Introducing Chlorhexidine in Nepal

A Brief Narrative

The first community-based randomized controlled trial (RCT) assessing mortality-reduction efficacy of chlorhexidine (CHX) applied to the umbilical cord was done in Nepal. When the results were available (~2005), they were immediately shared with the Ministry of Health and Population (MoHP) and other key partners in Nepal. These partners included, among others,USAID and two of its implementing projects, and key leaders in the medical community.

Over the following two to three years, findings of the RCT and implications for program work in Nepal were brought to multiple fora including the Child Health sub- Committee, the Safe-Motherhood and Neonatal Sub-Committee and annual technical meetings of professional associations (e.g., Ob/Gyns and pediatricians) and the topic continued to be actively discussed in other less formal settings.

From early on, major stakeholders were quite open to incorporating CHX into program work, although there were initially some concerns about possible confusion associated with changing essential newborn messaging on clean, dry cord-care. It was recognized as a simple, effective, relatively inexpensive intervention with the potential for delivery at high coverage even in the challenging conditions of Nepal.

From the project's outset, the technical assistance partners that were encouraging adoption remained in close and ongoing discussion with a key government official.

This official served throughout as the project's champion within the government.

The Nepal Family Health Program, USAID's public sector maternal neonatal child health and family planning technical assistance project managed by JSI Research & Training Institute, conducted formative research investigating the cord care perspectives of pregnant and recently delivered women, community health volunteers, traditional birth attendants (TBAs), and others to better understand the current practices and preferences.

They were presented with different possible formulations, seeking their reactions. Based on this preliminary work, it appeared that a product with a thick consistency—such as cream or gel—would be preferable to a liquid.

Over this period, PATH developed manufacturing specifications for both a liquid and gel product. And, from this time, the USAID technical assistance projects involved (NFHP and N-MARC) progressively developed an effective working relationship with Lomus, an interested local pharmaceutical company (see Chlorhexidine in Nepal: A Public-Private Partnership Case Study).

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As both the initial RCT and newer trials in Bangladesh and Pakistan tested the efficacy of a liquid formulation, a *non-inferiority trial* was conducted in Nepal to confirm that a gel formulation would be as effective as a liquid in suppressing bacterial growth on the cord.

At the same time, a small *acceptability study* in which pregnant women were given CHX in either liquid or gel form and followed up after delivery was conducted. Both products were well accepted, but there was a clear preference for gel.

By mid-2009, with the results of these studies in hand, and judging that the timing was ripe, the key government official involved decided that it would make sense to proceed with district-wide piloting in four districts (two in the plains area, two in the mountains). Because of suggestive findings from the initial RCT, as well as concerns about confusion on cord-care messaging, it was decided to proceed with piloting using day-of-birth application only (with the intention of reviewing this decision once results of the Bangladesh trial, looking at single-day application, became available).

This piloting was started late in 2009, using product provided by Lomus, and with technical support from the USAID project, NFHP. The primary channel of distribution was through an existing cadre, Nepal's Female Community Health Volunteers (FCHVs), who already had an established role making home visits to pregnant women and providing counseling. The FCHVs dispensed CHX late in pregnancy, with instructions on its use—in the event of home deliveries (which currently account for about half of deliveries in Nepal).

Chlorhexidine use was also introduced as a part of routine post-delivery care in health facilities in the four pilot districts. Piloting ran through early 2011, and demonstrated feasibility in achieving high coverage,[1] delivered through routine public sector services. Based on these results, late in 2011, the Ministry of Health and Population decided to move forward with adding CHX into routine care nationwide. Roll-out was to be integrated into ongoing efforts to implement a package of other maternal-newborn interventions. To facilitate this roll-out, late in 2011 funding was obtained under the Grand Challenges Saving Lives at Birth (SL@B) program.

Based on the Ministry's plans for newborn work, CHX roll-out was tied to implementation of the Community-Based Newborn Care Package (CBNCP) and by mid-2013, CHX has been incorporated into program work in all 36 districts where this Package has been implemented. Note that the requirement to tie roll-out to CBNCP has associated the CHX initiative closely with the responsible unit of the Ministry, the Child Health Division, with the effect of undermining a sense of ownership on the part of the Family Health Division, the primary unit responsible for maternal health and labor and delivery care. Another consequence of tying roll-out to the CBNCP imitative has been that monitoring is piggy-backed on the system used for CBNCP which, itself, has had data validity problems. This has complicated monitoring of CHX program performance. Note that a mid-term assessment was conducted beginning in mid-2013, with results expected by August 2013.

[1] Ranging from just under 60% to over 80%. Note that implementation depended on the government primary health care system, which is strong in some districts, weaker in others.

The primary channel for distribution has been during pregnancy home visits made by Female Community Health Volunteers, although CHX is also available through ANC and has been incorporated into routine immediate care of the newborn in birthing centers in these 36 districts. In mid-2013, apparently in part due to objections raised by WHO, the already-approved decision to include use for institutional births has been called into question.

KEY ISSUES

Participants

Important participants in this experience include key individuals with the research group responsible for the original trial (from JHSPH); the MoHP (including both Child Health and Family Health divisions); two USAID technical assistance projects (NFHP/JSI and NMARC/AED – now FHI360); USAID; several leaders in the medical community; staff in two US-based NGOs (PLAN and Save the Children); and Lomus, the local pharmaceutical firm. Others joined the effort over time. Regular contact and meetings between key individuals continued over a period of several years, providing an opportunity to reach consensus on how best to proceed. Over time, champions who were strategically placed in different ways emerged, key opinion leaders were progressively brought in, and a sense of shared ownership emerged.

Direction

Planning and decision-making required joint leadership. Over time, mostly on a quite informal basis, core and extended team members came together, contributing to decision-making, and, at various times, committing resources of their particular organizations.

Design

Various aspects of the project required decisions—product formulation and packaging, single vs. multiday, distribution channels to be used, and roll-out strategy. In most instances, these answers were based on Nepal-specific conditions.

Product

As noted, gel was adopted based on the results from formative and small-scale pilot work that indicated a preference for a gel formulation. With the decision to opt for single-day application, it was determined that 3gm would be a sufficient quantity and sachet packaging was considered. However, the pharmaceutical partner involved was not equipped to provide the product in this form. Furthermore, it was felt that the final packaging solution selected—using the same type of small aluminum tube used for other pharmaceutical ointments and creams—would help position the product as a credible pharmaceutical. Although not yet initiated, the eventual plan is to provide the gel in a pump-bottle for use in health facilities.

Resources

Although USAID was the major technical assistance supporter during the developmental stage, many other partners joined subsequently. During early piloting, the product was procured with non-USAID funds provided by JSI and Plan Nepal. During the first year of the national roll-out, in addition to support for technical assistance, SL@B funds were used in product procurement. In early 2013, the MoHP issued an

international tender and is expected to contract with a supplier by August or September 2013 for subsequent supply. In the formulation and format used in the Nepal program, the bulk cost has been approximately US$ 0.25 per newborn, but this may be reduced in future, with competitive procurement.

Time

The results from the initial RCT were first disseminated and discussed in Nepal in 2005. At that time, it was recognized that results from additional replication trials would be required before global recommendations could be made. However, Nepal has often historically taken initiative on new interventions, even in the absence of global recommendations.

From the time the intervention was proposed, there was interest and openness from key stakeholders. At the same time, there was not a feeling of urgency in immediately moving toward a national program. This allowed for a more measured process, first doing formative work, figuring out what would be the most suitable product for this setting. With the slower pace, it also provided time for all key players to reflect on the implications, and to come to consensus. Critical questions about timing and process were settled based on the judgment of the key government official involved. His role, in this regard, continued even with a change in his position (at the time of the decision to implement at national scale he was the Director General of the Department of Health Services).

CONCLUSION

Nepal has been charting new waters with chlorhexidine. Even as of July 2013, there is no new WHO guidance superseding recommendations dating to 1998. Some 10 years after the initial trial began in Nepal, the intervention is now available across about half of the country. Important challenges still remain. Distribution, and its tracking, needs to be fully institutionalized so that high coverage can be more reliably ensured. Current hiccups related to opposition to use in health facilities need to be worked through. Nepal has a history of pioneering successful programs involving distribution of simple commodities through community-based systems (with vitamin A supplements being the best example). Chlorhexidine could well be on a similar trajectory, as another Nepali model to the world about how to do sound public health programs.

The CHX Navi Care Program, supported by the Savings Lives at Birth partners and the Ministry of Health & Population, aims to prevent newborn deaths through the use of chlorhexidine.

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