagasy)
- Driving Demand for Chlorhexidine: a human-centered design toolkit for the development of demand generation materials

Orientation/training

Depending on the delivery strategy, various actors may have a role to play in ensuring proper use of chlorhexidine. This can include: managers, health professionals, community health workers (CHWs), TBAs, drug-shop employees, those involved in social-marketing programs, and others. Each needs to understand the rationale for the intervention and the role they are to play. Orientation or training is therefore likely to be an integral part of ensuring proper use. Initially, a “training of trainers” approach, which involves training a small group of master trainers who then can train others, works well for chlorhexidine.

Once established, an orientation on chlorhexidine should be appropriately reflected in standard training on essential care of the newborn. This can include pre-service and in-service training programs and also a component of existing training programs. Chlorhexidine training materials developed by other countries could be adapted.



Photo: PATH / Karina Collins

HELPFUL DOCUMENTS

- Training materials for single day application (Nepal)
- How to use chlorhexidine for umbilical cord care (training video)

Product manufacturing and distribution

Determining how much chlorhexidine is required and how to obtain it should begin by estimating the potential total market size and by developing an appropriate strategy for ongoing procurement and distribution. The potential total market size can be estimated based on the number of babies born annually in the country. This number should be adjusted based on the policy and guidelines that each country has adopted. For example, if a country has decided to use chlorhexidine only for home births, then the total number of babies born annually at home would be the total potential market for chlorhexidine. The market sizing tool developed by the CWG is an easy and rapid way to estimate the potential total market size. Note that since implementation will not instantly be at national scale, quantification calculations (for the purpose of procurement) need to make realistic assumptions about the expected volume delivered during the scaling-up process.

If the domestic market is sufficiently large, the country's local pharmaceutical manufacturers have capacity for producing chlorhexidine in good quality, and the country's regulatory system is robust enough to ensure approval and marketing of quality product, then working with local pharmaceutical manufacturers to produce chlorhexidine may be the best strategy. Otherwise, importing the product from established sources would be the next most viable option. In any event, countries should select whatever strategy best ensures consistent availability of high-quality, affordable chlorhexidine. The guidance document, "Selecting the right strategy to increase the availability of a quality, affordable medicine to reduce neonatal mortality" developed by the CWG, can help in-country planners evaluate various factors and determine whether chlorhexidine can be locally produced or must be imported.



Photo: PATH / Gabe Bienczycki

Regarding distribution within a country, one option is distribution of chlorhexidine to pregnant women during ANC at facilities or by CHWs in settings where there are programs in which CHWs have contact with pregnant women. Alternatively, mothers and other caregivers could obtain chlorhexidine from retailers such as pharmacies, if such distribution is feasible. Various product distribution channels/agents should be evaluated to determine which distribution strategies are feasible and would achieve maximum chlorhexidine coverage—keeping the target market segments/users profiles and their buying behavior for the current cord care substances in mind.



Photo: PATH / Patrick McKern

Potential distribution channels/agents may include:

- ANC service
- Public and private health care facilities
- Community health workers
- Public or private pharmacies and/or other drug vendors
- Social marketing operations

These distribution channels/agents are not mutually exclusive. The use of multiple channels may achieve a better reach across all market segments/target users.

In addition, if retailers are chosen as one of the distribution channels, it is important to consider how to incentivize retailers to stock and sell chlorhexidine. Because chlorhexidine for cord care would be a low-profit margin and slow-moving product, retailers may not be motivated to stock and sell the product. Quite often both push and pull strategies—pushing chlorhexidine to retailers while pulling demand from the target market segment/users—will be required.

HELPFUL DOCUMENTS

- CWG Chlorhexidine Market Sizing Tool
- CWG “Selecting the right strategy to increase the availability of a quality, affordable medicine to reduce neonatal mortality” (available in English and French)
- CWG “Key Considerations for Procurers of 7.1% Chlorhexidine Digluconate for Umbilical Cord Care” (available in English and French)

Monitoring and Evaluation (M&E)

For any new service or program, it is important to know how well implementation is going, as a basis for making any needed adjustments in order to get good performance. The development of an appropriate M&E plan for the use of chlorhexidine should begin by developing a measurable long-term goal/vision plus interim milestones for its implementation. Countries must also determine how they will track progress and outcomes, including what indicators they will use and how they will be measured. Most fundamentally, a program would need to track actual coverage (i.e., the proportion of newborns who have chlorhexidine applied to the cord within 24 hours of birth).

In addition, in order to determine how best to track performance, countries should consider what systems are currently being used which may be relevant for this intervention. Quite often, countries are already collecting some data through existing antenatal care, maternal, and post-natal care registries and health management information systems. While special tracking systems may be appropriate for piloting or special studies, standalone, vertical documentation and reporting will probably not be appropriate for incorporation into routine services. Testing indicators for including into health management information systems (HMIS) is important in order to ensure that indicators for chlorhexidine will properly be incorporated into HMIS for routine monitoring and evaluation. The M&E plan for introduction of chlorhexidine in Kenya is a helpful example.

HELPFUL DOCUMENTS

- Kenya M&E Plan
- Every Newborn Action Plan indicators (includes chlorhexidine)
- CWG Performance Indicators
- Demographic and Health Surveys (DHS) Newborn Module
- Lives Saved Tool (LiST)

Financing

The estimated cost of introduction, scale-up, and ongoing delivery of chlorhexidine for cord-care should be determined as part of an implementation plan. Specifically, recurrent costs for procuring the commodity need to be worked out as a basis for long-term procurement planning. If budgeting is devolved to the sub-national level (i.e., to states, districts, or counties), it is important to assess the budget impact of chlorhexidine implementation at the sub-national level. Frequently, low-resource countries require support from donor agencies in order to finance the introduction of chlorhexidine use. The costed, national scale-up plan can be used to communicate the financial need and gain support from donor agencies for the introduction phase. The National Scale-Up Plan in Nigeria is a helpful example to estimate the cost for chlorhexidine implementation.

Nonetheless, chlorhexidine is a comparatively inexpensive product—in most cases, once the service is established, countries can take on the recurrent procurement costs. Even if countries receive donor support initially to introduce the use of chlorhexidine, it will be important to consider financial sustainability over the long term.

PHASE 3

Execute



The main focus of this final phase is to ensure program sustainability.

As mentioned in the previous phase, “Plan”, the national scale-up strategy and implementation plan must be created with sustainability in mind, which should now be executed accordingly. The MOHs and other implementing partners continue monitoring performance, and make any needed adjustments to address performance problems. Following the M&E plan that was developed in Phase II, data should continue to be regularly collected and reviewed. Data from the initial phase of implementation should be disseminated to key stakeholders within the country. If the program is not performing as expected, corrective action should be taken. For example, if a decline in actual coverage is observed, the MOH or others program implementers should identify reasons and make needed adjustments. MOHs or key stakeholders might want to disseminate data about the progress of introduction and scale-up of chlorhexidine use in their country through international conferences or publications to help other countries accelerate the implementation of chlorhexidine.

The CWG web site is also a good place to share such information.

<http://www.healthynewbornnetwork.org/issue/chlorhexidine-for-umbilical-cord-care/>



HELPFUL DOCUMENTS

- Nepal progress towards program sustainability (timeline)
- Chlorhexidine for umbilical cord care presentations at the Global Maternal Newborn Health Conference (2015):
 - Introduction of Chlorhexidine in Sindh, Pakistan (MCHIP)
 - Introduction de la Chlorhexidine Digluconate 7,1% dans les soins ombilicaux en RDC (MSH/SIAPS)
 - Saving the Pair–Integrated Scale-up of Chlorhexidine and Misoprostol for Newborns and Mothers in Rural Madagascar (JSI)
 - Institutionalizing Chlorhexidine Program and Maintaining Coverage Chlorhexidine Cord Care Program in Nepal (JSI Research and Training Institute)

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