

# Scaling-Up the Use of Chlorhexidine for Umbilical Cord Care: Nepal's Experience

**Each year four million neonatal deaths occur worldwide, among which 99% occur in developing countries, and more than one-third can be attributed to infections (1, 2).**

A substantial proportion of these infections, such as tetanus, omphalitis, and sepsis, results from exposure of the umbilical cord stump to invasive pathogens often associated with traditional practices. In 1998, WHO recommended that umbilical cords should be kept clean and dry, and that topical antiseptics could be used where infection/exposure risk was high (3).

WHO also recommended further research to identify the appropriate antiseptic for cord care, thus the Nepal Nutrition Intervention Project-Sarlahi (NNIPS)/Johns Hopkins University, Bloomberg School of Public Health (JHU) conducted the first community-based cluster Randomized Controlled Trial (RCT) on the use of Chlorhexidine for the newborn cord care from 2002 to 2006 in Nepal. They used 4% Chlorhexidine, a broad spectrum antiseptic that is safe and effective for reducing bacterial colonization on the skin and umbilical stump of newborns. The study showed that the use of Chlorhexidine reduced neonatal mortality by 34% and prevented severe omphalitis by 75% (4).

Findings from two subsequent studies conducted in Bangladesh (5) and Pakistan (6) supported the JHU research work in Nepal. These findings were published and disseminated at a critical time for Nepal when the neonatal mortality was stagnant (33 per 1000 live births) between the period of two Demographic and Health Surveys (2006 and 2011)(7,8).

The Government of Nepal (GoN) was very receptive to consider new interventions that could contribute to a reduction in neonatal deaths and included the use of Chlorhexidine for cord care in 2011. From the beginning, stakeholders and partners were engaged to develop opportunities for local production of Chlorhexidine, conduct operational research to address remaining programmatic issues, and develop an appropriate implementation modality for nationwide scale-up. It took almost half a decade of rigorous efforts after the RCT results from Nepal were published, to prepare for Chlorhexidine scale-up and another five years to approach nationwide scale. Key milestones along the way and the importance of each are summarized below.



PREVENT INFECTION

## Nepal's Chlorhexidine Program (November 2017)

**9,600**

**Newborn lives have been saved**

**2,100,000**

**Newborns had Chlorhexidine applied**

**15,000**

**Health Workers have been trained**

**44,000**

**Female Community Health Volunteers have been trained**

**75 (100%)**

**Districts have implemented the Chlorhexidine program**

## PROGRAM IMPLEMENTATION STATUS (May, 2017)

- Population covered by the program: 95%
- Proportion of newborns with Chlorhexidine applied to cord among Chlorhexidine implementing districts: 69%
- Proportion of facilities with Chlorhexidine stock among Chlorhexidine implementing facilities: 95%
- Proportion of female community health volunteers having Chlorhexidine stock among Chlorhexidine implementing facilities: 64%

(Source: Technical Support Visit 2016/2017)

### RESEARCH FINDINGS: EVIDENCE FOR ADVOCACY



Onsite coaching on the use of Chlorhexidine for cord care at Maternity Hospital, Thapathali, Kathmandu. (Photo Credit: JSI/Pushkar Khanal)

In 2013, a meta-analysis conducted by Imdad et al. showed an overall 23% reduction in all cause neonatal mortality in the intervention group compared to control (9). After JSI R & T conducted one-on-one advocacy, with the aim of informing and convincing health professionals, policy makers, private pharmaceuticals and external development partners (EDPs) to introduce Chlorhexidine in Nepal, a consultative meeting was assembled in 2007 and a technical working group was formed in 2008.

### GOVERNMENT STEWARDSHIP: TECHNICAL WORKING GROUP FOR CHLORHEXIDINE

The Family Health Division under the Department of Health Services (DoHS) led the Technical Working Group (TWG). The TWG was composed of representatives from government, EDPs, academia, private pharmaceutical companies and professional

societies.

The TWG provided overall guidance to develop the product, protocol and implementation modality. The TWG also oversaw the conduct of an efficacy study and community professional study, for the different formulations of Chlorhexidine (gel vs. aqueous) (10). The GoN, with support from JSI and PLAN Nepal, conducted a Chlorhexidine pilot project in four districts, aiming to assess the compliance of Chlorhexidine use and identify any important implementation issues, integrated with ongoing government maternal and child health programs.

The pilot project showed positive results, with generally high coverage, and these were shared in various professional societies' conferences and government technical fora. In 2011, the GoN and USAID jointly organized a regional Chlorhexidine meeting, with representatives from the TWG of Nepal along with policy makers and researchers from seven countries (Bangladesh, Pakistan, India, Cambodia, Indonesia, Nepal, and the United States). During this meeting, the GoN made a commitment to scale-up Chlorhexidine as a national program.



Technical Working Group meeting at Family Health Division (FHD). (Photo Credit: JSI/CNCP)

## GOVERNMENTS AND IMPLEMENTING PARTNERS: MAKING EFFORTS JOINTLY



Chief consultant, Dr Shilu Aryal, from Nepal government providing training on the use of Chlorhexidine. (Photo Credit: JSI/Ananta Ghimire)

The JSI-led USAID-funded Nepal Family Health Program along with AED cultivated a working relationship with Lomus, a local pharmaceutical company capable of producing Chlorhexidine, to progressively encourage commitment on their part to provide the needed commodity. With oversight by the TWG, JSI implemented a research project to test the efficacy of the aqueous and gel formulations. The study, a randomized noninferiority trial, designed to answer the question: “Is gel equally efficacious as aqueous in terms of preventive use on the umbilical stump?” was carried out in a tertiary care hospital in Kathmandu (10). The study showed the gel formulation to be equally efficacious with the aqueous (10). Another question to address was: which formulation of Chlorhexidine do mothers prefer? So a community preference study of aqueous vs. gel was conducted in Banke (10). Mothers clearly preferred the gel formulation.

Again, with oversight of the TWG, JSI piloted a program for the use of Chlorhexidine in four districts, to determine if it could be effectively delivered at high coverage within existing government services and systems. The GoN approved the use of the gel formulation, delivering 4% Chlorhexidine, provided in 3 gm tubes, to be used as a single application to the umbilical cord stump, to be applied as soon after cord cutting as possible for all births.

The use of Chlorhexidine for cord care was piloted in Parsa, Banke, Jumla and Bajhang District. These four districts were selected because they represent different geographical and socio-demographic

characteristics in Nepal.

Following the successful completion of the pilot, the CNCP has continued to support the MoH to scale-up the use of Chlorhexidine for umbilical cord care, with the financial support of USAID since 2011. CNCP supported the enhancement of the government’s capacity by providing different trainings, on-site coaching, exposure visits, by updating the technical content of curricula and strengthening the information systems in order to effectively manage and monitor the program. Use of Chlorhexidine for cord care was included in the existing public health programs of the government, trainers were government staff and the major sources of information are the Health Management Information System (HMIS) and Logistic Management Information System (LMIS).

## IN-COUNTRY PRODUCTION: ENSURING THE QUALITY AND AVAILABILITY OF LOCAL PRODUCT

Quality in-country production is available since the pilot phase from Lomus Pharmaceuticals. To ensure Chlorhexidine quality USP provided technical support.

Since 1988, about 52,000 FCHVs have been serving at the community level to improve maternal, neonatal and child health in Nepal. FCHVs are supposed to provide Chlorhexidine to each pregnant woman in their catchment area during the 8th month of pregnancy, along with counselling on the importance and proper technique for use of Chlorhexidine.

The Health Facility also distributes Chlorhexidine tubes to pregnant women during ANC visits in the eighth month of pregnancy, along with proper counselling, if the pregnant woman has not received Chlorhexidine from her FCHV.

All the FCHVs and health facilities have received a baby doll, with a simulated umbilical cord, to demonstrate the application procedure of Chlorhexidine gel to the pregnant women and their family members. As Chlorhexidine is included in the essential drug list of Nepal, the drug is available free of cost in the government owned health facilities and through the FCHVs. Currently, Chlorhexidine is available for both facility and home births in the program districts. From 2017, Chlorhexidine is also available in pharmacies as an over-the-counter drug.

## GOVERNMENT OWNERSHIP: SUSTAINING THE PROGRAM

In December 2011, the MoH endorsed a policy for the use of Chlorhexidine for cord care at all deliveries, regardless of location. This policy emphasized that the program should be scaled up within relevant ongoing public health programs. Initially, Chlorhexidine was rolled out with CB-NCP, use of Misoprostol for prevention of Postpartum Hemorrhage at Home Birth and the Birth Preparedness Package. Chlorhexidine is included in the training curriculum for SBA and the pre-service training curriculum for ANM. In 2015, the GoN merged CB-NCP with the Community-Based Integrated Management of Childhood Illness (CB-IMCI) program, and thus developed a new package called the CB-IMNCI, which is now the main program in Nepal focusing on sick child care. Chlorhexidine has been identified as a key intervention for improving newborn health in other relevant program and policy documents, such as NENAP. Since 2013 the MoH has included the procurement of Chlorhexidine in their government long-term procurement plan and has started to procure from 2016.

## INFORMATION MANAGEMENT IS KEY TO MONITORING & EVALUATING THE CHLORHEXIDINE PROGRAM



JSI staff providing technical support to a pregnant woman at Bardiya district. (Photo Credit: JSI/Liladhar Dhakal)

Initially, the Chlorhexidine service was recorded and reported vertically through CB-NCP. From 2014, Chlorhexidine was included into the HMIS. Health workers record and report use of Chlorhexidine at the health facility and FCHVs record and report use

of Chlorhexidine at home births. The HMIS provides disaggregated data on Chlorhexidine use by place of birth. Challenges remain with determining accurate coverage of home births as data collection relies on the FCHVs, who are unpaid volunteers.

Chlorhexidine has been included in the LMIS since November 2015. LMIS provides the stock status of Chlorhexidine at service delivery sites on a quarterly basis throughout the country. Delays in the analysis of data could lead to delays in addressing stock outs and local solutions, at district and sub-district level, are needed to address this issue. The LMIS is a government based system which provides information on the availability of various drugs and medical equipment at service delivery sites throughout the country.

The mid-term assessment in 2013 revealed that without regular follow-up and technical support to service providers and individual service users, it is difficult to achieve and maintain high coverage at scale. Thus, in July 2013, JSI/CNCP initiated a performance improvement approach-Technical Support Visits (TSVs)-conducted by local field staff to ensure both the intervention's coverage and compliance. TSVs are targeted to districts with low coverage both at the health facility and home deliveries, densely populated districts, those with no other implementing partners, low reporting or chronic stock outs. Apart from routine health information management systems, Chlorhexidine variables are included in relevant surveys like the Demographic and Health Survey, Multiple Cluster Indicator Survey, and Health Facility Survey.

## SOCIAL BEHAVIOR CHANGE COMMUNICATION: DEMAND CREATION



Social Behavior Change Communication (SBCC) was part of the program from the inception to create demand. However, until the program reached a certain proportion of the target population, it was difficult to design a nationwide approach, so some local and regional options were utilized. For demand creation, multiple available approaches were utilized, including the use

of national radio and television stations, local FM stations, and community mobilization by FCHVs and healthy mothers' groups. Local FM radio stations still reach the largest population in Nepal.

Demand creation is also carried out through community mobilization and empowerment of individuals. Trained health workers and FCHVs were mobilized at the community level to deliver the messages of Chlorhexidine to the pregnant woman and her family members.

SBCC printed materials (reminder poster, application poster, action card, etc.) have been developed, distributed, and used for counselling about the importance and proper use of the Chlorhexidine gel. Advocacy videos have been produced and shared at national and international levels to target program implementers and policy makers. According to TSVs, still, 20% of recently delivered women were unaware about the use of Chlorhexidine for cord care despite the intensive SBCC campaign. Thus, targeted communication activities were conducted to reach the hard to reach communities. The activities include orientation and mobilization of the local leaders including health and school management committee members, street drama, wall painting, sticker and poster display and leaflet distribution.

## **FLEXIBILITY: ADAPTATION WITH CHANGING CONTEXT AND NEED**

Program partners have remained flexible and have made modifications as needed, as the program has expanded. For example, the original packaging of Chlorhexidine had 250 tubes in a single box. This was provided to all health facilities, irrespective of the number of pregnant women they served. Since 2016, smaller packages (10 tubes) and larger packages (100 tubes) have been made available, in order to address the issue of high expiration and wastage in health facilities serving a small number of pregnant women.

After the 2015 earthquake, there was a need for rapid implementation of many interventions, including those to address the high risk for newborns born in such vulnerable settings. The GoN identified Chlorhexidine as a priority intervention and rapidly scaled up Chlorhexidine in those districts hardest hit by the earthquake.

The GoN developed a list of emergency drugs to address the disaster relief needs, with guaranteed procurement and supply. This list includes Chlorhexidine.

The GoN also added Chlorhexidine to the Reproductive Health Kits, provided as part of the emergency relief, to increase coverage. JSI/CNCP mobilized all field staff to earthquake affected districts to roll out the Chlorhexidine program as quickly as possible when the need was greatest in those areas.

## **KNOWLEDGE SHARING: FACILITATING IMPLEMENTATION IN OTHER COUNTRIES**



*Leela Khanal, Project Director at JSI/CNCP, sharing Chlorhexidine scale-up experience in Nepal at Pakistan National Workshop on Developing Plan of Action for Chlorhexidine Scale up. (Photo Credit: JSI/Dr. Niraj Nakarmi)*

Nepal Chlorhexidine experts have been sharing materials, best practices and lessons learned to support Chlorhexidine programming in other countries. Through practical sharing of training manuals and techniques, job aids, behavior change communication materials, and recording and reporting tools, JSI/CNCP has helped to accelerate Chlorhexidine introduction within the global community.

Nepal has been a destination for learning visits for international delegates from 20 countries. To date, JSI has provided short-term technical assistance to Bangladesh, Ethiopia, Liberia, Madagascar, Mozambique, Niger, Nigeria, and Pakistan. In 2013, a Global Chlorhexidine technical working group was formed and through membership in this group, Nepal is sharing lessons learned and best practices for Chlorhexidine implementation.

## ACHIEVEMENT AND WAY FORWARD

The program has been rolled out in all 75 districts of Nepal. It is estimated that as of November 2017, 2.1 million newborns had Chlorhexidine applied to their umbilical cords, resulting in approximately 9,600 lives saved.

The MoH has accepted responsibility for all aspects of program implementation, including procurement of the Chlorhexidine product and integrated Chlorhexidine into major policies and programs. The 2016 DHS survey includes a module on Chlorhexidine use (the first time that such a module has been utilized in the DHS) and should give an unbiased figure for Chlorhexidine coverage.

## SUMMARY

In conclusion, Chlorhexidine is a simple, cost-effective life-saving intervention. This document summarizes the evolution of the program in Nepal from the release of research results to full implementation, spanning the period from 2006 to 2017. It may seem that 10 years was a long time to reach nationwide implementation, but since Nepal was the very first country, it was necessary to conduct some additional research, to develop consensus and policy, to support initial development of the product, to design and revise the delivery methodology and develop all the materials and tools for actual implementation.

Now many international bodies, such as WHO, UNICEF and USAID, have endorsed the use of Chlorhexidine for cord care to reduce neonatal mortality, many of the programmatic challenges have been addressed, and experts stand ready to provide technical support to other countries for early implementation. It is hoped that within this positive environment, other countries, with high neonatal mortality, can easily adapt policies, protocols and materials and adopt strategies and approaches to accelerate the introduction of Chlorhexidine use in their own settings.

## MAJOR PROJECT MILESTONES: TRANSLATING RESEARCH INTO POLICY AND PRACTICE

DATES	MILESTONE	IMPLICATION
2002-2006	Nepal Nutrition Intervention Project-Sarlahi (NNIPS) JHU RCT findings showed 34% reduction in newborn mortality and 75% reduction in severe umbilical cord infection in severe umbilical cord infections in neonates (3).	Evidence from host country served as a policy advocacy tool.
2007	National level consultative meeting on Chlorhexidine.	Provided guidance for formative research, feasibility for local production, implementation modality to integrate with ongoing public health programs.
2008	National Chlorhexidine Technical Working Group (TWG) formed under Family Health Division (FHD), Ministry of Health (MoH).	TWG initially acted as a steering committee to identify the local pharmaceutical capacity for Chlorhexidine production, test effectiveness of Chlorhexidine in gel vs. aqueous formulation, test community acceptability, implement a pilot project, and refine the scale-up model. Continued to guide the program to nationwide coverage.
2008-2009	Lomus Pharmaceuticals begin producing Chlorhexidine locally. US Pharmacopeia support to ensure a quality product.	Identified private partner for in-country production.
	Chlorhexidine gel vs. aqueous for Preventive Use on Umbilical Stump: A Randomized Non-inferiority Trial (10).	The study confirms Chlorhexidine gel is equally effective as an aqueous formulation. The study confirms that communities prefer gel formulation over aqueous formulation.
2010-2011	A district-wide pilot study conducted in four districts.	High compliance is possible if Chlorhexidine program is integrated into the health system.
2011	Regional dissemination meeting on Chlorhexidine conducted in Banke district.	High-level government officials announce a commitment to national level scale-up.
	Chlorhexidine included in the essential drug list.	Chlorhexidine becomes authorized drug for cord care.
	MoH approves the use of Chlorhexidine and nationwide scale-up.	Rapid scale-up was possible with MoH endorsement.
	Experienced technical assistance partners identified to support GoN for rapid scale-up.	Chlorhexidine Navi Care Program (CNCP) awarded to JSI by Saving Lives at Birth.

DATES	MILESTONE	IMPLICATION
2012	Chlorhexidine included in roll out of Community Based-Newborn Care Program (CB-NCP).	Chlorhexidine became an integral part of essential newborn care. Health workers (HWs) and Female Community Health Volunteers (FCHVs) were trained as a part of CB- NCP training.
	Initiated technical support program to many other countries.	Delegations from over 20 countries visited Nepal to learn about Chlorhexidine implementation at different stages. GoN, with support from JSI/ CNCP project, shared knowledge to facilitate rapid introduction and roll out in other countries. Lomus Pharmaceuticals, a Nepalese company producing Chlorhexidine, begins supplying product to other countries.
2014	Chlorhexidine included in Health Management Information System (HMIS).	Chlorhexidine data available from routine health information system and thus helped to monitor health facility and community progress.
	Health facilities started distribution of Chlorhexidine from ANC clinics.	In addition to distribution by FCHVs, health facilities also started to distribute Chlorhexidine to the pregnant women.
2015	Chlorhexidine included in Logistics Management Information System (LMIS) with routine tracking of stock situation.	Integration helps ensure availability and tracking of Chlorhexidine tubes at each health facility.
	Chlorhexidine included in roll out of Nepal's Community Based –Integrated Management of Newborn and Childhood Illness (CB-IMNCI) program.	Chlorhexidine is an integral part of all government sponsored maternal and child health packages. Rapid scale-up in tertiary care hospitals and pre-service training on Chlorhexidine for midwives.
	Chlorhexidine Incorporated into Maternal and Newborn Health (MNH) update package, Skilled Birth Attendant (SBA) curriculum, Auxiliary Nurse Midwife (ANM) reference manual.	
	Launched Chlorhexidine Social Behavior Change Communication (SBCC) campaign.	Increased awareness and increased demand from the community.
2016	GoN begins procuring Chlorhexidine for the first time.	Increased government ownership and commitment to the sustainability of the program.
	Chlorhexidine included in Nepal's Every Newborn Action Plan (NENAP) and National Health Sector Strategy – Implementation Plan.	Chlorhexidine included in government policy document.
2017	Chlorhexidine program rolled out in all districts of Nepal.	Nationwide reach achieved.
	Chlorhexidine coverage assessed through national surveys.	Integration in major population surveys such as Nepal Demographic Health Survey, Health Facility Assessment.



Lomus Pharmaceutical  
supplies Chlorhexidine to

12 countries

## REFERENCES

1. Lawn JE, Cousens S, Zupan J, Team LNSS. 4 million neonatal deaths: when? Where? Why? The Lancet. 2005; 365(9462):891-900.
2. Lawn JE, Cousens S, Darmstadt GL, Paul V, Martines J. Why are 4 million newborn babies dying every year? Lancet 2004; 364:2020
3. World Health Organization. Care of the umbilical cord. WHO/FHE/MSM-cord care. Geneva:WHO, 1998.
4. Mullany LC, Darmstadt GL, Khatri SK, Katz J, LeClerq SC, Shrestha S, et al. Topical applications of Chlorhexidine to the umbilical cord for prevention of omphalitis and neonatal mortality in southern Nepal: a community-based, cluster-randomized trial. The Lancet. 2006; 367(9514):910-8.
5. El Arifeen S, Mullany LC, Shah R, Mannan I, Rahman SM, Talukder MRR, et al. The effect of cord cleansing with Chlorhexidine on neonatal mortality in rural Bangladesh: a community-based, cluster-randomized trial. The Lancet. 2012; 379(9820):1022-8.
6. Soofi S, Cousens S, Imdad A, Bhutto N, Ali N, Bhutta ZA. Topical application of Chlorhexidine to neonatal umbilical cords for prevention of omphalitis and neonatal mortality in a rural district of Pakistan: a community-based, cluster-randomized trial. The Lancet. 2012; 379(9820):1029-36.
7. Ministry of Health and Population (MOH) [Nepal] NE, & Macro International Inc., Nepal Demographic Health Survey 2006. Kathmandu, Nepal: 2007.
8. Ministry of Health and Population Nepal, New ERA, Macro International Inc. Nepal Demographic and Health Survey 2011. Kathmandu: 2012.
9. Imdad A, et al, The effect of umbilical cord cleansing with Chlorhexidine on omphalitis and neonatal mortality in community settings in developing countries: a meta-analysis, The Lives Saved Tool in 2013: new capabilities and applications. BMC Pregnancy & Childbirth 2013
10. Hodgins S, Thala K, Khanal L, Aryal S, Suvedi BK, Baidya U, et al. Chlorhexidine gel vs. aqueous for preventive use on the umbilical stump: a randomized noninferiority trial. The Paediatric infectious disease journal. 2010;29(11):999-1003.



**DISCLAIMER:** This document is made possible by the support of the American People through the United States Agency for International Development (USAID). The contents of this document are the sole responsibility of JSI Research and Training Institute, Inc./ Chlorhexidine Navi Care Program and do not necessarily reflect the views of USAID or the United States Government.

©2017, John Snow, Inc./ JSI Research & Training Institute, Inc.