Chlorhexidine in Nepal: A Public-Private Partnership Case Study

Chlorhexidine Navi Care Program
JSI Research & Training Institute, Inc.
July 2013

SAVING LIVES AT BIRTH: A GRAND CHALLENGE FOR DEVELOPMENT
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Recommended Citation: Tuladhar, S. Chlorhexidine in Nepal: A Public-Private Partnership Case Study. Chlorhexidine Navi Care Program. JSI Research & Training Institute, Inc. 2013

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 CHX.

This product is made possible through the generous support of the Saving Lives at Birth partners: the United States Agency for International Development (USAID), the Government of Norway, the Bill & Melinda Gates Foundation, Grand Challenges Canada, and the World Bank. It was prepared by JSI Research & Training Institute, Inc. and does not necessarily reflect the views of the Saving Lives at Birth partners.

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Purpose of the Case Study

This case study documents the experiences of the Nepal Ministry of Health and Population (MoHP), a Nepali pharmaceutical company—Lomus Pharmaceuticals Private Limited—and two USAID-supported technical assistance projects, in the development of a chlorhexidine product and program. It is hoped that this case study will be useful to others involved in designing and implementing similar initiatives in other settings.

Acknowledgements

I would like to express my sincere gratitude to the following individuals who provided valuable information to this study as key informants: Dr. Yasovardan Pradhan (former Director General of Department of Health Services) and Dr. Shyam Raj Upreti from the Nepal Ministry of Health and Population, Mr. Peter Oyloe, FHI 360, Mr. Deepak Poudel from USAID, Mr. Pradeep Jung Pandey and Mr. Prajwal Jung Pandey from Lomus Pharmaceuticals, Dr. Stephen Hodgins from JSI, Dr. Kusum Thapa from JHPIEGO, and Ms Mutsumi Metzler from PATH.

My special thanks go to Dr. Stephen Hodgins who designed this study and provided feedback throughout the study, as well as to Ms. Sabita Tuladhar, who worked as consultant for CNCP to conduct this study. I would like to thank Mr. Hari Krishna Bhattarai and the CNCP team for supporting to conduct this study.

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ABBREVIATIONS

AED	Academic Education and Development
CNCP	Chlorhexidine Navi Cord Care Program
CB-NCP	Community-Based Newborn Care Program
CHD	Child Health Division
CRS	Contraceptive Retail Service
DDA	Department of Drug Administration
DoHS	Department of Health Services
FCHV	Female Community Health Volunteers
FHD	Family Health Division
GMP	Good Manufacturing Practice
JSI	JSI Research & Training Institute, Inc.
MoHP	Ministry of Health and Population
NESOG	Nepal Society of Obstetrician and Gynaecologist
NFHP	Nepal Family Health Program
NHTC	National Health Training Centre
N-MARC	Nepal Social Marketing and Franchise Project
NMR	Neonatal Mortality Rate
NNIPS	Nepal Nutrition Intervention Program Sarlahi
PPP	Public Private Partnership
RCT	Randomized Controlled Trial
SBA	Skilled Birth Attendants
TAG	Technical Advisory Group
USAID	United States Agency for International Development
% w/v	percentage weight by volume
VDC	Village Development Committee

EXECUTIVE SUMMARY

In Nepal, newborn mortality has remained unchanged at 33 per 1,000 live births over the five years preceding the 2011 DHS study, compared with the preceding five years. Cleansing newborn umbilical cord stumps with 7.1% Chlorhexidine Digluconate solution has been demonstrated to reduce newborn mortality by 23 percent. Chlorhexidine in a gel formulation has been found more acceptable to users; this product was developed and piloted in Nepal. After the success of the pilot, the Nepal Government endorsed use of chlorhexidine for cord care as a part of essential newborn care in December 2011.

By the start of 2013, Nepal is moving forward as the first country in the world to adopt chlorhexidine for newborn cord care and the intervention has reached 36 of 75 districts in Nepal is also exporting chlorhexidine gel to other countries for both piloting and program purposes.

Lomus Pharmaceuticals developed the product for Nepal—and now also supplies other markets. Lomus takes pride in being the first pharmaceutical company in the world manufacturing chlorhexidine gel for newborn cord care.

This experience of public-private partnership has taught us that members of the private sector are willing and can be flexible enough to invest in public health programs that do not have immediate commercial promise, if they are well informed of its impact, are fully involved as a partner, and are trusted by both the public sector and technical assistance partners.

Having a Nepali pharmaceutical company manufacture chlorhexidine has substantially reduced the cost of the program, which is an important factor for program continuity of the public sector. This has also contributed to building stronger in-country support, another important success factor in the program.

The trusting relationship that developed was found to be an important factor contributing to the evolution of this successful public-private partnership.

This case study maps out the development of that partnership, examines the issues confronted, and the lessons learned.

INTRODUCTION

The success of a partnership can be assessed from a variety of perspectives, including: the clarity of communication, goals, and responsibilities between the partners; efficient and fair sharing of risk; public sector cost reduction; incentives; monitoring mechanisms and dispute resolution; and political support within any enabling regulatory environment (Schulich-School of Business). This case study analyses the perceptions of various on the involvement of Lomus in the government's chlorhexidine program, and reviews the prospects for such partnerships in health.

Overview of Chlorhexidine Program for Newborn Care in Nepal

In 1996, Nepal's neonatal mortality rate (NMR) was among the highest in the world—50 per 1,000 live births. In 2004, the Nepal government endorsed the Newborn Health Strategy and newborn care became a part of the National Safe Motherhood Programme.

Cleaning newborn cords with chlorhexidine gel emerged as a promising option that could reduce neonatal mortality by 24%.

In Nepal, although institutional deliveries are increasing a large proportion of deliveries still take place at home, mostly unaided by skilled birth attendants (SBAs). These deliveries usually happen in an unhygienic environment and the traditional practice prevailing is to apply substances such as turmeric and mustard oil paste, cow dung, or vermillion etc., over the freshly cut newborns cord stump, despite the government's recommendation to keep the cord dry. The topical application of these and other locally available substances on the cord stump increases the chances of infection among neonates. Even in health facilities, hygiene conditions are often not to standard, and births in health facilities are usually followed by discharges within the first 24 hours after birth.

A randomized controlled trial (RCT) carried out by the Nepal Nutritional Innovation Program Sarlahi (NNIPS) in 2005 found that cleansing the umbilical cord stump with 7.1% weight by volume (w/v) Chlorhexidine Digluconate reduces mortality by 24% (34% when the analysis was restricted to those receiving first application on the day of birth).

In 2007, when the results of the Sarlahi trial were shared among stakeholders, a consensus developed regarding the prospect of implementing a chlorhexidine program in Nepal. However, the challenge was to manufacture chlorhexidine locally at a modest cost to ensure programmatic success. Securing the interest of a private pharmaceutical company to manufacture chlorhexidine did not happen immediately.

The USAID-funded Nepal Family Health Program (NFHP) II[1] helped the Nepal Ministry of Health and

The Nepal Family Health Program (NFHP), implemented by JSI Research & Training Institute, Inc., was one of the technical assistance partners to the Nepal MoHP helping with high impact FP-MNCH service delivery at community levels. NFHP II—which had already supported MoHP in the piloting and scaling-up of misoprostol use for preventing postpartum haemorrhage at home deliveries—was determined to engage in moving the chlorhexidine antiseptic into programming. This document highlights some of those efforts.

[1] The Nepal Family Health Program II was funded by USAID and implemented by JSI Research & Training Institute, Inc., and its partners in 22 districts of Nepal for five years from December 2007 to November 2012. The goal of the project was to increase the access to public sector family planning and maternal newborn and child health services at community level.

Population (MoHP) collect additional evidence on the usage of chlorhexidine for cord care and design a program to translate the evidence into programming. NFHP II supported a MoHP pilot to distribute chlorhexidine using the existing public health service delivery system and mobilizing female community health volunteers (FCHVs).

Between November 2008 and May 2009, NFHP carried out a non-inferiority study in Paropakar Maternity and Women's Hospital (PMWH) with one of the senior obstetrician/ gynaecologists at the hospital as the principal investigator. Also, during this period, a small-scale pilot study was carried out by NFHP in four village development committees (VDCs) of Banke and demonstrated a clear preference for gel (vs. liquid).

With results from these studies, district-wide pilots were conducted in 4 districts, demonstrating high coverage, through the MoHP programs and services. Based on this experience, the MoHP approved nationwide scale up in December 2011. The Chlorhexidine Navi Care Program (CNCP), funded by USAID and managed by JSI Research & Training Institute since September 2011, has been helping the MoHP scale up the program. As of June 2013, the chlorhexidine program had been introduced in 36 of 75 districts of Nepal.

Engaging the Private Sector

When the preliminary results of the Sarlahi study were made available in 2005, NFHP II informally gauged the interest of several local pharmaceuticals—but received little positive feedback. Gaining the interest of local pharmaceuticals in manufacturing chlorhexidine formulations was initially a frustrating process for NFHP II and other collaborators.

A key concern was that manufacturing a small quantity of chlorhexidine products for piloting purposes and no immediate prospect of large-scale sales, and without any significant financial support from a donor or the public sector, would require significant effort and without a clear business rationale. Moreover, the product had not yet been registered by the Department of Drug Administration (DDA). Furthermore, there was an expectation that chlorhexidine was to be supplied to the government at a relatively low unit cost, thus showing little likelihood of profit to the manufacturing company.

In the meantime, towards 2007, NFHP began working with the N-MARC[2] project which served as a facilitator to help develop an understanding with local pharma companies. N-MARC had already approached five local pharma companies about manufacturing family planning contraceptives for their project. During this time, NFHP II explored opportunities with N-MARC on the possibility of moving ahead with one of these companies to manufacture chlorhexidine. For N-MARC, Lomus emerged as the best prospect for a private sector partner—both because they were a high-quality operation and because they were interested in a partnership for development of their own family planning contraceptive manufacturing project. This led to another arrangement between NFHP II and Lomus for collaborating on chlorhexidine.

The role of the HealthTech Program, implemented by PATH, was also critical to exploring private sector pharmaceutical companies for producing chlorhexidine for the umbilical cord care project in

[2] N-MARC was a five-year (2006–2010) project funded by USAID and managed by AED (now FHI 360) together with Nepal Contraceptive Retail Sales (CRS) Company and the Nepal Fertility Care Center (NFCC). Its mission was to increase the availability and sustained use of family planning (FP), maternal and child health, and HIV/sexually transmitted infection (STI) prevention products and services in Nepal.

Nepal. In the beginning of 2007, HealthTech was involved in performing a manufacturing landscape and identifying feasible sources to produce chlorhexidine.

Desk research was carried out with the help of a consultant, and good manufacturing practice (GMP)-certified pharmaceutical companies were identified, engaged, and had their interests gauged regarding chlorhexidine production for cord care. Four pharmaceutical companies were identified through this process, at which point HealthTech recommended one manufacturer for further investigation. (Initially, Lomus was not included as they were not initially determined to be GMP-certified, but later it was found that Lomus was in fact GMP certified. Lomus had, however, already been brought to NFHP's attention by N-MARC.)

Lomus progressively became engaged as a partner to manufacture and supply chlorhexidine, initially for research and thereafter for piloting in 2008-2009. Over time, Lomus became a full technical partner, rather than simply a product manufacturer. They remained the only manufacturer of chlorhexidine even during the scaling-up phase of the chlorhexidine program that began in late 2011.

As of 2012, Nepal is moving forward as the first country in the world to adopt use of chlorhexidine for newborn cord care. Nepal and Lomus also take pride in being the only country as well as the first pharmaceutical company in the world to manufacture chlorhexidine gel for newborn cord care.

ENGAGING LOMUS

In an attempt to involve Lomus in the chlorhexidine program, the NFHP II Project Director and the N-MARC Program Manager had several meetings. Data on chlorhexidine were presented to Lomus to demonstrate to them that their involvement would contribute to saving lives in Nepal. After learning about the benefits of chlorhexidine, their perspectives on the program and the product to be manufactured changed.

In 2008, Lomus had a verbal agreement with NFHP to manufacture limited quantity of two chlorhexidine formulations—gel and solution—for the Paropakar Maternity and Women's Hospital (PMWH) non-inferiority study. It should be noted that Lomus was already producing a chlorhexidine mouthwash product. Lomus had initial concerns that JSI and N-MARC were asking them to do something that wouldn't actually benefit Lomus themselves.

Upon entering into a partnership with the MoHP (though a very informal one which was facilitated by the technical partners, NFHP II and AED) in 2008, the first task for Lomus was to manufacture a limited quantity of chlorhexidine for non-inferiority study carried out in PMWH as well as the community acceptability study at Banke. This was challenging because the investment in manufacturing a limited product is significant, and there was no assurance that this would develop into a routine program that would eventually be implemented in more districts and increase the demand for chlorhexidine. Moreover, it was clear from the very beginning that there would be little profit for the manufacturer; this represented a significant risk for Lomus to invest in the program.

It was only because of the efforts of JSI and N-MARC staff that the Lomus management board was convinced to work with the government and NFHP. The existing relationship that Lomus had with N-MARC played a catalytic role during this process. Lomus was collaborating with N-MARC/AED for the USAID matching fund program where they were the first manufacturers in-country of three oral

contraceptive pills. Due to the working relationship of Lomus with USAID and N-MARC, they became interested in also being a part of the chlorhexidine program.

Lomus gives credit to JSI and AED for changing their understanding and involving them as a private sector partner in the chlorhexidine program. For Lomus, this relationship and participation in the chlorhexidine program meant that they were looking at the bigger picture and increasing their future prospects.

NFHP's Project Director believes that this process of engaging Lomus in the manufacturing of a public health commodity was helped by the fact that N-MARC had already engaged in detailed discussions with Lomus about a broader range of potential collaborations. So even though chlorhexidine did not seem to have a lot of commercial promise, this collaboration with NFHP could be strategically helpful in cultivating a good working relationship that could also result in sales of other products. JSI played a significant role in managing the program implementation, and AED managed the manufacturing side of the private sector engagement. Throughout this process, the government institutions were also very supportive by helping in the decision-making process.

From the beginning Lomus was involved in all decisions, which was key to the success of the program.

Lomus in the Chlorhexidine Program—From Informal to a Full Technical Partnership

When initial attempts were made to involve Lomus in manufacturing chlorhexidine, the full extent of stakeholder relationships was not clear. Over time, however, this relationship developed into a promising example of public-private partnership.

The attitudes of both government and non-government stakeholders towards Lomus were positive throughout the program development. It is clear that in this evolving relationship, the government and NFHP II broadened the role of Lomus. For instance, Lomus was included as a member in the Technical Advisory group (TAG) which helped them in knowing all technical details of the program and its importance in public health, thereby developing a greater sense of ownership of the program. Lomus found that all the stakeholders have treated them with respect and as a full partner, and believe that this has been possible only because of the trust shown by NFHP and USAID.

Because Lomus was made a full partner in the chlorhexidine program and included in all the major technical activities—rather than just being treated as a manufacturer—Lomus was able to fully understand the value of chlorhexidine in saving newborn lives. This realization encouraged them to become emotionally invested, follow up with NFHP and CNCP, inquire about and monitor the sufficiency of the chlorhexidine stock, and ensure timely manufacture and supply of the products.

Manufacturing Chlorhexidine Gel: *Process, Concerns, and Results*

The chlorhexidine formulation used in the Sarlahi efficacy trial was an aqueous solution prepared by the research staff from bulk product. In the trial, the intervention consisted of daily application of chlorhexidine but the results pointed to the importance of chlorhexidine use on the day of birth. The current government messaging for newborn cord care, however, was to keep the cord stump dry, and chlorhexidine use would contradict this message. Thus, government officials wanted the chlorhexidine program to require minimum change in the behavioural recommendations so there

would not be confusion among women in communities. For this reason, and because the trial results suggested that it was the day-of-birth application that conferred most (if not all) of the mortality reduction benefit, it was decided that the program would use day-one-only application, until and unless additional evidence suggested that further application was necessary. Around this time, it was confirmed that a day-one replication trial would go forward in Bangladesh, which was expected to settle the question on the number of applications required.

During this period both NFHP II and N-MARC were in constant dialogue with Lomus about the manufacture of the chlorhexidine product needed for the pilot study.

Determining the type of chlorhexidine formulation—whether liquid or something thicker that sticks to the umbilical cord stump—was another question that arose. Early on—in the fall of 2005—the global working group felt that some other formulation may be more appropriate for program use. However, if another formulation besides aqueous solution was considered, it would be necessary to demonstrate equivalent efficacy with regards to suppressing bacterial growth on newborn skin.

By mid-2006, a formative study report suggested that caretakers prefer applying substances by hand on the freshly cut cord stump. At the time, the most common substance used by different cultural groups in Nepal was a mustard oil and turmeric powder paste. Recognizing this, the team worked to develop a formulation that looked like mustard oil and turmeric, was oily, and could be easily applied by hand, so that the caretakers would be willing to use it instead of mustard oil; this led to the decision to develop a gel.

By late 2007, Lomus had agreed to manufacture the product. In the meantime, a technical advisor from PATH/HealthTech Program came to Nepal and visited several pharmaceuticals to examine the production capacity, including checking the good manufacturing practice (GMP) certification and technical suitability for chlorhexidine production. During this period PATH developed product specification and packaging for the two variants: gel and liquid (*see box, Chlorhexidine Gel Specification, below*).

In the meantime, a list of Nepali names was proposed for the chlorhexidine gel and was discussed in the technical advisory group (TAG) meetings. In deciding on a suitable name for the product, a list of names was discussed with health workers, female community health volunteers (FCHVs), and mother/caretakers, with the most

CHX Gel Product Specification

Product name:	*Kawach* Navi malham
Generic name:	Chlorhexidine gel 7.1% w/v
Composition:	Chlorhexidine Gluconate Solution BP e.q. to Chlorhexidine 4% w/w
Description:	Yellowish or colourless semi-transparent gel filled in printed collapsible aluminium tube
Identification:	Positive for Chlorhexidine Gluconate as per HIS
Average fill weight:	NLT 3 gm
Uniformity of weight:	+_ 9%
pH of 10% w/v solution:	5.0-7.0
Active ingredients:	Chlorhexidine Gluconate Solution BP eq. to Chlorhexidine Label Claim- 4% w/w Limit- 90%-110%
Unit pack size:	3 gms of gel filled in printed collapsible aluminium tube.
Shelf life:	2 years from the date of manufacture

Chlorhexidine gel 7.1% w/v (*Kawach* Navi Malham)

preferred name being *Kawach* (shield). The term *Kawach* was familiar in both hills and plain areas, and means 'a protective shield.'

Before manufacturing the product, it was necessary to register the product at Department of Drug Administration (DDA). With the support of the Family Health Division (FHD) and the Child Health Division (CHD), Lomus was able to register 7.1% w/v chlorhexidine gluconate with the brand name *Kawach* at DDA during 2008 (including initiating stability testing).

While the chlorhexidine gel was being manufactured by Lomus, concerns were raised on monitoring the process to ensure quality; JSI closely monitored the quality of the product. Lomus was also taking full responsibility for making sure that their product quality was meeting international standards. In this process, AED helped by bringing in US Pharmacopia, which visited Lomus to make sure that their product would meet international standards.

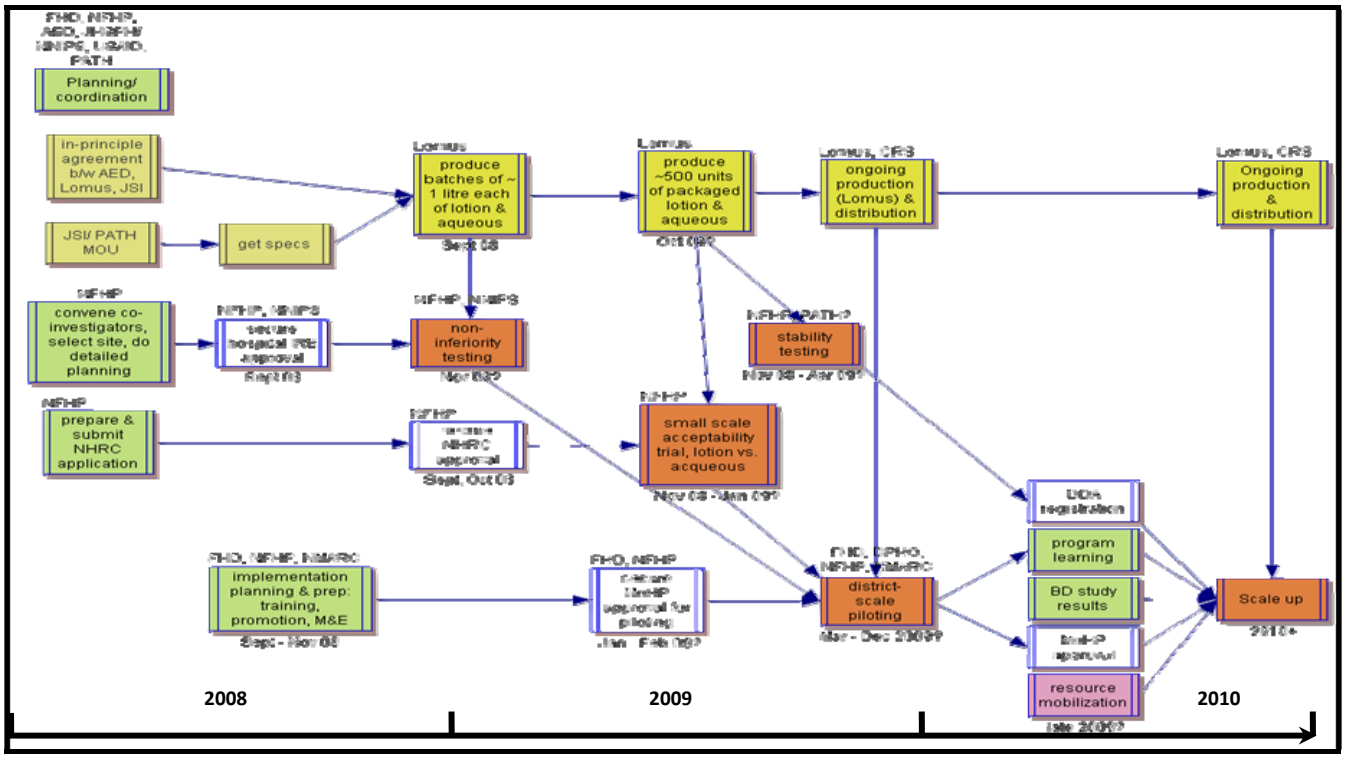
Coordinating for Implementation

The Family Health Division (FHD) of the Department of Health Services was the responsible institution on behalf of the Ministry (MoHP) to implement chlorhexidine introduction. After endorsing chlorhexidine as an essential component of newborn care during the scaling up phase, the Child Health Division (CHD) and Family Health Division (FHD) became the responsible government institution. To coordinate all the activities and make key decisions, a technical advisory group (TAG) on chlorhexidine was formed at the FHD level in 2008. The TAG was chaired by the FHD director and included other stakeholders (*see box, Technical Advisory Group, below*).

Both N-MARC and NFHP—key players in engaging Lomus—appreciate that Lomus was actually considered a pioneer for developing this product, even by the government. Lomus developed the packaging of the formulation and made the product available to the government to use.

Technical Advisory Group (TAG):

The planning/coordination relationships among the key players of the chlorhexidine program.



During the four-year span, Lomus was successful in gaining appreciation from all the stakeholders. Key informants from the DoHS, PMWH, and USAID shared that there were no concerns with regards to involving Lomus in the chlorhexidine program at any stage. According to USAID, given the positive relationship with Lomus during phase 1, that relationship should continue with the 2011 scale-up initiative, the Chlorhexidine Navi Care Project. Therefore, Lomus was approached by NFHP and later on became a partner in the new program. It should also be noted that Lomus has been supplying various other products to DoHS, with no concerns regarding product quality or price.

Issues & Considerations

While Lomus consistently came up as a very promising private sector partner to manufacture a public health commodity, there were, however, issues that had to be addressed—from developing product specifications to program scale-up and implementation. Other issues included: anti-competition (monopoly provider), product quality, ownership of *Kawach* brand, product packaging, packaging inside delivery kits, and contradiction with WHO recommendations.

Monopoly Provider and Anti-Competition

JSI and AED explain that the initial plan was to engage more than one pharmaceutical company in manufacturing chlorhexidine, and several other pharmaceutical companies were also consulted. Lomus was the only company, however, willing to invest the time and money that was needed in order to develop the product.

Thus far, the technical assistance partners have been purchasing the chlorhexidine gel from Lomus and supplying it to the districts where the program has been implemented. MoHP is expected to begin procurement later in 2013.

When the program is implemented in all 75 districts through the public health service delivery system, the government will need approximately 750,000 tubes a year—one for each birth. Lomus is very encouraged with its success and has the capacity to produce around 10,000 tubes of chlorhexidine gel per day (36,000,000 per year). Such a commitment from a private pharmaceutical company is very promising. Despite this commitment, however, from a broader national perspective there is also a need for contingency planning; questions arise on the problem of having a monopoly provider, and in the near future this might be a serious national-level concern. The entry of other pharmaceutical companies in the market also ensures a check and balance system, which is essential for a healthy marketplace.

Furthermore, for government procurement, international tenders will be required and bids from multiple companies will need to be obtained. In a monopoly market such a government requirement cannot be met, and this rigidity might be a barrier in the program management. (Sole sourcing was discussed but not possible in the Nepal context.)

It is clear that none of the stakeholders involved in the chlorhexidine program wanted to be locked in over the long-term to a single provider. Most of the key informants viewed Lomus very positively, but in the long run, the government needs to take a broader market perspective. In future, other pharmaceutical firms may show interest in manufacturing chlorhexidine. The advantage of having multiple manufacturers is in ensuring greater continuity of the product, maintaining higher quality, and reducing cost. One key informant's comment was that the government's and the partners' objective should not be the promotion of one company and the discouragement of others.

One key informant further reiterates the importance of having multiple manufacturers because, with the change in leadership of a pharmaceutical company, the company's priorities and performance may change. Clearly, all these issues have to be properly discussed and analysed while in the debate for and against monopoly provider and sole sourcing.

Ownership of the Kawach Brand

The name *Kawach* was determined by the TAG and was initially thought of as a generic name for the product. However, as Lomus registered the name and was the only group producing chlorhexidine gel, it ended up as the owner of the *Kawach* brand name.

Chlorhexidine gel in Nepal will be called "Navi Malham" instead of *Kawach* as Lomus owns the name

As the program was being implemented on a larger scale and the name *Kawach* was used in all official communications referring to chlorhexidine gel, stakeholders realized that they required another generic name for the product. NFHP and the government wanted *Kawach* to be used as a generic term, and not as a pharmaceutical company brand, however, as Lomus owns the name it has been decided that the chlorhexidine gel will be called "Navi Malham" (umbilical cord lotion) instead of *Kawach*.

Product Quality

There were some initial concerns among stakeholders regarding the quality of the product manufactured by a domestic pharmaceutical company, and whether a local group would be able to meet international standards. However, the concern was addressed when PATH and US Pharmacopia began monitoring production for quality assurance. Lomus has been found to be manufacturing a high-quality product over the four-year period, during which the US Pharmacopia has been monitoring by carrying out intermittent technical audits of the product.

Product Packaging

Product packaging was also an initial concern. NFHP wanted to use sachet packaging for the chlorhexidine gel; however, Lomus did not have the set-up to produce a sachet. Furthermore, use of new packaging equipment to produce a sachet package would have required a formal recertification process with DDA. Lomus weighed in that packaging medicine in a sachet does not convey a medicinal benefit as medicines in Nepal do not come in sachets. Instead, aluminium tubes were used to give a professional appearance to the product and to help ensure product stability. In addition, the chlorhexidine packaging was made a mustard colour to link it visually with the turmeric and mustard oil paste that was traditionally used.

Adding Chlorhexidine to Clean Home Delivery Kits

One issue found during the pilot introduction was confusion that arose from adding chlorhexidine gel to the clean delivery kit. Clean delivery kits were already in the market but there was no clear system for the process of incorporating a new product into the kits. This led to conflicts and, as a result, the DoHS administration asked the Contraceptive Retail Service (CRS)—which distributed the kits—not to send delivery kits with chlorhexidine to market. Additional concerns included cost—as adding chlorhexidine would increase the cost of each kit—and the chlorhexidine stability period, initially only 18 months, as it would trigger regulatory requirements for an expiration date on the kit, which could complicate logistics.

In the end, the government decided not to proceed with adding chlorhexidine to the kits; this was in part because they are promoting institutional

deliveries as opposed to home births—thus clean delivery kits would no longer be needed.

Contradictory Cord Care Message

Despite evidence on the effectiveness of cord cleansing with chlorhexidine, the government and technical assistance partners had to consider WHO's standing recommendation Despite this, , it was clear that new efforts for reducing newborn mortality were needed. Cleansing newborn cords with chlorhexidine gel came up as a promising option that could reduce neonatal mortality by 30 percent, so the government determined that it did not need to await new WHO recommendations to adopt the use of chlorhexidine in its newborn services.

One of the informants finds this partnership as the only Nepal example where the private sector was involved from the very beginning in the manufacture of a new public health commodity; this partnership is unique because Lomus was involved in the entire process, from inception to development and from pilot programming to scaling up.

Lessons Learned from the Public-Private Partnership

Lomus' involvement in the chlorhexidine program has made remarkable progress, and today Nepal is the first country to adopt use of chlorhexidine for newborn cord care. During the four-year period, several lessons were learned regarding involving the private sector in a public health program.

A private company has to look at long-term benefits to fully contribute to the national interest. This public-private partnership has been a new model and its success has benefited all involved. Had Lomus only looked at their immediate benefits when NFHP and N-MARC approached them to become a partner, they might have not agreed and would not have achieved their present success. It is very rewarding to Lomus that, because of their collaboration with the public sector, more newborns are surviving and the society and entire country have benefited.

Having an explicit market and demand and scale-up plan helps the private sector see the potential even when the market is initially small. As reported by one of the technical assistance partners, chlorhexidine for this use is a low-cost and low-profit margin product. In addition, large production/sales quantities could not be expected since it is for single-use only. Under these circumstances, it is usually difficult to attract a for-profit company to produce and market a new product; however the program was successful, primarily because of two factors. First, although the potential market for the product was small, there was an explicit demand for it from the government of Nepal. Explicit demand is more powerful than large "potential" demand. Second, there was a clear introduction and scale-up plan; this meant that Lomus could see how the demand of the product was expected to increase in the future without having to make a significant investment in promotion and market expansion.

The importance of engaging the right stakeholders cannot be overstated. Another lesson that this PPP taught is the importance of engaging the right stakeholders, from decision-makers to the program implementers, for the success of program. One of the key informants expressed that many community-based interventions in Nepal have succeeded, while in many other countries it is quite common to experience failure. One of the success factors for Nepal has been the rigorous participatory process followed in engaging different stakeholders.

It is important to explore options so as to further innovate and so that better solutions can be found; limiting a program to its initial set-up is not sufficient for achieving the best results. If options for chlorhexidine solution were not explored in this program, then it is possible that chlorhexidine gel might have never been manufactured and only chlorhexidine solution would have been used. This experience of partnership has also taught the stakeholders to be open to thinking outside the box.

Remaining flexible and open creates opportunities. In this evolving partnership, Lomus' flexibility has been most important. The willingness and flexibility that Lomus showed in this innovative program has given them an advantageous position, and this can benefit Lomus in several ways in the future.

In addition to being highly appreciated by stakeholders in Nepal, Lomus was also received acclaim from the international community. For instance, in global-level meetings on chlorhexidine, Lomus has frequently received notice. Engaging in the chlorhexidine program has opened up prospects for broader collaboration with the public sector and the international community for Lomus. One of the key informants points out that the private sector is often invisible in government programs, with their role confined to manufacturing and supplying of commodities. In this regard, Lomus has had the opportunity to become more involved in government's internal processes (such as in the technical committee), and through this network Lomus was able to get further secondary benefits. Key informants further state that by manufacturing chlorhexidine, Lomus can increase their market presence in the South-Asia region as well as on a global scale. Lomus' products are already known in neighbouring countries. So, if there is a future need for chlorhexidine gel in these countries, Lomus can seize the opportunity and move ahead.

Through this experience USAID's support has been important; however, as this kind of partnership was relatively unconventional, there were constraints on the kind of support that could be provided. One early limitation that the chlorhexidine program faced was related to funding. USAID's funds could not be used for drug purchasing, so the technical assistance partners had to explore other options for funding the manufacture of the chlorhexidine. The process of chlorhexidine program development could have been faster and easier, in its early stages if USAID had the flexibility to support procurement.

It should be noted however that USAID did provide significant support through NFHP for the early studies (e.g., the non-inferiority trial) and for the 4-district pilot. And current support to government through the CNCP project is funded by USAID.

Success Factors and the Future Prospects for Lomus

The contribution that Lomus and the chlorhexidine program made to the Nepal public health program is perhaps not known to the families that have benefited from it. Nonetheless, there is significant appreciation of Lomus' work among the government, funding agency, technical assistance partners, and professional associations. They have all found Lomus to be a reliable and professional partner that is quick and responsive toward chlorhexidine decision-making.

Though Lomus did not give the product for free to the program, they charged very modest costs, which demonstrated that they approached the collaboration from a broader perspective (*see box on Costs to Produce Chlorhexidine, below)*.

Today, Lomus is able to provide chlorhexidine gel to anyone wherever it is needed. Currently, Lomus supplies chlorhexidine tubes to JSI, Save the Children International, One-Heart Worldwide, CARE Nepal, Plan Nepal, and NNIPS in Nepal. Lomus has also sold Chlorhexidine gel to Uttar Pradesh, India for research purposes and to Madagascar and to the Government of Sokoto State, Nigeria (through a Nigerian pharmaceutical importer).

A government official confirms that USAID and JSI are highly satisfied with Lomus and, as these agencies operate in many other countries, they can advocate for Lomus and further benefit them that way. If demand is generated internationally for the manufacture and supply of chlorhexidine gel, Lomus—being the pioneer company—can contribute the social cause while at the same time generate revenue.

CONCLUSIONS

Reducing newborn mortality has been a huge challenge for Nepal—given the lack of progress over the past decade, there was a clear need for new efforts. In this context, chlorhexidine was proposed as a promising program investment with the potential for preventing about one in five newborn deaths in Nepal. The collaboration between the government, Lomus, and the technical assistance partners has been unique in Nepal and can be considered a model for the future. Most importantly, working with one pharmaceutical company and developing a good trusting relationship was found to be an important factor in the evolution of this partnership.

Public-private partnerships are one of the strategies of Nepal's government for achieving better health outcomes. This program initiative attempted to involve a for-profit private sector in the public health program, and succeeded in getting better public health results. In the long run, the program was able to educate those stakeholders who were not initially in favour of the program.

This program initiative, which can save hundreds of thousands of newborns worldwide, would have not have made the progress it has without government's real openness to engage with a private company in such an endeavour.

LOMUS COST SUMMARY

Particulars	Amount (USD)
Sales revenue	119,135.75
Lomus investment on CHX project so far	56,273
Cost of manufacturing*	82,816
Loss	(19,953.25)

*Lomus notes that there are a few additions of analytical equipment and lab modification in process which will increase the investment costs.

"Lomus has been involved in this project since the initial stage in 2007 when the first consultation meeting was held in Nepal. Lomus took initiative with a novel cause that is saving new lives in Nepal. With the increasing demand and project success es in several countries, Lomus is determined to continue supplying CHX for a global cause as well with a minimal profit mark-up. With a six-year involvement in CHX development, process validation, and maintaining a high-quality product, Lomus has the greatest satisfaction in saving newborns around the world." *Statement from Lomus*

ANNEX 1

STUDY METHODS

This study used qualitative research methods—primarily literature desk reviews and interviews with key informants engaged in the public-private partnership; it focused on the relationship between government, donors, technical assistance projects and a private sector partner in chlorhexidine intervention in Nepal.

Literature Review

The literature review involved going through relevant documents related to theories on public-private partnership in health and relevant case studies from other countries, documents on chlorhexidine antiseptic, Technical Advisory Group (TAG) meeting minutes and workshops and other reports produced by NFHP II, project documents on CNCP, and MoHP's policy documents on newborn health. The document review enabled the CNCP to develop a detailed timeline on the evolution of the events leading to the development of the PPP in the chlorhexidine program. The information derived from the literature review was combined with that from the key informant interviews so as to chronologically identify the key steps in chlorhexidine program development.

Key Informant Interviews

The key players of the chlorhexidine program were interviewed in developing this case study. These included:

- the then Director General of the Department of Health Services (DoHS),
- the then Director of the Child Health Division (CHD),
- the Chairperson and the Manager of the Lomus Pharmaceuticals Private Limited,
- Health Program Management Specialist of the United States Agency for International Development (USAID),
- the then project director of NFHP,
- the Project Manager of the then Nepal Social Marketing and Franchise Project (N-MARC),
- the Project Manager of the CNCP project,
- the technical advisor from PATH and
- the then Principal Investigator of CHX hospital-based study of the Paropakar Maternity and Women's Hospital (PMWH) of Nepal.

Interview guidelines were developed for each of the respondents to capture the key informants' perspectives on the involvement of Lomus in the chlorhexidine program at different phases and relating it to the PPP. The timeline developed through the literature review was used during the interviews to guide the informants in reflecting on past events of the chlorhexidine program development. With the consent of the key informants, tape recorders were used to record the interviews and were then transcribed on the same or following day to maintain the quality of the transcribed notes. Transcriptions were done covertly to reduce bias and the notes and the tapes were stored confidentially in the CNCP office. Out of the ten key informants interviewed, two were international. Their written interviews were carried out by sending the chlorhexidine

timeline and interview guidelines in e-mails. Triangulation of the information accrued from the interviews was sought through published and grey literature. The interviews were carried out during December 2012 and January 2013.

The detailed timeline of the events in chlorhexidine programming in Nepal helped the informants provide their views and experiences and comment on at different stages of the program evolution. The interviews sought specific perspectives of each of the players on the evolving partnership, capturing their particular concerns and expectations as they developed over time.

Key Players in Involving Lomus in Chlorhexidine Program

Discussions with the key informants revealed the important contribution made by the Project Director of NFHP and Program Manager of N-MARC in engaging Lomus in the manufacture of a public health commodity, and how they contributed greatly in development of a model public-private partnership. Lomus in particular finds the role played by NFHP Project Director and N-MARC Program Director to have been crucial in successfully engaging them in the chlorhexidine program. They recognize the contribution made by JSI and AED in this process and calls them 'The Initiators.' The NFHP II Project Director was the first person to move forward this agenda, and was strongly supported by Program Manager of N-MARC. Nevertheless, the positive cooperation shown by the Family Health Division, the Child Health Division directors, and the program focal persons were also crucial in engaging Lomus in the chlorhexidine program.

The NFHP II Project Director acknowledges the important contribution of N-MARC's Program Manager in facilitating the dialogues between NFHP and Lomus. His view is that the rapport and the quality of relationships between Lomus and AED were very important in engaging Lomus in the chlorhexidine program. An effective working relationship developed between NFHP and Lomus - and later with USAID and the government- thanks to AED support, and it has now developed into a successful public-private partnership. NFHP II Project Director also points out the important role played by N-MARC in facilitating development of a social-marketing component with contraceptive retail service (CRS), which included tying chlorhexidine to the delivery kit.

ANNEX 2

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