Chlorhexidine for Umbilical Cord Care:

Evidence Base and the Way Forward

PATH/Karina Collins

Report of regional dissemination meeting held:

September 15–16, 2011

Nepalgunj, Nepal

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Acronyms

ASHA	Accredited social health activists
CDK	Clean delivery kit
CHW	Community health worker
CHX	Chlorhexidine
ENC	Essential newborn care
EML	List of essential medicines or essential medicines list
FCHV	Female community health volunteers
IMCI	Integrated management of childhood illness
IMR	Infant mortality rate
LBW	Low birth weight
MCHIP	Maternal and Child Health Integrated Program
MDG	Millennium Development Goal
MOHFW	Ministry of Health and Family Welfare
MOHP	Ministry of Health and Population
NNHS	National Neonatal Health Strategy
NMR	Neonatal mortality rate
NRHM	National Rural Health Mission
PATH	Program for Appropriate Technology in Health
RCHII	Reproductive and Child Health Programme II
SBA	Skilled birth attendant
TBA	Traditional birth attendant
USAID	United States Agency for International Development
WHO	World Health Organization

I. Executive Summary

Each year 3.1 million newborns die globally, and infection causes more than a quarter of these deaths.[1] In resource-poor, high-mortality settings, infections can account for over half of the neonatal deaths.[2] Lack of hygiene and antisepsis at birth and in the first week of life increases the risk of deadly but preventable infections. While the World Health Organization (WHO) guidelines recommend clean and dry umbilical cord care, they also state that application of topical antiseptics to the cord stump in areas with high infection risk is acceptable.[3]

In September 2011, a group of experts, researchers, product specialists, and key program planners from Bangladesh, Cambodia, India, Indonesia, Nepal, Pakistan, and the United States met in Nepalgunj, Nepal, to hear the scientific evidence from clinical trials conducted in Nepal, Pakistan, and Bangladesh on the application of chlorhexidine (CHX) to the newborn cord during the first week of life and to outline next steps for moving forward with CHX work in these countries. Results from operational studies in Nepal and Bangladesh were presented, as well as the policy context considerations on the use of this intervention. The meeting was hosted by the Government of Nepal, Ministry of Health and Population, with support from the United States Agency for International Development, PATH, Save the Children/Saving Newborn Lives Program, the Maternal and Child Health Integrated Program, and Johns Hopkins School of Public Health.

The primary objectives of the meeting were:

- To present evidence from recent research relating to the efficacy and programmatic outcomes of using a 4% CHX product for umbilical cord care from Nepal, Pakistan, and Bangladesh.
- To assist country policymakers to identify next steps for introduction of CHX for umbilical cord care, as warranted.

Prior to the meeting, participants also had the opportunity to visit the pilot study sites in the district of Banke, Nepal, to observe how female community health volunteers and health workers are mobilized to use CHX in the context of a maternal and newborn program. Following the visit, participants met to discuss their observations. Overall, participants were impressed by how community health workers and volunteers contributed to increasing the use of CHX in communities.

Efficacy of chlorhexidine for umbilical cord care

In the three countries where CHX research has been conducted—Nepal, Pakistan, and Bangladesh—neonatal mortality is a high proportion of mortality for children under five years of age, and although institutional deliveries are increasing in these countries, the majority of births still take place at home. In addition, these countries have well-developed essential newborn care policies and guidelines, as well as policies on “clean and dry” umbilical cord care. All studies used first-day applications of 4% CHX solution, followed by once-daily applications ranging from 7 to 14 days after birth. The studies were all designed as cluster-randomized controlled trials.

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[1] United Nations Children’s Fund (UNICEF). *Levels & Trends in Child Mortality: 2011 Report.* Washington, DC:UNICEF;2011. Available at: http://www.unicef.org/media/files/Child_Mortality_Report_2011_Final.pdf.

[2] Lawn J, Cousens S, Zupan J. 4 million neonatal deaths: When? Where? Why? *Lancet.* 2005;365(9462):891–900.

[3] World Health Organization (WHO). *Care of the umbilical cord.* WHO/FHE/MSM. Geneva:WHO;1998.

Key findings from Nepal

A 4% CHX solution was applied each day for 7 days by community health volunteers. The study also evaluated the impact of soap and water and dry cord care alone.

CHX substantially reduced the risk of death within 28 days with an overall reduction in neonatal mortality of 24%, and a reduction of 34% if applied within 24 hours of birth. The risk of cord infection was reduced by 32% to 75%, depending on the severity.[4] Signs of cord infection were related to subsequent death.[5] In addition, soap and water did not reduce the risk of neonatal mortality.

Key findings from Pakistan

In the context of existing government programs, this effectiveness trial examined the promotion and traditional birth attendant distribution of CHX for cord application for the first two weeks, compared to the usual recommendation of dry cord care. Neonatal mortality was reduced by 38% in the CHX group compared to the dry cord care group, and severe cord infection was reduced by 42% for CHX cord cleansing compared to the dry cord care group.

Key findings from Bangladesh

The study evaluated three different cord care regimens:

- Single cleansing—4.0% CHX solution once as soon as possible after birth.
- Multiple cleansing—4.0% CHX solution as soon as possible after birth, and daily for 7 days.
- Dry cord care—no cord application, basic messages regarding keeping cord clean and dry**.**

Single CHX application on the first day of life reduced neonatal mortality by 20% and moderately reduced severe umbilical cord infection (omphalitis) as well as cord bacterial colonization. Seven-day CHX application reduced severe cord infection by 65%, reduced bacterial colonization, and neonatal mortality was 6% lower in this group (not statistically significant). In the preterm group, there was a 34% reduction in neonatal mortality in the single CHX cleansing arm (statistically significant) and a 12% reduction in the 7-day CHX cleansing arm (not statistically significant).

Despite high study power (80%), there was still a 20% chance that the study would not find a true impact on neonatal mortality.

Programmatic experience with chlorhexidine for umbilical cord care

Operational research in Pakistan and Bangladesh demonstrated that a number of different formulations (e.g., liquid, gel/lotion) of 4% CHX were acceptable to families and that families typically were able to use the product as recommended. A pilot project in the Banke district in Nepal showed that CHX cord cleansing was a feasible intervention to provide through the government's existing cadre of female community health volunteers and health workers.

Conclusions and recommendations

There is sufficient evidence to recommend inclusion of 4% CHX cord cleansing as a strategy to reduce neonatal mortality in settings where poor hygiene and high neonatal mortality are issues. The results from

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[4] Mullany L, Darmstadt G, Khatry S, et al. Topical applications of CHX to the umbilical for prevention of omphalitis and neonatal mortality in southern Nepal: a community-based, cluster-randomized trial. *Lancet*. 2006;367:910–918.

[5] Mullany L, Darmstadt G, Katz J, et al. Risk of mortality subsequent to umbilical cord infection among newborns of southern Nepal: cord infection and mortality. *The Pediatric Infectious Disease Journal*. 2009;28(1):17–20.

the clinical trials from Nepal, Pakistan, and Bangladesh showed a reduction of neonatal mortality from 20% to 38%, with a reduction of omphalitis from 24% to 75%. These trials also indicated that applying 4% CHX immediately after cord cutting was critical to reduce omphalitis and neonatal mortality.

CHX is a well-known antiseptic, commonly found in products for oral rinse and pre-surgical hand washing, and it has an excellent safety record. The World Health Organization Model List of Essential Medicine for Children includes CHX bulk (20% CHX gluconate) with the instruction to dilute for umbilical cord care use.

Countries represented at this meeting are currently following the WHO guidance of clean and dry cord care. However, introduction of 4% CHX for cord care is compatible with WHO's 1998 recommendations. Beyond the direct antiseptic effect, CHX may replace common, harmful practices, such as applying mustard oil and other substances to the cord.

At the end of the meeting, country delegations committed to hold national stakeholder consensus meetings on introduction of CHX for umbilical cord care as part of newborn care.

II. Meeting Report

Meeting overview

On September 14 and 15, 2011, the United States Agency for International Development (USAID), in collaboration with the Government of Nepal Ministry of Health and Population (MOHP), convened a regional gathering of researchers, program planners, and policymakers from Bangladesh, Cambodia, India, Indonesia, Nepal, Pakistan, and the United States (see Appendix 1. Participants) to review emerging research and program implementation of chlorhexidine (CHX) for umbilical cord care (see Appendix 2. Agenda). Held at a hotel in Nepalgunj, Nepal, the meeting was the result of an effort coordinated by PATH in collaboration with Saving Newborn Lives, Maternal and Child Health Integrated Program (MCHIP), and Johns Hopkins University. The primary objectives of the meeting were:

- To present evidence from recent research relating to the efficacy and programmatic outcomes of using a 4% CHX product for umbilical cord care from Nepal, Pakistan, and Bangladesh.
- To assist country policymakers to identify next steps for introduction of CHX for umbilical cord care, as warranted.

This regional meeting was a significant milestone which moved CHX for umbilical cord care toward implementation.

Field visits

On September 14, 2011, the Government of Nepal, the USAID/Nepal Mission, and the Nepal Family Health Program II guided participants on field visits to pilot sites currently using CHX for umbilical cord care in the context of a maternal/child health project. Participants visited six pilot sites in the Banke district.

The objectives of the visits were to understand the role and contributions of the District Public Health Office, health facilities, community health workers (CHWs), and female community health volunteers (FCHVs) on implementation of CHX and other maternal newborn health programs such as family planning, misoprostol, maternal newborn health at the community level, and community-based integrated management of childhood illness (IMCI).

Participants were provided with an overview of the Nepal health system and then visited the communities or facilities that are currently using CHX. Following the visit, participants met to discuss their observations. Overall, participants were impressed by how CHWs and volunteers contributed to increasing the use of CHX in communities.

Scientific presentations on efficacy of chlorhexidine for umbilical cord care

Presentation: Community trial of newborn skin and umbilical cord cleansing on neonatal mortality in Nepal

Presenter: Luke Mullany, PhD, Johns Hopkins University

Background on chlorhexidine

CHX is a broad spectrum antiseptic solution commonly used worldwide and with excellent safety records. Topical application of CHX to the umbilical cord stump became routine practice in many facilities throughout the 1970s and 1980s.

CHX is also part of the World Health Organization (WHO) Model List of Essential Medicines (EML) for Children. The WHO 1998 recommendations on optimal cord practices included use of CHX for umbilical cord care when exposure risk is high,[3] while calling for rigorous population-based research on the impact of topical antiseptics for cord care.

The Nepal study was designed as a community-based cluster-randomized trial to examine the impact of CHX cord cleansing on:

- Umbilical cord infection.
- Neonatal mortality.

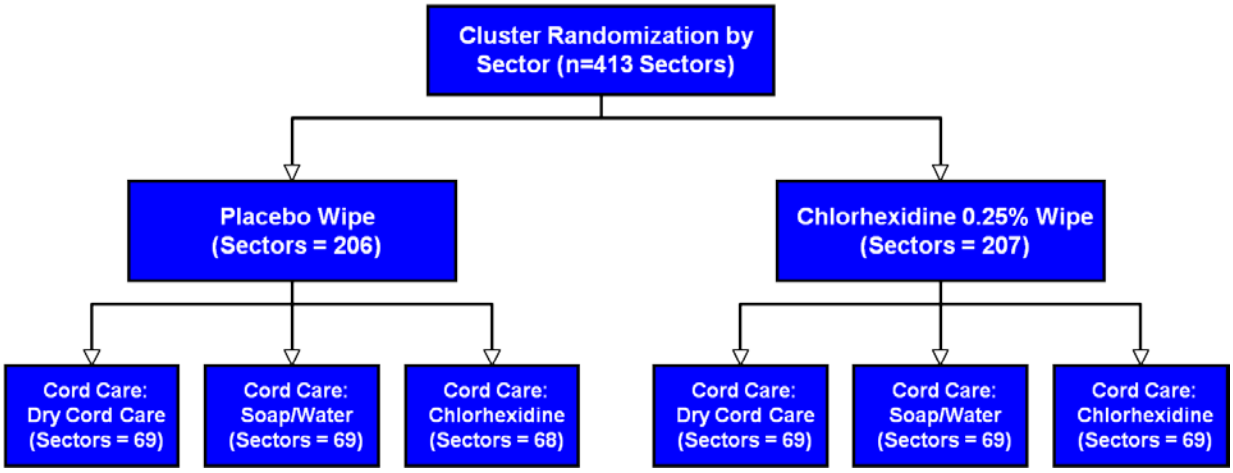
A total of 413 sectors (defined as the families cared for by one female health worker) in the Sarlahi district were randomized to one of two full-body skin cleansing interventions immediately after birth:

1. Placebo (normal baby wipes).
2. 0.25% CHX solution (enhanced baby wipes).

Each sector was also randomized to one of three umbilical cord care regimens (see Figure 1):

1. 4.0% CHX solution cord cleansing.
2. Soap and water cleansing.
3. Dry cord care alone.

Figure 1. Study randomization and cord care regimens (from presentation)



Methodology

Pregnant women were identified through weekly surveillance by local female staff (n=413). At the sixth month of pregnancy, women were provided with:

- Vitamin A (weekly), iron-folic acid supplements, and albendazole.
- Clean delivery kit (CDK); cord and newborn care education.
- Maternal tetanus toxoid vaccine.

Newborn infants were enrolled at the first visit. Home visits throughout the neonatal period were conducted during days 1–4, 6, 8, 10, 12, 14, 21, and 28. At each household visit, field workers collected morbidity and vital status data.

During home visits, health workers evaluated signs of infection such as:

- Presence of pus.
- Redness at the base of the stump (none/mild/moderate/severe).
- Swelling at the base of the stump (none/mild/moderate/severe).

No umbilical cord stumps were cultured for bacterial colonization.

Summary of study results
Clusters were randomized based on demographic characteristics, labor and delivery characteristics, weight at birth and gestational age, household socioeconomic characteristics, ethnicity and caste, and season of enrollment.

CHX substantially reduced the risk of death within 28 days, with an overall reduction in neonatal mortality of 24%, and a reduction of 34% if applied within 24 hours of birth. The risk of cord infection was reduced by 32% to 75%, depending on the severity.[4] Signs of cord infection were related to subsequent death.[5] In addition, soap and water did not reduce the risk of neonatal mortality.

Presentation: Evaluation of topical application of chlorhexidine to the umbilical cord for reduction in umbilical cord infection and neonatal mortality

Presenter: Sajid Soofi, PhD, Aga Khan University

Introduction
Globally, every year 3.3 million newborns are estimated to die within the neonatal period that contributes to 41% of deaths of children under five years of age. Unfortunately, almost all (>98%) deaths occur in low- and middle- income countries, which can be attributed to infections among neonates.[6] Pakistan, a low-income country, has a high neonatal mortality rate (NMR) of 42 out of 1,000 live births. More than 65% of deliveries take place at home, often attended by unskilled traditional birth attendants[7] (TBA) who do not consistently employ clean delivery practices.[8]

Umbilical cord infection is a significant risk factor for neonatal morbidity and mortality.[9] This study aims to estimate the independent and combined effects of application of 4% CHX solution to cord stump and/or hand washing with soap in reducing omphalitis and neonatal mortality.

Methodology
The present study, a community-based cluster-randomized trial, was conducted in the Dadu district of Sindh province in Pakistan over a period of one year. Dadu is a rural district with an estimated population of one million. The study area was divided into clusters, catchment populations of TBAs (approximately one to two villages with populations of about 1,000).

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[6] Oestergaard M, Inoue M, Yoshida S, et al. Neonatal mortality levels for 193 countries in 2009 with trends since 1990: a systematic analysis of progress, projections, and priorities. *PLoS Med.* 8(8):e1001080.

[7] National Institute of Population Studies (NIPS) [Pakistan], and Macro International Inc. Pakistan Demographic and Health Survey 2006-07. Islamabad, Pakistan: National Institute of Population Studies and Macro International Inc; 2008.

[8] Darmstadt G, Lee A, Cousens S, et al. 60 million non-facility births: who can deliver in community settings to reduce intrapartum-related deaths? *International Journal of Gynaecology and Obstetrics.* 2009;107:S89–S112.

[9] 8. Thaver D, Zaidi AKM. Burden of neonatal infections in developing countries: a review of evidence from community-based studies. *The Pediatric Infectious Disease Journal.* 2009;28:S3–S9.

Sample size was calculated using 52 clusters per arm to detect 20% reduction in neonatal mortality and 35% reduction in omphalitis (~2,500 per group). A 2x2 factorial design was used and clusters were randomly allocated to one of the following four groups using computer-generated numbers: group A received 4% CHX solution along with hand washing promotion messages, group B received hand washing promotion messages only, group C received 4% CHX solution only, and group D received neither CHX nor hand washing promotion messages. Intervention was delivered at the household level by TBAs working under the supervision of CHWs, who provided CDKs with 4% CHX to the TBAs. TBAs applied CHX on the umbilical cord on day one and taught the procedure to the mother so they could continue application for the next 14 days in the CHX groups. CHWs visited households in their assigned populations on days 1, 3, 5, 7, 14, and 28. The documented signs of umbilical cord infection included redness or swelling/pus, or both, on the cord stump or skin. If redness or swelling/pus was moderate to severe, CHWs referred mothers to the nearest health facility. They documented materials applied to the cord in the previous 24 hours.

The primary outcomes were incidence of neonatal omphalitis and neonatal mortality. All the live births from pregnancies within the trial clusters were eligible for enrollment in this study. Infants with birth defects and infections were excluded.

Summary of study results

Baseline characteristics. All four groups had almost similar baseline socioeconomic and household characteristics. The highest number of households (8,559) and the highest population (68,737) were reported in group D, while the lowest number of households (7,801) and lowest population (62,869) were reported in group B. Almost all groups reported using electricity as a major source of lighting. Use of animal dung as fuel for cooking was highest in group A (48.0%) and group D (49.2%), while use of firewood was highest in group B (45.9%) and group C (43.9%). The majority of households, in all groups, were using their own hand pump for their source of drinking water. In all groups, the majority of deliveries were conducted at home by *dais*/TBAs. In baseline practices, the majority of households in all groups—highest was group B (62.7%) and lowest was group D (57.1%)—reported practicing application of traditional substances (*surma*) on the cord stump. Use of Dettol® alcohol antiseptic, mustard oil, cicatrin powder, talcum powder, and ash were also reported.

Study findings showed that a total of 4,867 live births were recruited in the CHX groups (A and C), whereas 4,874 were recruited in the non-CHX groups (B and D). However, 111 and 176 neonatal deaths were reported in the CHX groups and non-CHX groups, respectively. Similarly, 166 and 309 cases of omphalitis were reported in the CHX groups and non-CHX groups, respectively.

Observed CHX practices. Findings showed that 96.5% of the respondents from groups A and C reported applying daily CHX on the umbilical cord. However, respondents reported applying CHX 2.7 times per day. The overall mean time of cord separation in these two groups was 7 days, whereas duration of applying CHX was 11.1 days. Findings further showed that the vast majority of all groups had cord separation by day 7.

Incidence of omphalitis (factorial analysis). Findings further showed the incidence of omphalitis in the CHX groups (A and C) compared to the non-CHX groups (B and D). Omphalitis cases were higher in non-CHX groups (309) compared with CHX groups (166). Similarly, the rate of omphalitis was higher in non-CHX groups (10.8) compared with CHX groups (5.7). Analysis indicated strong evidence of a reduction in risk of omphalitis associated with the CHX risk ratio 0.58 (0.41, 0.82). This study demonstrated that the risk of omphalitis was significantly lower in CHX application groups, with a significant P value of 0.002.

All cause neonatal mortality. Factorial analysis indicated strong evidence of a reduction in neonatal mortality in children receiving CHX (risk ratio=0.62, 95% CI, 0.45–0.85, P=0.003), as the number of

neonatal deaths reported in non-CHX groups was higher (176 with 36.1 NMR compared with CHX groups (111 with 22.8 NMR).

Impact on omphalitis and mortality. This study further showed that the odds of neonatal mortality were 39 times (95% CI, 0.48–0.79) lower in children with CHX application compared to children with non-CHX application. In addition, the odds of neonatal omphalitis was 48 times (95% CI, 0.43–0.63) lower in children with CHX application compared to children with no CHX application.

Conclusion
This study revealed strong evidence that this CHX intervention was effective in reducing the risk of neonatal mortality (38%) and was also effective in reducing the odds of omphalitis (42%). In addition, application of 4% CHX is safe, and it was well accepted in the community.

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Study Coordinator: Dr. Sajid Bashir Soofi, Assistant Professor, Department of Paediatrics and Child Health, The Aga Khan University, Pakistan. Email: sajid.soofi@aku.edu.

Presentation: Impact of cord cleansing with chlorhexidine on neonatal mortality in rural Bangladesh: a community-based, cluster-randomized trial

Presenter: Abdullah Baqui, DrPH, MPH, MBBS, Johns Hopkins Bloomberg School of Public Health

Background
The Project for Advancing the Health of Newborns and Mothers group was established in 2001 in an effort to improve newborn and maternal health in Bangladesh. The group is a partnership between the Bangladesh Ministry of Health and Family Welfare (MOHFW), International Centre for Diarrhoeal Disease Research–Bangladesh (ICDDR,B), Shimantik, and Johns Hopkins University.

Study design
The Project for Advancing the Health of Newborns and Mothers (Projahnmo) Bangladesh clinical trial was designed as a cluster-randomized clinical trial. The study was conducted in Sylhet, Bangladesh. An average cluster size was approximately 4,000 neonates. The study had a total of 133 clusters, randomized to one of the three cord care regimens. All babies alive within seven days of birth, regardless of intervention status, were considered enrolled. CHWs delivered a basic package of maternal and neonatal health care with or without CHX solution across all clusters.

The specific aims of the study were:

- To assess the impact of two different regimens of CHX cord care on neonatal mortality compared to “dry cord care.”
- To assess the impact of these regimens on omphalitis and cord colonization compared to “dry cord care.”

The cord care regimens used during the study were:

- Single cleansing—4.0% CHX once, as soon as possible after birth.
- Multiple cleansing—4.0% CHX as soon as possible after birth and daily for 7 days.
- Dry cord care—no cord application, basic messages regarding keeping cord clean and dry.

CHWs conducted home visits as soon as possible after birth (preferably within 24 hours) and on days 3, 6, 9, 15, and 28 after birth. Newborns were examined for signs of cord infection and other signs of morbidity.

Summary of study results
Overall, there was a 20% reduction of neonatal mortality in the single CHX cleansing arm, which was statistically significant. The 7-day CHX cleansing arm showed a 6% reduction in neonatal mortality, which was not statistically significant. In the preterm group there was a 34% reduction in neonatal mortality in the single CHX cleansing arm, which was statistically significant. The 7-day CHX cleansing showed a 12% reduction in neonatal mortality, which was not significant.

There was also an effect on cord infection and colonization. The 7-day CHX cleansing arm reduced severe cord infection by 65%, which was statistically significant. The 1-day CHX cleansing reduced severe cord infection by 23%, which was not statistically significant. In terms of cord colonization, the 7-day cleansing was associated with 36% lower cord colonization, which was significant, and the single cleansing was associated with 18% lower cord colonization, which was also significant.

Conclusion
Single-day CHX cleansing has a moderate effect on cord infection and colonization and 20% statistically significant reduction of neonatal mortality. The 7-day CHX cleansing has a maximum reduction of cord infection and colonization, but no significant neonatal mortality reduction. Mortality reduction was greatest in preterm babies.

The lack of mortality effect in the 7-day CHX cleansing group was not expected and most likely due to chance because:

- There was no group difference in background characteristics, age at enrollment, and intervention coverage.
- The 7-day group had the lowest cord infection and cord colonization rates.
- Prior data from Nepal and concurrent data from Pakistan showed significant reduction of NMR with multiple (7–10 days) cleansings.
- Chance of missing an effect was 20%, and chance of seeing an erroneous effect was 5%.

Presentation: Meta-analysis of results from chlorhexidine randomized controlled trial

Presenter: Luke Mullany, PhD, Johns Hopkins University

Preliminary pooled analysis of the data from all three community-based trials in South Asia indicates that CHX applications to the cord can reduce risk of death in the neonatal period by approximately 23% and prevent 68% of serious cord infections.

Panel discussion for scientific presentations

Participants had the opportunity to ask questions and clarify information that was not clearly understood during the presentations. Main topics for discussion were:

Effect of confounding factors on study results
Attendees requested clarification on the effect of specific factors, such as different bathing schedules, hand washing, breastfeeding, and diapering techniques, on neonatal mortality in the various groups. To this question speakers responded that there can be many confounds between groups and that some effects cannot be measured. There was little difference between groups in Pakistan and Bangladesh. In addition,

about 60 different variables were measured in both the Nepal and Bangladesh trials in hopes that the cluster-randomized trial could take care of small differences in local practices.

Rationale for using chlorhexidine over cheaper antiseptics
There are other antiseptic substances, such as alcohol, that could play a similar role as CHX in the prevention of neonatal mortality by maintaining clean stump. However, CHX was chosen over alcohol and other topical antiseptics because alcohol does not have safety records on preterm skin.

Single-day versus multiple-day application
There was a lengthy discussion on single-day versus multiple-day application of CHX for umbilical cord care. Participants asked repeatedly for clarification and a unified voice regarding this important topic. In addition, they requested clarification on the length of application in the Nepal and Pakistan trials (14-day and 7-day application, respectively). Participants expressed confusion over the results of the 1-day versus 7-day application regime in Bangladesh.

The following concerns were expressed by participants regarding application regime:

- Application regime has direct operational implications.
- Cost of 1-day versus 7-day regime.
- Behavior change: 1-day application could be beneficial, as mothers or providers do not have to remember to apply the medication every day for 7 days.
- Reduction in the number of times the stump is manipulated may help prevent infection.
- Available evidence regarding 1-day application may not be enough to decide application regime.

Presenters discussed all these concerns with the participants and concluded that based on the available evidence, 1-day application of CHX could be sufficient. The key message is that application should occur as soon as possible. If feasible, application should be repeated once daily during the first week of life, or until the cord separates, whichever occurs earlier. Further benefits may be realized from multiple applications, including reduced local infection or improved hygiene practices.

Safety
A 4% CHX has been used for cord cleansing for about 50 years and there has been no reported side effects of the use of this presentation. There was a safety review published looking at different kinds of CHX cleansing. There is some evidence that if it is used on the entire body of the newborn, it can result in trace absorption in preterm babies. This is not the case for 4% CHX for umbilical cord care. None of the trials presented showed side effects on babies.

Rationale for using 4% chlorhexidine over other concentrations
A 4% CHX was used because it has been used for cord care since the 1950s/1960s. Other concentrations, such as 2% CHX, are more common for pre-operative skin cleansing.

Translation of research into policy and action
Participants said that the WHO statement, as it is, is ambiguous, and countries need clear guidelines on dry cord care versus the use of CHX.

Presenters concluded that there is enough evidence to demonstrate to WHO the need for revision of the current cord care guidelines. It will be important to clearly define guidelines for countries with high infection rates in line with WHO's goal to keep the cord clean.

Behavior change
Participants stressed the importance of behavior change as a key component of a successful implementation of CHX intervention.

Pooled analysis and need for more evidence
Participants requested clarification on control groups in the meta-analysis. Presenters explained that it is difficult to do a pooled analysis and assume the results are true for all settings. "We are not saying that dry cord care doesn't work, but rather that it is very hard to achieve. CHX would have the greatest effect in areas with least dry cord care."

There is a parallel between CHX and Vitamin A. In three trials in South Asia, Vitamin A showed it could reduce NMR by 50%. The same was not true for Vitamin A trials in Africa, and the pooled analysis led to the decision to do more trials. For CHX we need results from sub-Saharan Africa, which will add to the global body of evidence. There is an evidence base in South Asia, where there is a culture of applying substances to the cord, and CHX can help by switching this behavior to an intervention that is proven effective and safe.

Presenters agreed that another trial is probably not needed. There is evidence from the three clinical trials and the operations research already and this should be sufficient to shift from research to policy and action.

Policy considerations on cord care in the context of essential newborn care

Nepal

Presenter: Dr. Naresh Pratap KC, Director, Family Health Division, Department of Health Services

Background and context
Nepal has been marked by a decline in infant and child mortality but with less improvement with neonatal mortality. There has been no change in neonatal mortality in the country from 2006 to 2011.

Facility delivery rate has improved rapidly, as well as rate of births attended by a skilled birth attendant (SBA). In addition, there has been increasing involvement of FCHVs in maternal and neonatal health, as well as rapid scale-up of newborn care packages.

The major cause of neonatal death is infection (42%), followed by injury (19%), birth asphyxia (15%), congenital anomalies (8%), preterm low birth weight (LBW) (6%), and other causes (10%).

In terms of delivery practices, 78% of recently delivered women reported using a CDK or new/boiled blade to cut the umbilical cord, with significant regional variability.[10] In addition, only 26% reported putting something on the cord after cutting.[10] Practices of applying something to the cord vary considerably (e.g., in Banke 58% applied something, mainly mustard oil).[11] Infection risk is also increased by other practices (e.g., surface used for cord cutting, where infant is placed after cord cutting, etc.).

Current recommendations for neonatal practices in Nepal include:

- Early initiation of breastfeeding:
    - 41% had breastfeeding initiated within 1 hour of birth.[11]

[10] Ministry of Health and Population (MOHP) [Nepal], New ERA, and Macro International Inc. *Nepal Demographic and Health Survey 2006.* Kathmandu, Nepal: Ministry of Health and Population, New ERA, and Macro International Inc; 2007.

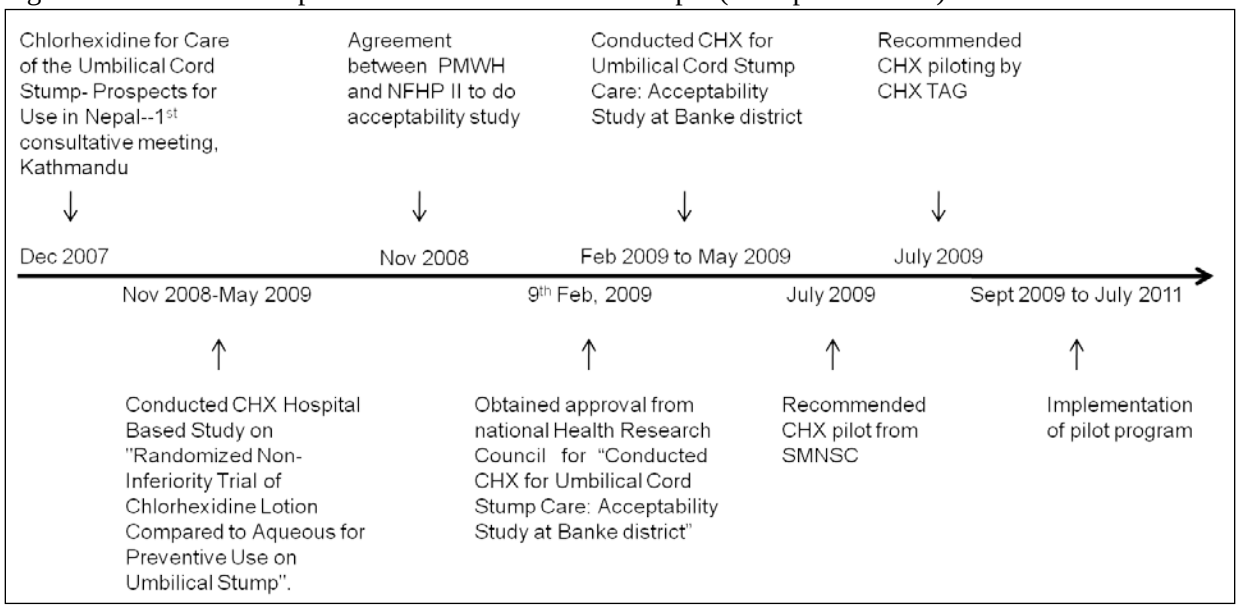
[11] Nepal Family Health Program II and New ERA. *Family Planning, Maternal, Newborn and Child Health Situation in Rural Nepal: A Mid-term Survey for Nepal Family Health Program II.* Kathmandu, Nepal: Nepal Family Health Program II and New ERA; 2010.

- Postnatal check-ups:
  - 36% received a postnatal check-up.[11]
- Care of sick baby [12]:
  - 61% of mothers whose baby was sick reported that illness started in the first 7 days of life.
  - 76% of caretakers reported that care was sought within 24 hours of illness.

Timeline for exploration of chlorhexidine

Nepal has undergone a process of exploration of CHX for umbilical cord care for the past four years. Figure 2 captures the steps and considerations for implementation and scale up of CHX in Nepal.

Figure 2. Timeline for exploration of chlorhexidine in Nepal (from presentation)



Issues and challenges that Nepal needs to overcome in order to achieve national scale-up of this intervention include:

- Revising current dry and clean cord policy.
- Integrating CHX with ongoing programs.
- Fully replacing traditional harmful cord care practices.

The Government of Nepal considers the following as critical next steps: disseminating the results of the pilot study, setting the stage for policy development, and planning for scale-up.

[12] *Compiled by presenter from 2009 UNICEF survey data from 6 districts (Chitwan, Dang, Kavre, Palpa, Dhankuta, Bardiya).*

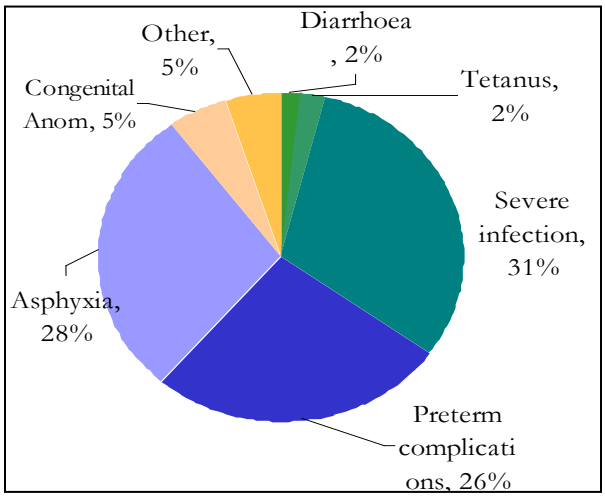
Bangladesh

Presenter: Dr. Syed Abu Jafar Md. Musa, Deputy Director Planning and Research, Directorate General of Health Services/MOHFW

Country background

- Neonatal mortality: 37 per 1,000 live births.
- Main causes of neonatal death: severe infection, asphyxia, preterm complications, congenital anomalies, tetanus, diarrhea, and others (see Figure 3).
- Institutional and home delivery:
    - Facility delivery: 23.4%
    - Urban: 37.7%
    - Rural: 19.1%
- SBAs at births: 26.5%
- SBAs at home births: 4.4%

Figure 3. Causes of neonatal death in Bangladesh (from presentation)



Essential newborn care in Bangladesh

The standard package of essential newborn care (ENC) in Bangladesh includes:

- Clean and safe delivery: clean cord cutting and tying.
- Prevention and management of hypothermia: drying and wrapping, skin-to-skin care, and delayed bathing.
- Assessment of breathing status (management of birth asphyxia): tactile stimulation, bag-and-mask resuscitation, mouth-to-mouth resuscitation.
- Initiation of breastfeeding immediately after birth.
- Appropriate cord care: Applying nothing to the cord.
- Appropriate eye care.
- Provision of special care for LBW neonates: two additional home visits, assisted feeding if needed.
- Identification, referral, and management of complications.

Although national policy calls for clean and dry cord care, there are several regions of the country in which harmful practices are still common.

Key activities and steps to inform decision-making

Bangladesh is targeting reduction of neonatal mortality from 37/1,000 live births to 21/1,000 live births by 2015.[13] Targeting neonatal mortality is an effort that requires political commitment. Bangladesh considers the following steps and activities essential to incorporation of CHX for umbilical cord care into newborn care practices:

- Translation of global policy/strategy into national policy/strategy through a structured process:
  - Sharing information with policymakers and other stakeholders through workshops, seminars, and meetings.
- Incorporation of study findings:
  - Formal dissemination of the study results for Bangladesh.
  - Sharing with policymakers and other stakeholders through workshops, seminars, and meetings.
- Formulation and updating of strategies.
- Major shift in the programmatic management of newborn care by developing a separate operational plan for maternal, newborn, and child health under the Health, Population, and Nutrition Sector Development Program.

Anticipated opportunities and challenges

- National Neonatal Health Strategy (NNHS) October 2009 guideline—provided guideline with well-defined ENC for different levels of health care facilities and communities.
- NNHS recommended dry cord care as per WHO recommendation.
- Increase accessibility for newborn care by establishing cord care.
- IMCI guidelines incorporated into newborn care and the community.
- Health, Population and Nutrition Sector Development Program; Population Information Program; and operational plans of Maternal, Newborn, and Child Health and Maternal, Newborn, Child and Reproductive Health line directorates prioritize implementation of NNHS.
- NNHS recommended initiation of research to improve the management of neonatal infections.
- ENC, including cord care at the home.
- Consensus to change any established policy.
- Conclusive evidence.

Cambodia

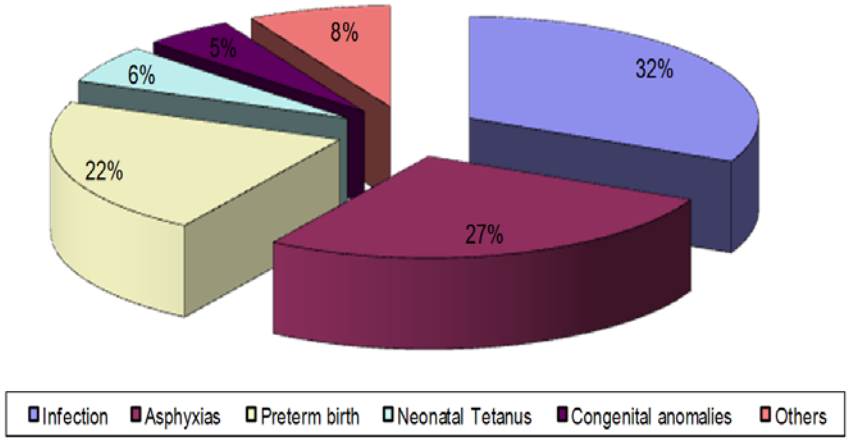
Presenter: Dr. Seang Sody, Chief of Neonatal Care Unit, National Maternal and Child Health Center, Ministry of Health

Country context

In 2010, Cambodia registered 54% as facility births. Skilled attendance during home births is at 24%. The NMR in 2010 was registered at 27/1,000 live births. The main cause of neonatal death is infection, followed by asphyxia, preterm birth, other causes, neonatal tetanus, and congenital anomalies (see Figure 4).

[13] Bangladesh Ministry of Health and Family Welfare. *Environmental Assessment and Action Plan for the Health, Population and Nutrition Sector Development Program (HPNSDP) 2011–2016.* Government of the People's Republic of Bangladesh, Dhaka; 2011.

Figure 4. Major causes of neonatal death in Cambodia (from presentation)



Essential newborn care practices
Cambodia currently implements ENC practices at community and institutional levels. Practices are implemented soon after birth and in the maternity room. Practices focus on resuscitation, if needed; prevention of hypothermia; early breastfeeding; umbilical cord care; eye care; and immunization.

National policy on umbilical cord care includes:

- Hand washing before and after touching the cord.
- Apply nothing on the cord stump.
- Cover cord stump only with clean dry clothes; do not wrap cord stump or bandage baby's belly.
- If stump is soiled, wash it with clean water and soap and dry it thoroughly with a clean cloth.

New interventions
In 2008, the Cambodia Ministry of Health announced a "Fast Track Initiative" for improving reproductive, maternal, newborn, and child health. The initiative consists of four core components:

- Emergency obstetric and newborn care.
- Skilled birth attendance.
- Family planning.
- Safe abortion.

The initiative also consists of three "Enabling Environment Components":

- Behavior change communication.
- Removing financial barriers.
- Maternal death surveillance and response.

In addition, the section on ENC in the Safe Motherhood Protocol is currently being agreed upon and rewritten. Considerations should include umbilical cord care and key activities to inform decision-making.

Anticipated opportunities and challenges
- Limitation of human resource capacity and number.
- Currently strong political support.
- Support from development partners.

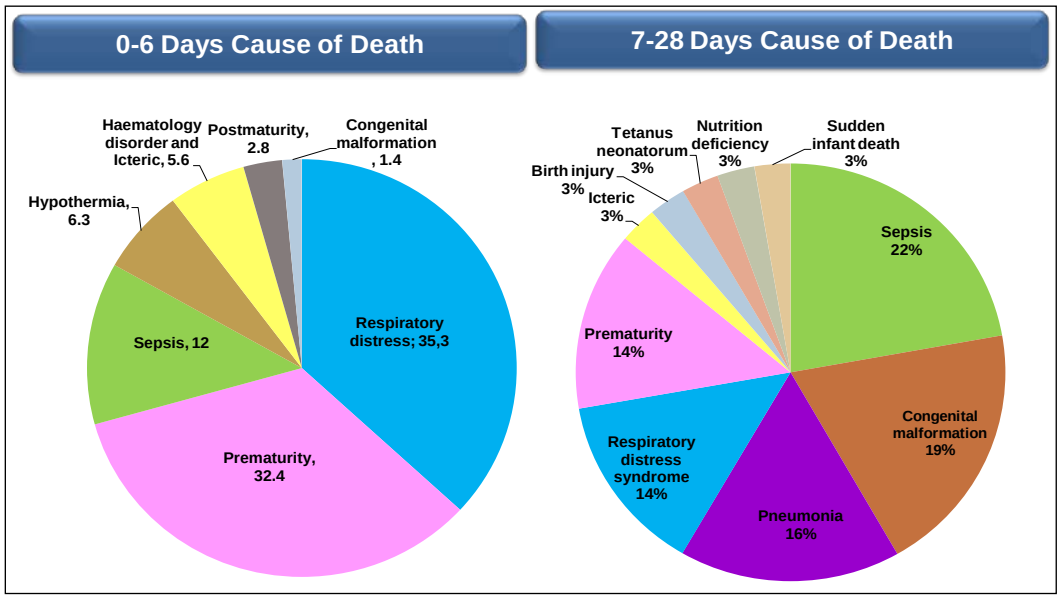
Indonesia

Presenter: Nida Rohmawati, MD, Government of Indonesia

Country context

Data from 2010 indicates that 55.4% of births in Indonesia occur in health facilities, 43.2% occur at home, and 1.4% occur in maternity huts. In regard to neonatal mortality, data from 2007 indicates an NMR of 19 per 1,000 live births. Main causes are seen in Figure 5 below.

Figure 5. Causes of neonatal mortality in Indonesia (from presentation)



Source: Basic Health Research 2007

Current essential newborn care practices in Indonesia

Figure 6 summarizes the current newborn practices being used in Indonesia.

Figure 6. Current newborn practices in Indonesia (from presentation)

At Birth	Day-1st	Day-3rd	Day 8th -28th
Health personnel: • Management of asphyxia • Immediate Breastfeeding • Keep the baby warm • Infection prevention • Vit K_1 injection • Hepatitis B 1 injection • Emergency care • Referral case management • Maternal and perinatal mortality audit **Family: MCH Handbook**	**Health personnel:** • 1st Neonatal visit using IMCI • Neonatal care counseling, exclusive breastfeeding • Vit K_1 & Hep B injection (for non skilled birth attendant delivery) • Referral case management • Maternal and perinatal mortality audit **Family: MCH Handbook**	**Health personnel:** • 2nd Neonatal visit using IMCI • Neonatal care counseling, exclusive breastfeeding • Referral case management • Maternal and perinatal mortality audit **Family: MCH Handbook**	**Health personnel:** • 3rd Neonatal visit using IMCI • Neonatal care counseling, exclusive breastfeeding • Referral case management • Maternal and perinatal mortality audit **Family: MCH Handbook**

In regards to umbilical cord care practices, Indonesia is currently following WHO recommendations for dry and clean cord care. In health facilities, the policy calls for open, dry, and clean care or use of alcohol, povidon iodine, or brilliant green, gentian violet dan proflavin hemisulfate (Triple Dye), at Dr. Sutomo teaching hospital.

In communities, the national recommendation is dry, clean, cord care with no addition of any natural or chemical substances to the cord.

Key activities and steps to inform decision-making
It is critical for Indonesia to disseminate information from the Nepal meeting to decision-makers at the Indonesia Ministry of Health (maternal and child health, medical services, drug and health equipment supply, human resources, research and development board, etc.), professional organizations, and some medical faculty and midwifery schools. Equally important is to find more data and information about cord care practices at community and health facilities, umbilical infection prevalence, CHX availability, accessibility, price and utilization, and research on umbilical cord care in Indonesia

Challenges: Adaptation process→Policy change
- Policy of open, dry, and clean cord care just changed in 2008.
- Pilot study at selected area might be needed.
- Perhaps it will not be nationwide implementation, only for high-risk areas.
- Insert 4% CHX in national essential drug list.
- Availability, distribution, and accessibility.
- Neonatal care guidelines revision and socialization to pre-service, institution, and in-service training.
- Many stakeholders involved at all levels (central, province, district, and community)**.**

Opportunities:
- Collaboration with nongovernmental organizations to conduct pilot project and research around issues of high percentage of home delivery, neonatal infection, and poor sanitation.
- Health volunteers and TBAs partnership program.

India

Presenter: Dr. Sila Deb, Assistant Commissioner-Child Health, MOHFW

Country context
The Child Health Division, under the umbrella of Reproductive and Child Health Programme II (RCHII)/National Rural Health Mission (NRHM), has been striving to reduce infant and child mortality and improve health of children in all aspects across the country through various programs and interventions. The effort is to achieve the goals and objectives for child survival set up under NRHM, the India 11th Five-Year Plan, and commitments under the Millennium Summit's Millennium Development Goals (MDG).

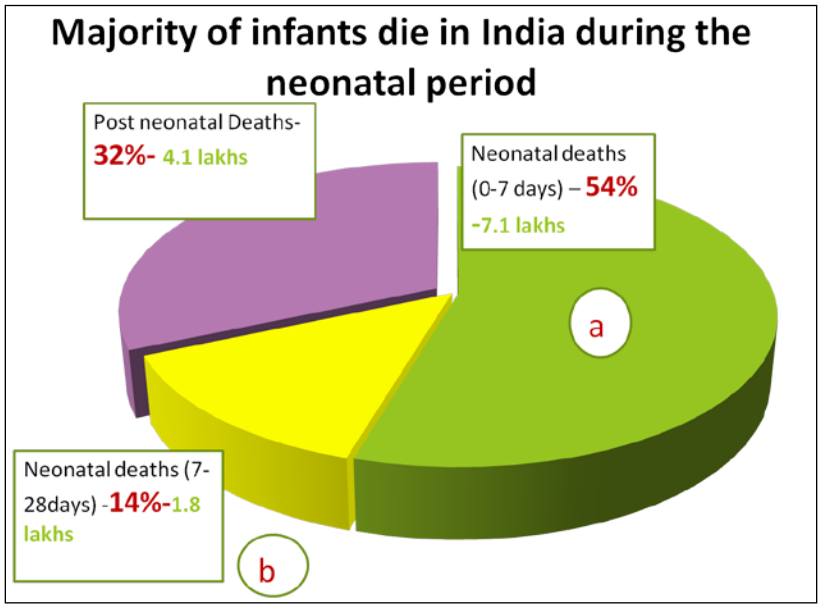
Table 1 outlines the national goals and current status of child mortality and nutrition indicators. The MDG-4 has the target of achieving the under-5 mortality rate of 38/1,000 by 2015, and the present status in India is 69. The RCHII/NRHM and National Population Policy goal was to reduce the infant mortality rate (IMR) to less than 30 by 2010, and the 11th plan goal is to reduce it to 28. However, as of Sample Registration Survey 2009, the national average is still at 50. Similarly, India is lagging behind in reducing NMR. Despite the target of reducing it to less than 20, India is still at 35.

Table 1. Mortality and morbidity indicator status in India (from presentation; source: Sample Registration Survey 2009)

Indicator	Goals	Target	Status
Under-5 mortality rate Underweight children under 5 years of age	MDG-4 for 2015	38	64
	MDG-1: "eradicate extreme poverty and hunger"	27%	
Infant mortality rate	National Population Policy, NRHM, and RCHII for 2010	<30	50
	XI Plan goal for 2012	28	
Neonatal mortality rate	National Plan of Action for Children goal for 2010	18	34
	Enabling goal for RCH II program for 2010	<20	

Neonatal mortality constitutes 68% and over 50% of under-5 child mortality (see Figure 6). The main causes of neonatal mortality are prematurity and LBW (32%), neonatal infections (26.7%), and birth asphyxia (18.8%).

Figure 6. Deaths in the neonatal period in India (from presentation)



Essential newborn care practices

Considering the current situation of neonatal mortality in India, the government has adopted strategies to promote demand generation for institutional deliveries through cash incentives to the mother and the accredited social health activist (ASHA), the facilitator. The results can already be seen. There has been a steep rise in institutional deliveries to 73% in 2009–2010, compared to 40.9% in 2002–2004. The challenge for India now is to deliver quality newborn care services.

The current policy for ENC states that all births (institutional and home births) should be attended by a SBA and that all birthing points at the facility level must provide ENC services.

Along the same lines, the Government of India has a detailed and clear list of guidelines for umbilical cord care to be followed by an SBA during and after deliveries at a health facility or in a home. Clean and dry cord care is emphasized in these guidelines.

Opportunities

- Increased institutional deliveries.
- National Rural Health Mission.
- Improved infrastructure; availability of second auxiliary nurse-midwife at outreach facilities.
- ASHAs—the frontline health volunteers; incentivized for maternal and child health care, including promoting institutional deliveries.
- 12th Plan being formulated with major push to newborn care.

Challenges

- Large birth cohort.
- Tribal and remote communities—inaccessibility to health care.
- Home deliveries and traditional practices still continue—requiring change in mind-set.
- Social and cultural issues leading to delay in seeking care, in case of complications.
- Limited skilled human resources in the rural areas.

Pakistan

Presenter: Dr. Iqbal Memon, President of Pakistan Pediatrics Association

Country background

According to the 2007 Pakistan Demographic and Health Survey, NMR in Pakistan is 54 per 1,000 live births. The major causes of neonatal mortality are LBW/prematurity, neonatal sepsis, and birth asphyxia. These three causes account for 87% of all newborn deaths.

In addition, more than 60% of deliveries are conducted at home by unskilled providers. Only 26.6% of mothers received postnatal care (for the last live birth by time after delivery). The overall number of home deliveries in Pakistan account for 65% of all births, institutional (public plus private: 34%) and other types (0.1%).

Essential newborn practices in Pakistan

The following are the current interventions implemented as part of ENC care practices in Pakistan:

- Initiation of breathing and resuscitation: early asphyxia identification and management.
- Clean childbirth and cord care: dry cord care and prevention of newborn infection.
- Thermal protection: prevention and management of newborn hypothermia/hyperthermia.
- Early and exclusive breastfeeding.
- Eye care: prevention and management of ophthalmia neonatorum.
- Immunization: at birth, Bacille Calmette-Guerin vaccine, oral polio virus vaccine, and hepatitis B virus vaccine.
- Identification and management of sick newborn.
- Care of preterm and/or LBW newborn.

Although national policy emphasizes dry and clean cord care, there are regions in the country where harmful practices are still in use.

Pakistan needs to evaluate several considerations for inclusion of 4% CHX for umbilical cord care into the newborn care package:

- Goals/vision for reduction in mortality over the neonatal period.
- Goals/vision for reduction in incidence of severe omphalitis.
- Process in-country to move forward with program/policy changes.

- Key activities and steps to inform decision-making.
- Anticipated challenges and opportunities.
- Involvement of stake holders, mainly community/teachers and health care providers.
- Education of masses (rural areas) about ENC messages/agreed steps.

Panel discussion regarding policy consideration presentations

The following is a summary of the discussion from the policy consideration presentations from all country delegations.

Coverage and implementation issues for maternal and child health interventions

All delegations said that they struggle with coverage issues for scale-up and implementation of successful interventions. Participants stressed the importance of having CHX be part of a package of interventions and not a stand-alone program. Other key issues referred to by participants were:

- Achieving coverage for the most remote areas.
- Human resources and manpower at the community level; how to create incentives for retention of trained personnel.
- Cost and out-of-pocket expenditures.
- Policy change.
- Government commitment.
- Behavior change.

WHO policy on dry cord care

WHO is already aware of the process we are undertaking and will look at the evidence within the next 6 months. However, it is important to decide how to move forward while waiting for the WHO decision, as done with other interventions such as misoprostol for postpartum hemorrhage prevention.

In addition, CHX is a good, safe, and efficacious medicine, and moving ahead with CHX is not going against WHO guidelines. WHO has indicated that where infection is high, a topical antiseptic can be used.

The best scenario is for delegations to go back to their home country and consider what is needed for implementation of CHX without waiting for a WHO policy change.

Product supply considerations

Presenter: Mutsumi Metzler, MBA, PATH

PATH reported the results of a 6-month accelerated stability tests performed by a contract laboratory in the United States. The stability tests showed that both the gel and liquid formulations stayed within specs during the stability tests, indicating that they are stable for 24 months at room temperature. PATH also shared its perspectives on how to select commercialization partners and emphasized the importance of considering multiple factors—including pharmaceutical industry structure, supply chain, strategic goals, and capability of potential partners—in order to ensure sustainable product supply.

Programmatic experience with chlorhexidine for umbilical cord care

Preliminary experience with chlorhexidine for cord care in Nepal

Presenter: Dr. Naresh Pratap KC, Director, Family Health Division, Department of Health Services, MOHP

Background
Following the randomized controlled trial and prior to the operational study, Nepal conducted two studies:

1. A maternity hospital study conducted in 2008–2009 to determine non-inferiority of gel/lotion versus aqueous preparation. The objective of this study was to establish whether 4% CHX in a gel/lotion formulation is at least as effective as the aqueous formulation, as measured by presence of culturable skin flora on newborn peri-umbilical skin 24 hours after CHX application. The study demonstrated that gel/lotion is non-inferior to aqueous solution.
2. A community acceptability study was conducted in Banke in 2009. The objective of this study was to examine acceptability and ease of use of the two different CHX formulations for prophylactic application to the freshly cut umbilical cord stump. The study concluded that the use of CHX has largely, but not completely, displaced the practice of applying other substances to the cord stump. In addition, although both products were liked by almost all participants, there was a clear preference for the gel/lotion.

Rationale for implementation
Nepal is eager to implement this intervention for several reasons:

- Umbilical cord infection is a major cause of neonatal infection (Neonatal Health strategy 2004); 62% of local bacterial infection was from umbilical infection in Morang (report from MINI in Morang).
- The freshly cut cord stump is an open wound through which there can be direct bacterial seeding, causing sepsis without apparent cord infection.
- Application of CHX to the umbilical area of neonates was associated with a 24% decrease in neonatal mortality, 34% if applied on the day of delivery.[4]

Product
The product used during these studies was a gel/lotion of 4% CHX, thickened with guar gum. The application regime was a single 3 cc application, applied by fingers (freshly washed with soap and water).

Intervention channels
CHX was used at health facilities as a part of routine ENC practice. It was distributed by FCHVs for application by themselves, mother, or other birth attendants. In addition, CHX is being considered for social marketing to increase availability through the retail sector.

The pilot evaluation has been conducted in three districts (Banke, Bajhang, and Jumla) over a period of 18–22 months, due to slight differences in starting dates.

Nepal has identified various opportunities for providing CHX: antenatal care, FCHV contacts, health facility deliveries, and social marketing. Opportunities for scale-up have also been identified:

1. Incorporate within community-based neonatal care package.
2. Introduced with misoprostol scale-up.
3. Incorporate within other maternal/newborn programs.

Conclusions

- Implementation through existing infrastructure in Nepal can achieve reasonable coverage, which should improve with program maturity.
- Compliance with correct use can be achieved.
- Based on randomized controlled trials evidence, this should contribute to reduction in neonatal infection, and its contribution to mortality.

Chlorhexidine operations research study 2008–2009 in Bangladesh

Presenter: Luke Mullany, PhD, (on behalf of Peter Winch, PhD, Johns Hopkins School of Public Health)

Background

The CHX operations research sought to develop a low-cost and scalable approach to delivering CHX to neonates, suitable for settings in which a large proportion of births occur in the home. The specific aims of this research were:

- To identify and evaluate strategies for delivering CHX to households:
    - Promotion through various mechanisms.
    - Stand-alone product versus addition to CDKs.
- To identify and evaluate strategies for promoting correct and timely CHX cord cleansing.

Methodology

The study activities were divided into two phases. The first phase included relatively limited promotion and distribution of CHX. FCHVs (project staff) provided direct visits to households or community meetings for two months. CHX was also distributed freely at antenatal care visits (family welfare centers), and there was direct observation of use and semi-structured interviews. Final product packaging for phase two was determined based on a product attribute study conducted by AC Nielsen and PATH and input from study partners. Product packaging and accompanying instructions were pretested during this phase.

In the second phase, CHX was manufactured by a local manufacturer in Bangladesh. The product was packaged in a nozzle bottle to meet user preferences, and it was promoted through various channels of communication. CHX was bundled with CDKs and distributed for free at family welfare centers and satellite clinics, given to the Expanded Programme on Immunization health assistants and family welfare assistants, and sold in the private sector.

The project used several communication channels to disseminate the information, including community meetings, posters, leaflets, stickers, and folk songs.

The research was initiated in May 2009 and completed in September 2009. There was a household survey of women who delivered during the project period (n=314, n=299 live births), as well as direct observations of CHX application in the home (n=25) and in-depth interviews and focus discussions with mothers, husbands, providers, and TBAs.

Results

CHX scale-up was broadly accepted and coverage went from 0% to 60% in 5 months (68% among home births and 48% among facility births). About 80%–85% of families using CHX acquired the product before delivery. Use within 24 hours varied substantially (79% among home births and 19% in facility births).

TBAs were the most common source of CHX, reaching 50% of those who collected CHX. Other large delivery channels were the Expanded Programme on Immunization health assistants (31%) and family

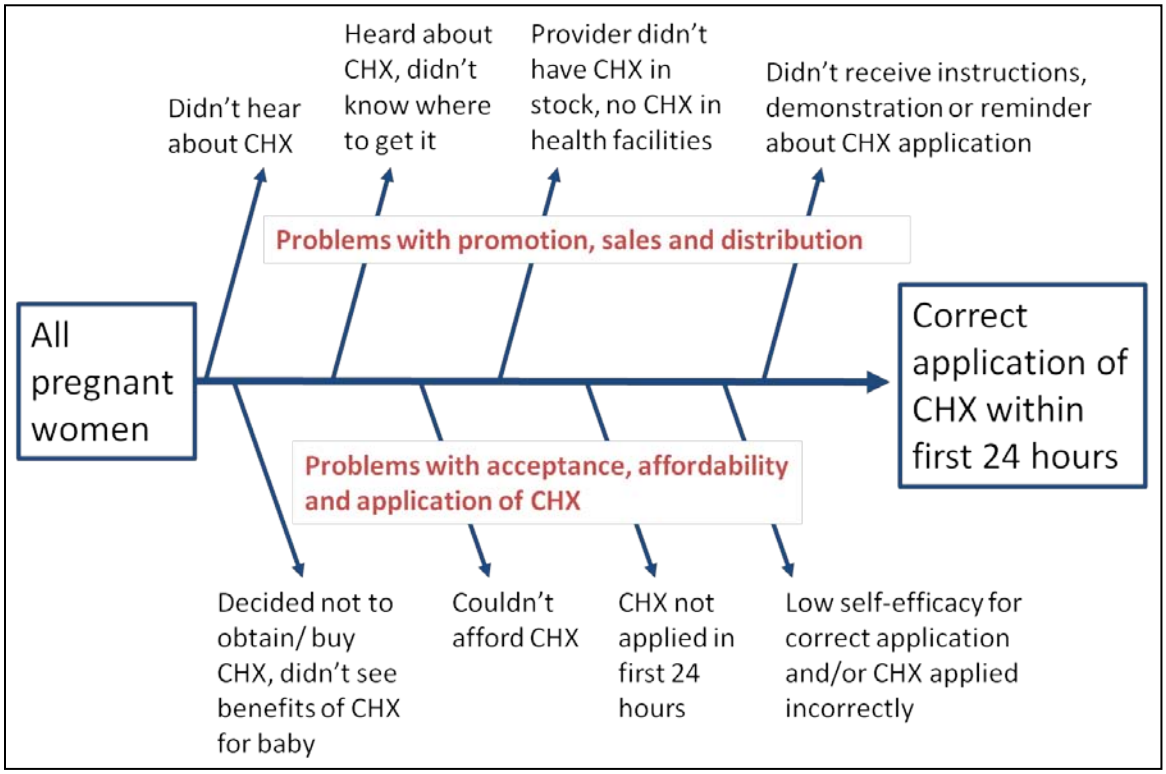
welfare centers (22%). The bundle seemed to be more common (84% got CHX within CHX/CDKs bundle).

The reported mean number of days of application was 7.2 days, and 83.1% reported washing hands before application. A delay in application was strongly associated with delivery in a health facility, where 54% first applied immediately after cutting. Additionally, a high proportion followed instructions closely (91% self report, 73% in direct observation).

Conclusions and recommendations

Figure 7 captures some of the challenges identified through the research associated with promotion and acceptance, affordability, and application of CHX.

Figure 7. CHX challenges in operations research (from presentation)



For CHX to be an effective intervention in reducing neonatal mortality, families should obtain the product prior to delivery. This can be achieved by:

- Increasing attendance at community meetings.
- Making CHX part of routine care in health facilities.
- Increasing exposure to information about CHX, preferably with a strong mass media component.
- Increasing reminders and focusing on target groups:
    - Reminders to collect CHX.
    - Reminders that use of CHX is one of most important factors of safe birth.
    - Target reminders to pregnant women in scaled-up programs (should remain target group; the just-delivered woman was the most common applier of CHX).
    - Also could target reminders to husbands, mothers-in-law, TBAs, etc.

Program considerations for introduction of chlorhexidine

Presenter: Steve Hodgins, DrPH, MCHIP

For this exercise, delegations met individually to brainstorm about next steps and action items required to consider CHX for umbilical cord care in their countries. The main objective of the exercise was for countries to identify next steps in regard to potential introduction of CHX into existing newborn programs. To conduct the exercise, participants were provided with a discussion guide (see Appendix 3) and a scale-up map guide (see Appendix 4). The main proposed areas for discussion as stated in Appendix 1 were:

- Policy/advocacy.
- Commodity-related issues.
- Distribution channels.
- Roll out.
- Program performance.

Participants were also provided with a draft CHX technical brief as a tool to engage with colleagues in government, the medical profession, donors, and other important stakeholders in their countries. The following two points are particular issues that require thinking and analysis by country delegations, and that would be addressed in an updated version of the CHX technical brief. These points are based on the discussion from the first day of this meeting.

1. Potential introduction of CHX into a program in the context of the 1998 WHO guidance on cord care. Adoption of CHX into newborn programs is **consistent** with WHO guidance in that:
    a. It will help to ensure dry and truly **clean** cord care.
    b. It will entail use of an antiseptic in settings with high pathogen exposure—as provided for in the existing guidance.
    c. It is based on the type of research called for in the 1998 guidance.
2. Single-day versus multiple-day application.

The content of the CHX technical brief was revised and expanded subsequent to the meeting.

Summary of country plans

At the end of the exercise, countries presented a summary of the country plans and next steps for inclusion of CHX into their country settings. In consensus, countries identified similar key steps for introduction of CHX for umbilical cord care as part of newborn care:

- *Consensus building and policy alignment.* It will be critical for countries to gain stakeholder consensus to consider a potential change in policy from dry cord care to CHX for umbilical cord care. Consensus is obtained by informing key stakeholders at the government level and in professional associations. Available information from cluster-randomized controlled trials plus conclusions from this meeting will be shared with stakeholders to the start a decision-making process of inclusion of CHX as part of newborn practices.
- *Agreement on dose regime and form (gel/lotion vs. liquid).* Based on available evidence, countries will need to decide the most appropriate dose regime for their context. Some countries specified that qualitative research to identify preferences for form is required.

- *Selection of manufacturer or channel for acquisition of product.* This is required in countries where there are not current producers of CHX. It may be necessary to import from neighbor countries in some situations.
- *Identification and allocation of resources for product and intervention.* Country delegations acknowledged that resources are scarce and that it will be important for countries to identify where resources for this intervention will come from. Some countries emphasized that donor involvement may be required.
- *Inclusion of CHX into the essential medicines list.* As part of the process of introduction of CHX into newborn care, countries require to have the product included into their EML. In addition, to ensure success and continuity, countries said the product should be incorporated into existing procurement channels.
- *Behavior change, communication, and capacity-building of providers.*
- *Operational research versus scale-up.* Countries represented at this meeting are at different stages. Based on the stage, some countries may require piloting the intervention and others may be ready for scale-up and introduction.

III.Conclusions and Recommendations

Based on the presentations and discussions from this meeting, the following are preliminary conclusions and recommendations:

- CHX is a well-known antiseptic. It is commonly found in products for oral rinse and pre-surgical hand washing and has an excellent safety record. The WHO EML for children includes CHX bulk (20% CHX gluconate), with the instruction to dilute for umbilical cord care.
- There is sufficient evidence to recommend inclusion of 4% CHX cord cleansing as a strategy to reduce neonatal mortality in settings where poor hygiene and high neonatal mortality are issues. The results from the clinical trials from Nepal, Pakistan, and Bangladesh showed a reduction in neonatal mortality from 20% to 38%, with a reduction in omphalitis from 24% to 75%.
- These trials also indicated that applying 4% CHX immediately after cord cutting was critical to reduce omphalitis and neonatal mortality. If cultural norms permit or favor, 4% CHX can be applied for subsequent days for additional benefits, including reduced local infection and improved hygiene practices.
- There are two biological mechanisms for the effect of CHX cord cleansing-prevention of sepsis resulting from direct bacterial seeding of the blood through patent umbilical vessels and prevention of severe omphalitis sepsis. Therefore, the most rational approach to the introduction of CHX appears to be early (first day) application, and, if feasible, subsequent daily applications until cord separation.
- Countries represented at this meeting are currently following the WHO guidance of clean and dry cord care. However, introduction of 4% CHX for cord care is compatible with WHO's 1998 recommendations. According to recommendations published in 1998 by WHO, clean and dry cord care practices are preferred. In settings where the risk of bacterial infection is high it may be prudent to use an antiseptic (such as CHX) per local preference. Beyond the direct antiseptic effect, CHX may replace common, harmful practices such as applying mustard oil and other substances to the cord.

- Operational studies in Nepal and Bangladesh demonstrated that both liquid and gel/lotion forms of 4% CHX were acceptable by users. The operational studies in Nepal and Bangladesh also identified that engaging health facilities as well as communities is a key aspect to ensure successful implementation of the intervention.
- The pilot project in Nepal demonstrated that cord cleansing with 4% CHX can be successfully incorporated in maternal and newborn care programs using existing cadre of FCHVs.
- Country delegations committed to hold national stakeholder consensus meetings on introduction of CHX for umbilical cord care as part of newborn care.

IV. Action Items and Suggestions

The technical committee will continue engagement and follow-up with country delegations interested in pursuing CHX for umbilical cord care.

Country delegations suggested continuing dialogue and finding more opportunities to meet and share progress. Specifically, they called for a meeting to discuss scale-up. Countries also suggested that it will be important for scientists to visit countries when countries are ready to present plans to their ministries.

Country delegations will share information from this meeting with key national stakeholders to build consensus on potential introduction of CHX for umbilical cord care in the context of newborn care.

An electronic mailing list has been created to share information on CHX. This will serve as an opportunity for interested countries to ask questions and engage with scientific experts and implementers.

V. Acknowledgments

The CHX technical committee includes key individuals from the United States Agency for International Development, the Maternal and Child Health Integrated Program, PATH, Save the Children/Saving Newborn Lives Program, and the Johns Hopkins School of Public Health. This collaborative effort was made possible by: the generous support of the American people through the United States Agency for International Development, the Bill & Melinda Gates Foundation, and the Government of Nepal.

The technical committee would like to express its sincere appreciation to the USAID missions of Bangladesh, Cambodia, India, Indonesia, Nepal, and Pakistan for assisting in coordinating travel and identifying key stakeholders who participated in this meeting. Special thanks to all participants and presenters who traveled thousands of miles to attend this important regional meeting.

This report was prepared by PATH on behalf of the CHX technical committee.

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INDONESIA

Surname	First Name	Organization
Bateman	Massee	USAID/Indonesia
Lawintono	Laurensia	Indonesian Midwives Association
Putra	Riskiyana Sukandhi	Government of Indonesia
Rachmadi	Bulan	Government of Indonesia
Roeslani	Rosalina Dewi	Indonesian Pediatric Society
Rohmawati	Nida	Government of Indonesia

NEPAL

Surname	First Name	Organization
Aryal	Shilu	Government of Nepal
Houston	Robin	NFHP II
Kang	Han	USAID/Nepal
KC	Naresh Pratap	Government of Nepal
KC	Ashish	Save the Children, Saving Newborn Lives Program/Nepal
Khanal	Leela	NFHP II
Limbu	Naramaya	USAID/Nepal
Malla	Jeevan	Government of Nepal
Mehta	Pankaj	UNICEF
Paudel	Deepak	USAID/Nepal
Shrestha	Ashoke	NFHP II
Thapa	Kusum	Paropakar Maternity Hospital
Thapa	Paras	USAID/Nepal
Upreti	Shyam Raj	Government of Nepal

PAKISTAN

Surname	First Name	Organization
Ali	Nabeela	JSI Research and Training Institute
Asghar Khan	Ali	Save the Children
Isa	Muhammad Ahmed	USAID/Pakistan
Memon	Iqbal	Aga Khan University Hospital; Pakistan Pediatric Association
Mir	Qurban	Government of Pakistan
Qadir Nausherwani	Masood	Government of Pakistan
Soofi	Sajid Bashir	Aga Khan University
Yasmin	Haleema	Society of Obstetricians & Gynaecologists of Pakistan; Jinnah Postgraduate Medical Centre

UNITED STATES

Surname	First Name	Organization
Baqui	Abdullah	Johns Hopkins School of Public Health
Brandes	Neal	USAID
Collins	Karina	PATH
de Graft-Johnson	Joseph	MCHIP
Gutestam	Monika	Save the Children, Saving Newborn Lives Program
Handley	Kathleen	USAID
Hodgins	Steve	MCHIP
Hulse	Jessica	Save the Children, Saving Newborn Lives Program
Lwanga	Esther	USAID
Markham	Carol	PATH
Metzler	Mutsumi	PATH
Mullany	Luke	Johns Hopkins School of Public Health
Segre	Joel	Consultant to the Bill & Melinda Gates Foundation
Villadiego	Shirley	PATH
Wall	Steve	Save the Children, Saving Newborn Lives Program

Chlorhexidine for Umbilical Cord Care: Evidence Base and the Way Forward

Date: September 15th and 16th, 2011
Venue: Kitchen Hut, Nepalgunj, Nepal
Facilitator: Han Kang, USAID Nepal

Meeting objectives:

- To present evidence from recent research relating to the efficacy and programmatic outcomes of using a 4% chlorhexidine product for umbilical cord care from Bangladesh, Nepal, and Pakistan.
- To assist country policymakers to identify next steps for introduction of chlorhexidine for umbilical cord care, as warranted.

Day 1 (Sept 15, 2011)

Timing	Agenda	Facilitator/Presenter
9:00-9:15 a.m.	**Welcome**	Dr. BK Suvedi, Chief, Policy Planning and International Cooperation Division, Nepal Ministry of Health and Population
9:15-9:30 a.m.	**Review of meeting objectives and overview of agenda**	Neal Brandes, MS Health Advisor, USAID
Efficacy of chlorhexidine for umbilical cord care by country:		
9:30-9:50 a.m.	**Nepal**	Luke Mullany, PhD Associate Professor, Johns Hopkins Bloomberg School of Public Health
9:50-10:00 a.m.	**Questions and Answers**	
10:00-10:20 a.m.	**Bangladesh**	Abdullah Baqui, DrPH, MPH, MBBS Professor, Johns Hopkins Bloomberg School of Public Health
10:20-10:30 a.m.	**Questions and Answers**	
10:30-10:50 a.m.	**Pakistan**	Sajid Soofi, PhD Professor, Aga Khan University
10:50-11:00 a.m.	**Questions and Answers**	
11:00-11:15 a.m.	**Tea break**	All
11:15-11:35 a.m.	**Meta-analysis of results from chlorhexidine RCTs**	Luke Mullany, PhD Associate Professor, Johns Hopkins Bloomberg School of Public Health
11:35-12:30 a.m.	**Discussion**	Neal Brandes, MS Health Advisor, USAID
12:30-1:30 p.m.	**Lunch**	All

Day 1 (Sept 15, 2011)

Timing	Agenda	Facilitator/Presenter
Policy considerations on cord care in the context of essential newborn care		
1:30-1:45 p.m.	**Nepal**	Dr. YV. Pradhan, Director General, Department of Health Services
1:45-2:00 p.m.	**Bangladesh**	TBD
2:00-2:15 p.m.	**Cambodia**	Dr. Seang Sody, Chief of Neonatal Care Unit, National Maternal and Child Health Center, Ministry of Health
2:15-2:30 p.m.	**India**	Dr. Sila Deb, Assistant Commissioner-Child Health, Ministry of Health and Family Welfare
2:30-2:45 p.m.	**Indonesia**	Dr. Nida Rohmawati, Ministry of Health
2:45-3:00 p.m.	**Pakistan**	Dr. Iqbal Memon, President of Pakistan Pediatrics Association
3:00-3:30 p.m.	**Discussion**	Facilitator
3:30-3:45 p.m.	**Tea break**	All
3:45-4:05 p.m.	**Product supply considerations**	Mutsumi Metzler, MBA Program officer, PATH
4:05-4:30 p.m.	**Wrap-up**	Facilitator
4:30-6:30 p.m.	**Break at your hotel rooms**	
6:30 p.m.	**Shuttle to Kitchen Hut for guests of Hotel Siddartha and Travellers Village**	
7:00 p.m.	**Reception / Dinner**	USAID Nepal and Nepal Ministry of Health and Population

UPDATED AGENDA Day 2 (Sept 16, 2011)

Timing	Agenda	Facilitator/Presenter
8:30-8:40 a.m.	**Welcome/ recap of pending issues from day 1**	Facilitator
Panel discussions:	**Programmatic experience with chlorhexidine for umbilical cord care**	
8:40 -9:00 a.m.	**Nepal**	Dr. Naresh Pratap KC Family Health Division Director, Nepal Ministry of Health and Population
9:00-9:10 a.m.	**Bangladesh**	Luke Mullany, PhD Associate Professor, Johns Hopkins Bloomberg School of Public Health
9:10-9:50 a.m.	**Discussion**	Facilitator
9:50-10:00 a.m.	**Tea break**	All
10:00-10:15 a.m.	**Program considerations for introduction of CHX**	Steve Hodgins, DrPH Global Leadership Team Leader, MCHIP
10:15-11:30 a.m.	**Break-up session for country plans** **Bangladesh** *Kitchen Hut (Conf. room)* **Cambodia** *Kitchen Hut (Restaurant)* **India** *Kitchen Hut (Conf. room)* ***Indonesia*** *Kitchen Hut (Lobby)* **Nepal** *Kitchen Hut (Restaurant)* **Pakistan** *Kitchen Hut (Conf. room)*	Country teams
11:30-1:00 p.m.	**Break**	All
12:30-1:45 p.m.	**Lunch**	All
Presentation of country plans		
1:45-1:55 p.m.	**Pakistan**	Country team facilitators
1:55-2:05 p.m.	**Bangladesh**	
2:05-2:15 p.m.	**India**	
2:15-2:25 p.m.	**Cambodia**	
2:25-2:35 p.m.	**Indonesia**	
2:35-2:45 p.m.	**Nepal**	
2:45-3:15 p.m.	**Summary and adjourn for CHX meeting**	Facilitator
3:15 p.m.	**Tea break**	All

Discussion guide for country-level planning

There are a number of questions below which are offered as a prompt for your thinking and discussion on next steps when you go back home. ***Do*** *quickly read them all over first. But* ***do not*** *feel that you need to address every one of these questions or limit yourselves to only discussing these specific questions. They are intended to help move you into a productive line of discussion that could be a useful starter for much more detailed serious discussions, later.*

Policy

- Are there particular questions or issues that you feel need more attention (e.g. on CHX efficacy or compatibility with other programs) before there's an effort in your country to move forward with adopting CHX use?
- To move forward towards incorporating CHX into routine program use, what process is required in your setting?
- Who are the key individuals or institutions whose support will be important to move this forward in your country/ state setting? How will you go about building the necessary support?
- What problems or barriers might you face? How would expect to deal with them?

The Commodity

- Formulation and packaging:
    - Are there particular reasons in your setting for opting for either gel or liquid?
    - How important would it be in your setting to ensure that the packaging volume be sufficient for a whole week's supply?
- Are there drug companies in your country which would be good candidates as reliable, low-cost, quality producers?
- What is likely to be the source of funds for an initial supply of commodity to get a program started? What would be the best approach to ensure long-term sustainability of commodity supply?

Distribution Channels

- Considering where women currently deliver (HF, home) and what opportunities are available to ensure that CHX is available at the time of delivery, what mix of distribution channels would be both feasible and ensure the highest possible coverage in your setting (consider distribution during ANC, by CHWs/ TTBAs, through social marketing, use in HFs at time of delivery, etc.)?
- What will it take to develop each of the selected channels? What partners need to be engaged? What distribution networks? What training/ orientation?

Roll-Out

- Consider roll-out on a phased basis with fairly rigorous monitoring and documentation during the initial phase, to help validate and refine your program approach. How would you design this initial phase to yield the most useful information for planning and implementing further scale-up?

Program Performance

- To help ensure that the program is actually reaching a large proportion of births (i.e. high population coverage), and to guide program managers in quickly dealing with any problems that arise, you will need good routine monitoring. In your context what would be feasible? How would you go about ensuring robust-enough monitoring?

Scale-up Maps

Scale-up maps can be considered a kind of *logic model* or *program theory* or *theory of change* (similar to Results, M&E or Benchmarks Frameworks); they share in common with such frameworks a focus on causal relationships and a family resemblance to management tools like Gantt charts.

Several specific features of scale-up maps include:

- Indicates expected time line
- 1-page, visual presentation
- Content consists of major *strategic tasks*, showing *all* needed elements, not only those of one particular partner and is *specific* to the particular initiative and setting
- Reflect the *systems context*
- Used as a tool for *joint planning* and *ongoing management* (and is useful in formulating a monitoring and evaluation plan)

A scale-up map is intended to be a picture of the major strategic tasks involved in a scale-up effort (including not only roll-out but what's needed to ensure program performance on a sustained basis), showing: causal dependencies, expected time-line, and what players are expected to take the lead on particular strategic tasks; it's a close cousin of Gantt charts and other graphic project management tools. So it's a big-picture summary of an expected process. Scale-up maps can be used for local, national, regional or global level initiatives.

A scale-up map is used to get multiple players literally on the same page, making explicit all the big pieces of work that need to be attended to, so that there's a shared understanding about what needs to be done, who needs to do what, how the pieces fit with each other, and roughly when each of the big pieces is expected to be addressed (including anticipating and preparing for later key steps).

Developing a scale-up map can be a useful exercise in clarifying what is really important. For it to serve this purpose, a scale-up map should be *specific* and should be the product of some good hard thinking about the *particular* initiative and setting where this work is being done. For its use to be most productive, this should be a joint process involving, for example, appropriate individuals from the Ministry of Health, and key donor, private-sector and technical assistance partners (e.g. professional associations, WHO, etc.). As the map is developed, all the big tasks, regardless what agency may be responsible, should be captured or represented. Between each of these key strategic tasks indicate *dependencies* (for example, certain implementation steps may require prior policy decisions or resource commitments). For each strategic task, determine players responsible, key issues involved, and what kind of timeline is expected. Where helpful, separate maps of each major strategic task can be developed, outlining sub-tasks in more detail.

The scale-up map is a tool that can be used on an ongoing basis for partners to chart progress, revising, updating and modifying it as the process moves forward. So it is a joint management tool, used across partners. It can also help facilitate clearer communication between donors and implementers about the rationale for planned inputs and how they fit into a broader program effort; this can help better ensure mutual accountability for prioritization of program efforts and progress against plans/ commitments.

Creating a scale-up map

To build a scale-up map, start by asking what is your ultimate goal in this effort (e.g., close to 100% population coverage for a particular service or household practice). This would be what goes into your final box on the extreme right side of the page (figure 1 shows a generic scale-up map).

What is it going to take for this to happen? What are the big strategic tasks (including systems conditions) that will need to be adequately addressed? The scale-up map is intended to show all the elements that would need to be in place, adequately addressed, to achieve the intended goal. So you should try to identify all the key strategic tasks, not only those that your particular organization or project is responsible for.

To determine the major strategic tasks the effort will involve, the checklist (figure 2) can be used as a starting point, getting you thinking about what the necessary pieces may be. In some change or scale-up efforts, an intervention may already have been introduced, and the challenge is to increase its use (e.g. use of oral rehydration salts for treatment of diarrhea) or a function may be present but the initiative consists in improving its quality (e.g. injection safety or other infection prevention practices); other change efforts involve introducing an intervention that may not previously have been used in that setting and will require policy and systems changes (e.g. use of $MgSO_4$ for the treatment of eclampsia); and yet in other scale-up efforts, though the specific intervention is new, it can be being introduced in a fairly standardized way through an existing platform (e.g. new vaccines). Depending on the particular challenge, the key strategic tasks that need to be dealt with may fall at different points along the continuum reflected in the checklist, from pre-introduction to mature implementation, and what those tasks consist of will depend on the particular intervention or change effort and the particular setting. On the pages following the checklist, there are two actual examples of scale-up maps. Figure 3 takes us only to the beginning of early implementation.

More information on the following figures

Figure 1 shows a *generic* scale-up map. Note that this is provided only to help you get started thinking strategically about the overall set of tasks that may be involved in moving a particular scale-up effort forward. Similarly **figure 2** (the checklist) can help you identify the key strategic tasks that will need to be addressed over time.

But for this to be as useful as possible for you, your scale-up map needs to be *specific*. **Figure 3** is very specific. Don't worry too much about understanding all the details. It is an actual scale-up map that was used throughout the development process shown in the figure, which concerned early piloting in Nepal of the antiseptic chlorhexidine for application to the umbilical cord stump. Those involved, working in several partner agencies, met regularly and used this map to review progress and plan next steps.

Figure 1: A Generic Scale-Up Map

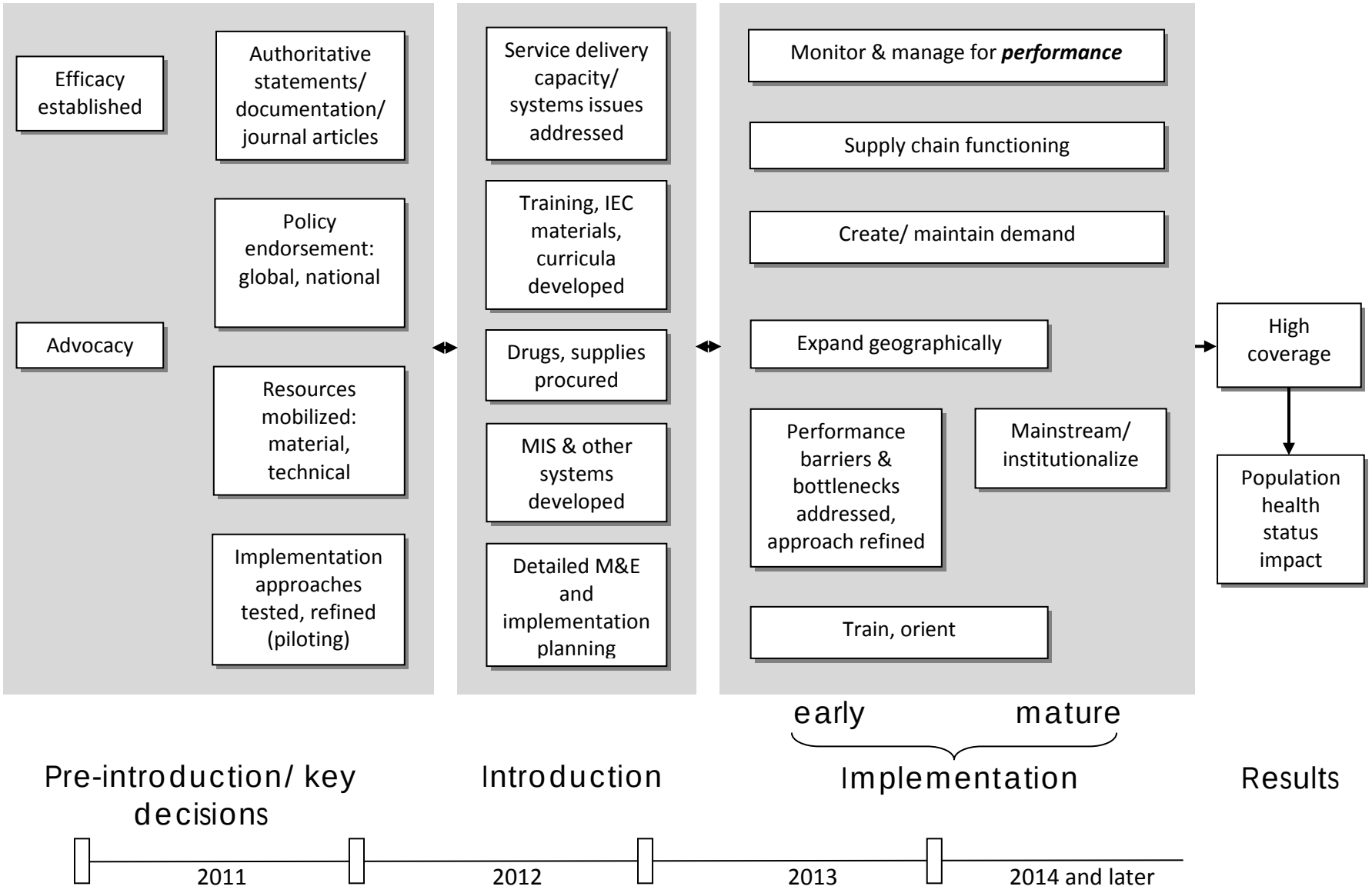

Figure 2: Change Effort Checklist

Pre-introduction ◄►Definitive decisions	◄►Introduction ◄► Early implementation ◄► Mature implementation			
from unaware/ uninterested to building consensus	consensus building to motivating	motivating to implementing	implementing	implementing to sustaining
☐ convene interested partners ☐ ask important questions ☐ begin change process ☐ characterize problem ☐ consider possible solutions (reviewing evidence of efficacy) ☐ assess pros & cons, concerns ☐ broaden partner base, build commitment, work toward consensus ☐ test/ refine approaches (pilot) ☐ cultivate champions	☐ secure official policy endorsement/ approval ☐ reflect in normative documents (Policies, Strategies, National Norms) ☐ secure financial commitments ☐ formalize permanent working group	☐ do detailed implementation planning ☐ develop an M&E plan ☐ develop training curricula & plans ☐ develop all needed materials ☐ modify current systems to accommodate innovation (MIS, logistics, etc.) ☐ procure needed drugs, supplies ☐ address capacity issues	☐ conduct orientations & training ☐ ensure availability of drugs & supplies at point of service ☐ monitor inputs, processes and quality and use the results to improve the program ☐ address barriers ☐ address unintended consequences	☐ maintain oversight ☐ monitor fidelity ☐ monitor and evaluate outcomes and impact ☐ network with others ☐ ongoing training ☐ expand geographically ☐ transform organizational culture ☐ institutionalize ☐ adapt as needed

Figure 3: A Specific Example (early chlorhexidine work in Nepal)