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ORIGINAL ARTICLE

INTEGRATING CHLORHEXIDINE FOR CORD CARE INTO COMMUNITY BASED NEWBORN CARE IN ETHIOPIA

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ABSTRACT

Introduction: Ensuring adequate cord care at birth and in the first week of life is crucial to prevent sepsis and cord infections, and to reduce preventable neonatal deaths. WHO recommends application of 7.1% chlorhexidine digluconate daily to the umbilical cord stump during the first week of life for newborns born at home in settings with high neonatal mortality.

Objective: This article describes the introduction of chlorhexidine for cord care in Ethiopia using the Community-Based Newborn Care (CBNC) platform and early lessons.

Methods: Data related to chlorhexidine introduction inputs and processes from minutes, reports, and related documents from 2013 to 2017 were assessed and described using steps from the three phases to ensure sustainable implementation introduced in a recent guideline from the Global Chlorhexidine Working Group.

Results: Chlorhexidine was included as one of the components in CBNC after consensus building, and it was manufactured locally. Current implementation status in four zones is described. Early lessons include the fact that chlorhexidine for cord care is feasible and acceptable in Ethiopia. Critical gaps in knowledge, practice, and attitude on the service providers' and mothers' sides were observed. In addition, product availability was limited outside of facilities. Poor documentation and parallel supply-chain management also require further attention.

Conclusion: Government leadership and integration within the existing platform were key to the introduction of chlorhexidine for cord care in Ethiopia. Issues that require further attention include synchronization, behavior change communication, monitoring, and evaluation, as well as financing for sustainable product availability.

Key words: Community based newborn care, chlorhexidine, cord care, manufacturing, application.

INTRODUCTION

Infections such as sepsis and meningitis cause about 15% of the 2.7million global neonatal deaths occurring annually (1), with poor hygiene at birth as one of the contributing factors. A meta-analysis of three cluster-randomized community trials conducted in Nepal, Bangladesh, and Pakistan found that application of chlorhexidine to the umbilical cord of the newborn in the intervention groups resulted in a 23% reduction in all-cause neonatal mortality as compared to a control group (2). Therefore, chlorhexidine has a huge potential for impact, is safe, stable with no special storage requirements, cost effective, and highly acceptable, and it has multiple possible distribution channels, as health workers as well as family members can easily administer it (3). In 2014, WHO recommended application of 7.1% chlorhexidine digluconate to the umbilical cord stump soon after birth and continuing daily during the first week of life for newborns who are born at home in settings with high neonatal mortality (30 or more neonatal deaths per 1000 live births) (4).

However, two recent studies conducted in Pemba and Zambia settings with low neonatal mortality (14 per 1000 live births) found no reduction in newborn mortality after chlorhexidine application.

These findings are consistent with current WHO recommendations, in that a meta-regression of all five trials found larger effects of chlorhexidine cord cleansing on neonatal mortality reduction in settings with higher mortality rates and higher proportions of home deliveries (5).

The objective of this paper is to describe the process of introduction of Chlorhexidine for cord care in Ethiopia, using the Community Based Newborn Care program and to share early lessons so that other stakeholders could learn and adapt to their specific contexts.

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MATERIALS AND METHODS

This paper uses the recent Guide to implementing Chlorhexidine for cord care from the Global Chlorhexidine Working Group to assess data related to chlorhexidine introduction inputs and processes from minutes, reports, and related documents from 2013 to 2017 and describe the process using steps from the three phases to ensure sustainable implementation (6).

It also outlines some of the bottlenecks and lessons learned, and provides recommendations for introducing, sustaining, and scaling chlorhexidine into existing platforms in settings that may be of benefit.

RESULTS

Description of key considerations in chlorhexidine introduction

Gaining consensus through a stakeholder consultation process: When Ethiopia introduced the Community-Based Newborn Care (CBNC) package in 2013, the Federal Ministry of Health (FMOH) and partners in the National Child Survival Technical Working Group (NCSTWG) reached a consensus to include the application of chlorhexidine on the umbilical cord as one of its components (7). Evidence summaries provided by global experts and observation of Nepal's program during the joint learning trip by CBNC leaders were important contributors to policy decisions. There was high-level commitment by the FMOH, but only if the product could be manufactured locally. As the development of manufacturing capacity proceeded on one track, a sub-group of the NCSTWG drafted implementation guidelines. While there was wide involvement of child health stakeholders, few maternal health experts participated in consensus-building activities, ultimately resulting in conflicting guidelines.

Generating evidence to support introduction and planning: In 2013, the Maternal and Newborn Health in Ethiopia Partnership (MaNHEP) supported an exploratory qualitative study to provide insight into community perspectives and current practice related to cord care and supplies of chlorhexidine in four kebeles of four regions (Amhara, Tigray, SNNPR, and Oromia). Results showed there was widespread application of various substances to the cord, especially butter and Vaseline to soften or moisturize the cord and to hasten cord separation. Almost all respondents said that they would be willing to use a product that prevented infection of the cord.

They preferred a chlorhexidine product that was in gel form packaged in a plastic bottle, distributed through health posts and health centers, with messaging that addresses its benefits over traditional products, duration and timing of application. The potential for local, market-based sale and distribution could be explored once demand was concretized (8,9).

Aligning policies and guidelines: Informed by a synthesis of global evidence and country context, key stakeholders in the NCSTWG under the leadership of FMOH decided that chlorhexidine should be applied to the cord for seven days as per WHO guidelines for both home and facility deliveries. The rationale for facility-based application was the lack of hygienic conditions in health facilities, early discharge from facilities after birth, to households with poor hygienic practices and possible application of harmful substances after discharge. The complexity of trying to implement chlorhexidine differently in co-located sites (facility and community) was also an important consideration. Discussions also included the need for careful branding to promote acceptability and uptake and to avoid confusion with any existing topical drugs.

Accordingly, this high-impact intervention was included in the current National Newborn and Child Survival Strategy (NNCSS) and Integrated Community Case Management (ICCM), CBNC, Integrated Management of Neonatal and Childhood Illnesses (IMNCI), Neonatal Intensive Care Unit (NICU), and Newborn Corner (NBC) training materials. The fifth edition of the national essential medicine list includes Chlorhexidine 4% gel (10). Yet, there are inconsistencies with other training packages that still recommend dry cord care as the standard. This inconsistency has resulted in some confusion between different cadres at facility level, underscoring the need to ensure harmonization among all guidelines and standard operating procedures regarding cord care from the outset.

Disseminating policy and guidelines: Chlorhexidine was integrated into the CBNC package and was disseminated as a whole, even before the product was available.

Demand generation: The initial formative assessment provided information on target users and other influencers that helped shape messaging for cord care. Different implementing partners had different strategies or models for demand generation for the iCCM and CBNC package as a whole, rather than specific chlorhexidine demand-generation plans.

Posters and leaflets were prepared and used to raise awareness about the benefits and proper use of chlorhexidine, targeting health workers, health extension workers (HEWs), and families. However, wider promotion such as inclusion in the Family Health Guide or use of mass media was not done to avoid creating demand for a product that was not yet widely available.

Orientation/training: Training was provided to health workers (usually from under-five clinics) and HEWs as part of the CBNC training, including practical skill building sessions at the beginning of implementation in 2014. Since the product was not available then, the first round of performance review and clinical mentoring meetings (PRCMM) included chlorhexidine-related refresher training for HEWs. Orientation was later provided for midwives in some areas as they had continued to provide dry cord care as per BEmONC standards.

Product manufacturing and distribution: Initial quantification for procurement of chlorhexidine was done using a chlorhexidine market sizing tool (11). Funding and technical assistance was provided to explore supply, manufacturing, regulatory requirements, and the potential roles of different stakeholders, and to suggest a way forward. DKT Ethiopia (DKT/E) assessed the potential for using the Pharmaceutical Funding and Supply Agency's (PFSA) existing distribution system and noted that it would be sufficient to distribute chlorhexidine to the public sector. An independent good manufacturing practices consultant assessed national manufacturers based on several factors including Food, Medicine and Healthcare Administration and Control Authority (FMHACA) licensure, independent laboratory testing of products, frequency of internal and international audits, capacity for internal laboratory quality control, packaging capacity, and interest in manufacturing chlorhexidine. The assessment also examined the regulatory approaches for the adoption of chlorhexidine in Ethiopia, including the timeline and cost for registration of new products with Ethiopia's FMHACA (12). DKT/E recommended two manufacturers based on their capability to produce a high-quality chlorhexidine product at reasonable prices within six months of the time an order is placed. Based on the above, FMOH chose local production of chlorhexidine gel in a tube, to have consistent availability of high-quality, affordable chlorhexidine. The selected local manufacturer received technical support from a manufacturer in Nepal who reviewed the factory, made recommendations, and shared know-how on manufacturing of the product. There were many delays, and the first batch was made available in May 2015, two years after the process was started rather than the expected six months.

Chlorhexidine for cord care was piloted in four zones, one in each of the four regions of Tigray, Amhara, Oromia and SNNPR. DKT/E shipped the chlorhexidine to its hub stores in the regions and then CBNC implementing partners distributed the drugs in their implementation areas. Eighty percent of the drugs went to health centers and 20% to health posts based on facility delivery rates from routine data. This support was provided as a stop gap measure until the product could be included in PFSA's distribution list. Distribution was only through public health care facilities with the possibility of expanding to other retailers or using social marketing. Chlorhexidine 4% gel was included in the essential medicine list in 2015 and in the over-the-counter list in 2016. Furthermore, chlorhexidine has been included in national quantification exercises for child health commodities since 2013.

Monitoring and evaluation: Since chlorhexidine for umbilical cord care was introduced as part of the CBNC program, monitoring and evaluation were incorporated into the iCCM/CBNC platform. Some indicators were captured in the CBNC indicator list, namely the development of policy and drug availability at facility level. Chlorhexidine-related indicators were also included in the CBNC baseline and will be evaluated at the end of the initial program. The supportive supervision checklist includes checking drug availability at health post level. Otherwise, no indicators were included in the health management information system. The lack of consistent information about utilization or adherence has made monitoring the introduction of chlorhexidine challenging. Moreover, monitoring adherence at home even amongst those who have received the product, has not been feasible.

Financing: Startup costs for chlorhexidine production were provided by a donor. The second batch was procured by the government. Though chlorhexidine for cord care has been included in child health commodity quantification exercises since 2013, a source of sustainable funding has yet to be identified for regular procurement. Recurrent costs for procurement still need to be calculated and devolved to the sub-national levels for sustainability.

Status of implementation

A cross-sectional, quantitative, and qualitative study looked at current chlorhexidine program implementation in the four pilot zones 14 months after introduction. The survey was conducted in 16 facilities. Chlorhexidine was available in most health centers (88%).

The majority (66%) had the supplies in ante-natal care units in addition to other areas, including delivery rooms and pharmacies. Many key informants mentioned the lack of recording or reporting templates, which made monitoring the utilization of chlorhexidine very difficult. Only 50% of nurses and midwives interviewed received orientation or training, and many reported a lack of proper training and orientation as a challenge. However, all health workers in the study knew that chlorhexidine prevents infection in the newborn and that it is lifesaving. All HEWs were able to describe the benefits of chlorhexidine, as well as the timing and duration of application.

Six hundred eleven mothers, who gave birth in the six months preceding the survey, were interviewed. Most (86%) delivered at a facility, with only 1% and 13% delivering at a health post or home respectively.

Among mothers who delivered at home, the majority (83%) used razor blades to cut the umbilicus, of which 95% were new and 57% were boiled. Two percent and 15% of mothers used Vaseline and butter on the cord respectively. The prevalence of chlorhexidine use amongst participants was 53% (95% CI: 47%-57%). Primiparous women were less likely to apply chlorhexidine than women who gave birth to more than one baby. However, the most important determinant was place of delivery, as mothers who delivered at a facility had a 10.28times (95% CI: 8%-26%) higher chance of using chlorhexidine. Concerning the timing of application, 37% stated that chlorhexidine was applied within an hour, 63% said for a duration of 2-7 days, and 55% reported that chlorhexidine was applied once per day (Table 1). The fact that 14% applied the drug for more than seven days and that 40% reported applying it twice daily needs serious attention.

Table 1: Timing of Chlorhexidine Application (n=314)

Variable	Sub category	Number
Timing of first Chlorhexidine Application	Less Than an Hour	37% (n=104)
	Hours	28% (n=80)
	Days	7% (n=21)
	Don't Know	28% (n=81)
Duration of Chlorhexidine Application	One Day	2% (n=7)
	2-7Days	83% (n=257)
	Morethan7days	14% (n=42)
	Don't Know	1% (n=4)
Frequency of Chlorhexidine Application	Once	55% (n=169)
	Twice	40% (n=125)
	Three times	4% (n=11)
	Don't know	1% (n=3)

Regarding proper application, 92% of mothers mentioned washing their hands before application, 79% reported application on the tip, 81% reported application around the umbilicus, and 74% reported air-drying. The majority (78%) of respondents who had not used chlorhexidine on the cord for their last birth said that they did not have any information about chlorhexidine, while 19% and 3% stated that they did not receive the product and that it was not available at time of delivery, respectively.

In view of Figure 1, showing low utilization of the available product, this will need close attention, as both service providers and maternal factors seem to affect the utilization of available chlorhexidine, and this needs to be addressed for further scale up.

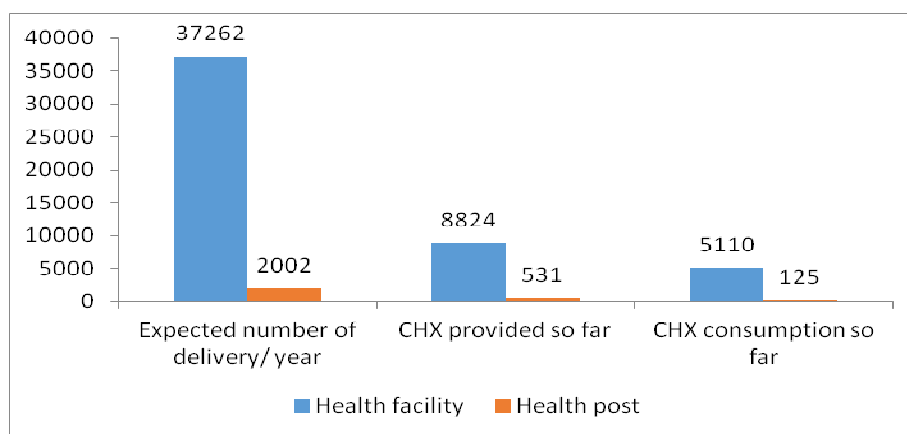


Figure 1: Chlorhexidine distribution and utilization in previous year before data-collection period (Zonal Health Department and Facility data)

DISCUSSION

Government leadership and integration within the existing iCCM and CBNC platform were key to the introduction of chlorhexidine for cord care in Ethiopia. There are still areas that need further effort such as the need for wider and more inclusive consultation with all relevant stakeholders, especially professional societies. This should facilitate harmonization of guidelines and training materials for uniform cord care practice by different cadres.

Other issues, including improving knowledge, attitude, and practice among service providers, notably midwives, and integration of chlorhexidine in the national supply chain management to ensure its continuous availability at health facilities, need to be given due attention as the way forward in Ethiopia. In addition, strengthening the monitoring and evaluation through the recording of utilization in registers and inclusion in future demographic health surveys is crucial.

The low utilization of chlorhexidine, especially amongst home deliveries, requires a special focus on increasing access to and utilization of chlorhexidine for home deliveries through behavioral change communication using updated family health cards, mass media, and other methods. The most important factor for sustainable implementation will be to ensure reliable financing through multiple mechanisms such as inclusion in health insurance schemes, social marketing, and support through corporate responsibility.

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Conflict of interest:

Authors have no conflicts of interest to declare.

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