Nepal

Clean Home Delivery Kit

Evaluation of the Health Impact

path
Program for Appropriate Technology in Health
4 Nickerson Street, Seattle, WA 98109

Vivien Tsu, Ph.D.
May 2000

ACKNOWLEDGMENTS

Special thanks go to the field team of dedicated men and women who worked under very difficult conditions to collect the data for this study. We would also like to recognize the assistance of Nebin Lal Shrestha, who did all the data entry and preliminary analysis of several aspects of the study. Save the Children U.S. assisted in managing the administrative aspects of the study. Barbara Crook and Sandra Laston gave valuable advice and assistance in setting up the study. Sumitra Bantawa and Renuka Munankarmi of MCH Products Pvt., Ltd., makers of the delivery kit, played critical roles in the development of the study protocol, in coordinating local meetings of the technical advisory committee, in supporting the researchers administratively, and in targeting their marketing efforts to ensure the availability of kits in the study areas. USAID/Nepal provided assistance and technical input at various points during the study. Finally, the technical advisory committee in Kathmandu provided useful input at the planning phase and after the preliminary data analysis was completed, and reviewed the final draft.

Funding for the study was provided primarily by United States Agency for International Development (USAID) under the Technologies for Health (HealthTech) project, Cooperative Agreement No. HRN-A-00-96-90007-00, with supplemental funding from Save the Children U.S.

TABLE OF CONTENTS

EXECUTIVE SUMMARY

Tetanus and sepsis are among the leading causes of maternal and neonatal death and illness in developing countries. These infections occur mainly as a result of contamination from an unclean environment and from harmful delivery practices, including the use of unclean materials during the delivery. To address these problems, a clean home delivery kit was developed (with technical assistance from PATH and Save the Children U.S. and funding from USAID, UNICEF, and UNFPA) and has been produced and sold by MCH Products Pvt., Ltd. since 1994. After more than three years of experience and more than 300,000 kits sold, USAID supported PATH under the HealthTech project to undertake an evaluation of the health impact of kit use. The study evaluated both short-term health impacts and intermediate outcomes, such as changes in knowledge or behavior, that might reasonably be expected to have a beneficial impact on health in the long term.

Due to the difficulty in detecting significant changes in mortality without very large sample sizes, the study focused on simple cord infection, a more common illness, as a precursor to more serious infections and an indicator of potential exposure to tetanus. Important intermediate outcomes potentially associated with use of clean delivery kits include behaviors, knowledge, and intentions, such as the birth attendant washing her hands before the delivery and the cord cutting, correct use of the items in the kit, and safe reuse or disposal of kit items after the delivery. Factors potentially related to kit use, client satisfaction with the kit, and reasons for not using the kit were also explored.

From July to November 1998, a total of 1,660 households in three districts in the Terai (Morang, Siraha, and Sunsari) were contacted 7 to 28 days after the birth of an infant. All home births with an infant who survived at least 24 hours after birth were eligible. Six teams of field workers (a male and female on each) located and interviewed the new mothers and inspected the infant's umbilicus. Mothers were enrolled in one of four possible cohorts: kit user with trained attendant, kit user with untrained or no attendant, kit non-user with trained attendant, and kit non-user with untrained or no attendant. A neonatologist reviewed the data from mothers' responses to the survey (including selection from among several color photos of cord stumps) and the field worker's observations of the baby to determine whether cord infection was likely or not. Multiple logistic regression was used to determine relative risks and 95% confidence intervals for infection risk factors and to control for potential confounding factors.

There were several interesting findings with regard to birth practices in this particular area of Nepal:

- More than 90% of kit non-users (96.7% with trained attendants and 91.6% with untrained) used a new or boiled blade to cut the cord.
- Among trained attendants slightly more kit users washed their hands before cutting the cord (96% vs. 90%), but among untrained attendants many more kit users than non-users washed their hands (91% vs. 76%). Kit users were more likely to use soap, among both trained (96% vs. 73%) and untrained attendants (84% vs. 46%).

- About 70% of all attendants put nothing on the cord immediately after cutting. Of those who put something on, trained attendants were more likely to use Dettol while untrained attendants used ash.
- About 60% of all attendants put mustard oil on the stump later, while about 30% put nothing on it.
- About half put a clean cloth on the stump, and less than 5% left it uncovered.
- A high proportion of kit users (89-99%) used the various components correctly, but <20% followed the pictorial messages about prompt wrapping or immediate breastfeeding.

The key findings with regard to infection, kit use, and other factors were:

- There were 271 cases of "likely" infection (16% of all eligible births) and 28 deaths (1.2%).
- Kit non-users were divided into 4 groups, based on blade type and cutting surface, and were then compared with kit users. Infection rates for the various groups were:

  kit users – 18.3%
  kit non-users:
    new blade with coin or nothing – 9.9%
    new blade with other cutting surface – 18.2%
    boiled blade with coin or nothing – 16.9%
    boiled blade with other surface or other blade with any surface – 1.6%
- Infection rates varied by district and exhibited a seasonal trend, and infection detection varied by how soon after birth the baby was seen and by which field worker conducted the interview. Therefore, the logistic regression model had to be adjusted for these confounders.
- Kit users had less than half the infection rate (0.45; 95% C.I. 0.25-0.81) of kit non-users who did not use a new or boiled blade and clean cutting surface (after adjusting for confounders), but there was no significant difference between kit users and any other group of kit non-users, suggesting that clean cord cutting is the one of the most important practices in preventing infection.
- Although not statistically significant, use of mustard oil, Dettol, and *harro* were somewhat protective, while use of ash increased infection.
- Use of a clean cloth or none on the stump (vs. a dirty cloth) and washing hands with soap before cutting the cord were both significantly associated with reduced infection.
- Health workers were the most common source of information about kits. Kits were most commonly bought from traditional birth attendants (TBAs) in Morang and Sunsari and from pharmacies in Siraha. More than 90% of users planned to buy kits again.

In conclusion, where unhygienic practices are widespread, inexpensive clean delivery kits designed to suit local needs and tastes can contribute to a reduction in infection, but not in isolation. If clean cutting implements are already used, special

kits may not add much benefit. Although management of cord cutting is a critical step, what is put on the cord afterwards in terms of foreign substances or cloth dressings is also important. The kit can provide the necessary components to make compliance with hygiene messages easier, but its value can be reduced if it is not part of a comprehensive strategy to reduce obstetric and newborn complications.

To the extent that the Terai differs from other places, the results from this study may not be true for other parts of Nepal or other countries, but some recommendations for program managers can be suggested from the findings.

- If use of a clean (new or boiled) implement for cutting the cord is already widespread, introduction of a specially designed kit may not greatly reduce infection.
- Where use of a clean implement is not well established, sale of a clean home delivery kit can provide a convenient way for families to get appropriate supplies while utilizing the private sector to do the promotion of clean deliveries. Promoting the use of clean or boiled blades may achieve a similar effect.
- A kit (or clean supplies) will not work in isolation, without addressing other practices such as topical substances put on the stump afterwards and leaving dirty cloths on as dressings.
- This study does not provide sufficient evidence for changes to the current kit components, but suggests that the plastic disk may not be necessary. The study was not designed to provide information on new components like gloves or antimicrobials. The sensitivity to kit cost expressed by users, though, suggests that any additions to the kit should be weighed carefully against the effect of increasing the cost.
- While pictorial instructions were effective in ensuring correct use of kit components, they were much less effective in promoting other behaviors.

I. INTRODUCTION

Tetanus and sepsis are among the leading causes of maternal and neonatal death and illness in developing countries. These infections occur mainly as a result of contamination from an unclean environment and from harmful delivery practices, including the use of unclean materials during the delivery. Both mother and baby are exposed to the risk of infection. The high rate of home deliveries, of births attended by people with little or no training in hygienic delivery practices, and of shortages of suitable clean implements and materials all contribute to the problem of perinatal infection. To address these problems, a clean home delivery kit (CHDK) was developed (with technical assistance from PATH and Save the Children U.S. and funding from USAID, UNICEF, and UNFPA) and has been produced by MCH Products Pvt., Ltd. and sold in Nepal since 1994. A needs assessment was carried out to identify important components, appropriate configuration and packaging, priority messages for the pictorial insert, and an acceptable price. Prototype kits were evaluated in a field trial involving 131 births, and then test marketing was carried out in two districts, during which more than 2,000 kits were sold. Since that time, the kit has been marketed and promoted throughout Nepal.

With more than three years of experience distributing kits and more than 300,000 kits sold, it is important to evaluate the impact clean delivery kits can have on the well-being of mothers and newborns. While WHO (1998) and others recommend provision of disposable delivery kits to women and community birth attendants, it is recognized that it will be difficult to prove that they have a beneficial impact independent of other interventions (Smith and Fortney, 1996). This study was intended to evaluate short-term health impacts and intermediate outcomes such as changes in knowledge or behavior that can reasonably be expected to have a beneficial impact on health in the long term. The study was funded by the HealthTech Technologies for Health project (a cooperative agreement between PATH and USAID), with technical assistance from PATH and administrative and financial support from Save the Children U.S.

II. STUDY QUESTIONS

Immediate Health Impact

Since the kit is primarily designed to reduce the risk of infection by providing a clean delivery surface, clean cutting instrument and ties for the cord, and clean hands for the attendant, the main health benefit to be expected is a reduction in maternal and newborn infection rates, particularly cord infection. Although maternal tetanus and puerperal infection are serious problems, they are sufficiently uncommon that it would be difficult to detect a change in their rates without a massive study and very large sample size. Similarly, it would require observation of several thousand newborns to be able to detect a change in the neonatal tetanus rate. Therefore, the study focused on simple cord infection, a more common illness, as a precursor to more serious infections (Garner et al, 1994) and an indicator of potential exposure to tetanus.

Intermediate Outcomes

Important intermediate outcomes potentially associated with use of clean home delivery kits include behaviors, knowledge, and intentions that might reasonably be expected to be related to longer-term improvements in health or to health impacts that cannot be detected in smaller surveys. These would include indicators of behavior change such as the birth attendant washing her hands before the delivery and the cord cutting, correct use of the items in the kit, and safe reuse or disposal of kit items after the delivery. Changes in knowledge related to the pictorial insert would be indicated by understanding of one or more of the eight messages in the insert (not just the practices but the concepts of three cleans). Client intention to use the kit herself in future deliveries and/or to recommend it to others would be an indicator of an enhanced perception of the importance of a hygienic delivery, as well as the likely continued purchase of the kit.

Factors Potentially Related to the Use or the Effectiveness of the Kit

Factors that help characterize the study populations and that might be related to the use of kits or to the health outcomes of interest include: sociodemographic factors (like age, education, religion, economic status); health history factors (like parity, previous perinatal deaths, use of antenatal care, prior tetanus toxoid); and events associated with the delivery (such as type of attendant and/or cord cutter, type of delivery surface, preparation of cord care items, and application of foreign substances to the cord stump). Access to other information (besides the kit insert), that might affect knowledge of clean delivery practices, were assessed by asking about the content of any information they have about delivery hygiene and the source(s) of information, (e.g., the radio, safe motherhood events, trained birth attendants).

Acceptability of and Access to Kits

Although not the primary focus of this impact evaluation, some data were collected from kit users on client satisfaction with the kit, source of kit they used, price of kit, and preferred outlet for obtaining future kits. Non-users were asked why they did not use a kit.

III. METHODOLOGY

General Design

The study involved 4 cohorts of women, both kit users and non-users, interviewed within 7 to 28 days after giving birth to collect information on newborn health status during the first few weeks of life; reported delivery practices; and mother's knowledge, experience, and intentions. The study was carried out from July to November 1998 in three districts in the Terai—Morang, Siraha, and Sunsari—selected on the basis of access to sufficient numbers of pregnant women, either kit users or non-users, and the ability to have field workers identify and visit mothers within one to four weeks postpartum. Within the selected districts, a random sample of village development councils (VDCs)

encompassing the target number of wards was selected. All wards within the selected VDCs were canvassed regularly throughout the data collection period to identify all eligible births until the requisite number of births in each of the four study blocks was enrolled. Publicity campaigns and discounts to distributors were used to increase the sale of kits in the selected study areas to ensure full enrollment of births involving kit use.

Participants and Sample Size

Eligible participants included all women in the study sites who delivered a live infant (who survived at least 24 hours after birth), born at home between 7 and 28 days prior to interview. Information on the newborn's health status was obtained from other significant caregivers in the household, where applicable; information on delivery practices was obtained from others present at the delivery, where possible. Mothers were enrolled in one of four possible cohorts: kit user with trained attendant, kit user with untrained or no attendant, kit non-user with trained attendant, and kit non-user with untrained or no attendant. Eligible households were identified by runners, who visited assigned wards on a regular schedule to inquire from health workers, community health volunteers, TBAs, and other relevant community members about any new births. Visits of the interviewers to identified eligible households were coordinated closely with the runners to ensure the minimum delay in completing interviews with identified households.

Based on an estimated incidence of cord infection in 10-12% of births, the sample size required to test the hypothesis that kit use reduced cord infection by at least 50% is 400 newborns in each cohort (with a one-sided 95% confidence interval and 80% power). The expected number of neonatal deaths in each cohort would be about 20, so it would be unlikely that a noticeable reduction in mortality due to infection could be observed or documented.

Data Collection

Six teams, consisting of a female interviewer and a male runner in each, were recruited in Kathmandu to collect the data. Data were collected by interviews with mothers of newborns, with members of the mother's household who were present for the delivery or were caretakers of the newborn, and with some trained TBAs who participated in eligible deliveries. In addition, the field interviewers directly observed the newborn's abdomen and cord area, wherever possible, and were to consult with medical records when they were available. The interviewers used a structured questionnaire to gather data on newborn status (alive/dead, visible signs of cord infection such as redness and pus, and signs of more generalized or severe infection such as fever, poor feeding, and lethargy) during the neonatal period; other newborn or maternal infection; behavior of the birth attendant during delivery with regard to hand washing and wrapping the baby; initiation of breastfeeding within an hour of birth; and intention to use a delivery kit in the future (questionnaire available upon request). The field interviewers noted the infant's sex and asked questions to determine whether the infant appeared to be of low birthweight or significantly premature at the time of birth, since these three factors might be related to newborn susceptibility to neonatal problems or mortality. In addition, kit users were

asked about use of the kit contents; disposal or reuse of the kit contents after the delivery; and understanding of the key messages in the kit insert. All mothers were asked about factors that might be related to the actual use of kits, their effectiveness or the analysis of the kit's impact, such as sociodemographic factors, health history factors, and events associated with the delivery. Mothers were asked about acceptability of kits and access to kits, such as preferred outlets for obtaining delivery kits.

Since the mother might not be aware of all the details of what happened during the delivery, other women in the household who were present at the delivery were asked to provide information as needed. The information recorded on the primary data collection form represents a consensus of household opinion or recollection. A slightly altered version of the standard questionnaire was used in the case of a neonatal death, with some change in wording to take account of the newborn's death and some additional questions to determine whether the cause of death was related to newborn cord infection.

A supplementary interview form was used to gather information from a subset of trained birth attendants to validate mothers' reports on birth attendant practices. This follow-up interview was conducted as soon as possible after the mother's interview and covered aspects of the behavior of the birth attendant during delivery with regard to hand washing and wrapping the baby, mother's initiation of breastfeeding within an hour of birth, use of the kit contents, disposal or reuse of the kit contents after the delivery, and understanding of the instructions and key messages in the kit insert. The data provided by the TBA was compared with reports provided by the mother and her household members who observed the delivery.

Data collection instruments were translated into the required local languages, back-translated, and pretested before use. A field manual (translated into Nepali) was prepared as a reference for the field workers. The six field interviewers received one week of training, including role playing the interviews. The Field Director reviewed all interview forms for accuracy and completeness and observed each field interviewer periodically throughout the study, to ensure quality and uniformity of data collection. An assistant coded open-ended questions.

Determination of infection status. Color photos of normal and infected cord stumps were shown to respondents to help them determine whether or not the newborn had an episode of cord infection. In addition, the interviewer inspected the baby's cord and/or abdomen to ascertain its status at the time of the interview, whenever possible. A neonatologist reviewed all records with any indication of possible infection—including mother's report of symptoms and appearance and interviewer's observations—and made the final determination as to whether a cord-related infection was involved (rating it as "definite", "probable", "possible", or "unlikely").

Data Analysis

The interview form was precoded for computer entry. Data were entered into an Epi Info 6.0 data entry program (with appropriate checks built into it) by a bilingual statistician in

Nepal. After checking the data for internal consistency and possible errors, summary descriptive analysis and multivariate analysis using multiple logistic regression were carried out using SPSS 8.0. Multiple logistic regression was used to determine relative risks and 95% confidence intervals for infection risk factors and to control for potential confounding factors. Likely cord infection (defined as "definite" or "probable" infection) was considered the outcome of interest.

Continuous variables such as age, hours of labor, and price paid for the kit were grouped into categories. A socioeconomic summary variable was constructed by summing positive responses about ownership of land, a metal roof, radio or television, and cows or buffaloes, and about having sufficient income.

IV. RESULTS

The following results deal primarily with the issue of kit use and cord infection, and factors related significantly to both. Other issues such as kit marketing and distribution, other birth practices, and sources of information are reported briefly. For the purpose of this analysis, "likely" infection included those cases considered by the neonatologist to be either definite or probable infection. In fact, the findings are very similar when "possible" infection is included in the infection group, but they are not presented here.

Description of Participants

Because of the difficulty of coordinating enrollment over several districts, the number in each cohort varied slightly (see Table 1).

Table 1. Number of participants in each district, by cohort

	Kit User, Trained	Kit User, Untrained	Kit Non-user, Trained	Kit Non-user, Untrained	District Total
Siraha	137	58	174	123	492
Morang	132	141	127	188	588
Sunsari	151	199	103	127	580
Total	420	398	404	438	1660

The distribution of birth attendants in each district is shown in Table 2. Siraha had the smallest proportion of health workers among its trained birth attendants. Among kit users, Siraha had the highest proportion of TBAs in the untrained group (vs. family, neighbors, and others) while Sunsari had the lowest proportion. Among kit non-users, the reverse was true. Among the untrained attendants, about 28% were female family members, about 14% were self-delivered, about 3% were delivered by husbands, and the rest were attended by friends and neighbors. The proportions were similar between kit users and non-users.

Table 2. Type of birth attendants, by kit use and district

	KIT USER				KIT NON-USER			
	Siraha	Morang	Sunsari	**Total**	Siraha	Morang	Sunsari	**Total**
Trained TBA	132	121	141	394	168	113	97	378
%	96.4	91.7	93.4	93.8	96.6	89.0	94.2	93.6
Health worker	5.0	11	10	26	6	14	6	26
%	3.6	8.3	6.6	6.2	3.4	11.0	5.8	6.4
Total Trained	137	132	151	420	174	127	103	404
Untrained TBA	46	64	65	175	47	78	60	185
%	79.3	45.4	32.7	44.0	38.2	41.5	47.2	42.2
Family/neighbor	12	77	134	223	76	110	67	253
%	20.7	54.6	67.3	56.0	61.8	58.5	52.8	57.8
Total Untrained	58	141	199	398	123	188	127	438

From Tables 3 and 4 on characteristics of the households and the mothers, it is apparent that kit users and non-users as a whole do not differ greatly. More users are literate and in the higher socioeconomic category, but generally the differences between those with trained and untrained attendants are greater than those between kit users and non-users. In particular, there are some significant differences between kit users with trained and untrained attendants. Kit users with a trained birth attendant had:

- Higher proportion of female head of household.
- More heads of household who were 50 years or older.
- Higher literacy rate for head of household and for mothers.
- Higher land ownership rate.
- Higher proportion in mid-level socioeconomic status.
- Younger mothers.
- More first pregnancies, fewer with five or more pregnancies.
- More mothers with antenatal care and with tetanus immunization.

Because of these differences and the possibility that some of them may be related to infection outcome, it was apparent that it might not be possible to pool the two groups of kit users during the analysis. Although there were only minor differences between the characteristics of the two groups of kit non-users (more households headed by the father-in-law rather than the husband and consequently more household heads who were 50 years or older), they differed substantially in birth practices (see below). The differences in antenatal care and tetanus toxoid (TT) were clearly related, since those with no antenatal care were much more likely to have no TT (57.6% vs. 9.4%).

Table 3. Household characteristics, by cohort

		Kit User, Trained (Col %)	Kit User, Untrained (Col %)	Kit Non-user, Trained (Col %)	Kit Non-user, Untrained (Col %)
Female Head of Household (HoH)		4.0	1.0	2.2	1.4
Occupation HoH[1]	None	0.7	0.8	0.2	0.2
	Agriculture	43.6	43.2	47.8	52.5
	Shopkeeper	11.4	9.3	9.7	8.2
	Laborer	28.3	35.7	32.7	30.4
	Service	15.7	11.1	9.7	8.7
	Other	0.2			
Age HoH[2]	Up to 29 yrs	45.0	43.5	36.4	45.2
	30-49 yrs	35.2	42.5	44.1	43.4
	50+ yrs	19.8	14.1	19.6	11.4
Literacy HoH[2]	Illiterate	39.0	47.7	51.2	51.4
	Literate	61.0	52.3	48.8	48.6
Enough Income[2]	Enough	63.1	62.6	57.2	52.7
Own Land[1]	Yes	61.7	52.0	60.6	59.6
Socioeconomic Status (SES)[2]	Low SES	45.7	55.8	51.7	54.8
	Mid SES	22.9	13.8	22.8	21.0
	High SES	31.4	30.4	25.5	24.2
Religion	Hindu	94.3	91.5	90.3	90.4
	Non-Hindu	5.7	8.5	9.7	9.6

[1] $p<.05$
[2] $p<.01$

Using eight major ethnic groupings, there were only minor differences overall among the cohorts, with kit users having more Brahmin Chhetri (22% vs. 20%), Hills origin (12% vs. 10%) and Tharu (23% vs. 17%) and fewer Muslims (3.5% vs. 6.9%) and fewer Yadav (4.9% vs. 8.1%) than kit non-users.

Table 4. Mother's characteristics, by cohort

		Kit User, Trained (Col %)	Kit User, Untrained (Col %)	Kit Non-user, Trained (Col %)	Kit Non-user, Untrained (Col %)
Mother's age[1]	Low-19 yrs	19.3	11.6	16.6	15.3
	20-34 yrs	76.4	84.2	76.5	74.9
	35 + yrs	4.3	4.3	6.9	9.8
Mother's literacy[1]	Illiterate mother	55.5	67.1	73.0	74.7
	Literate mother	44.5	32.9	27.0	25.3
Prior pregnancies[1]	0	40.0	20.4	27.0	28.1
	1-4	55.0	71.9	61.4	62.3
	5 +	5.0	7.8	11.6	9.6
Prior neonatal death 1-14 days[2]	0[3]	98.1	94.2	95.5	95.7
	1	1.9	5.8	4.5	4.3
Prior facility delivery[4]	No	85.7	90.2	87.8	87.6
	Yes	14.3	9.8	11.9	12.4
Antenatal care[1]	Yes	67.6	58.8	51.5	45.2
Recent TT Reported[1]	None reported	19.5	30.9	32.2	42.0
	1-2 TT reported	80.5	69.1	67.8	58.0

[1] p<.001
[2] p<.05
[3] Includes those with no deliveries
[4] Includes only those with prior delivery

Description of Births

Table 5 shows the types of supplies used during the current delivery within the different cohorts. Most noteworthy is the fact that more than 90% of kit non-users used a new or boiled blade to cut the cord (96.7% of trained attendants and 91.6% of untrained). More than half (71%, 54%) used new thread to tie the cord, and 18% of non-users with trained attendants used a new plastic for the delivery surface. Kit users were more likely to use soap, among both trained (96% vs. 73%) and untrained attendants (84% vs. 46%).

Table 5. Supplies used at current delivery, by cohort

		Kit User, Trained Col %	Kit User, Untrained Col %	Kit Non-user, Trained Col %	Kit Non-user, Untrained Col %
Delivery surface	CHDK plastic	91.7	85.7	0.2	0
	Hay/jute mat	4.0	6.8	44.6	60.7
	Dirt floor	3.3	5.3	26.2	28.8
	Other new plastic	0	0.3	17.6	4.8
	Cloth	1.0	1.8	10.6	5.7
	Other	0	0.3	0.7	0
Cord cutter	CHDK blade	99.3	99.0	0	0
	Other new blade	0	0.5	53.0	63.5
	Boiled blade	0.7	0.3	43.7	27.1
	Other	0	0.3	3.3	9.4
Cutting surface	CHDK coin	97.4	98.2	0	0
	Coin	1.4	1.3	85.6	83.3
	Nothing	0.7	0.5	6.2	7.8
	Brick/iron	0	0	1.7	6.4
	Other	0	0	2.7	2.1
	Don't know	0.5	0	3.7	0.5
Cord tie	CHDK thread	98.8	99.7	0	0
	Other new thread	0.7	0.3	70.7	54.1
	Old thread	0.5	0	29.3	45.0
	Did not tie	0	0	0	0.9
Soap	CHDK soap	87.0	79.9	0.3	0
	Other soap	8.7	4.3	72.9	46.3
	Water only	2.5	6.4	22.2	29.5
	Never wash	1.7	9.4	4.7	24.2

Table 6 shows other birth practices possibly related to infection, such as substances put on the cord immediately after cutting or later, the covering put on the cord, and whether and when the attendant washes her hands. Most attendants put nothing on the cord (67%-76%). When they did use something, trained attendants were more likely to use Dettol (a common antiseptic) while untrained attendants were more likely to use ash. Mustard oil was the most commonly applied substance later (55%-66%), followed by "nothing" (26%-38%). Kit non-users with trained attendants were the most likely to use herbal preparations later (11% vs. 2-4%). Among kit users, babies delivered by untrained attendants were the most likely to have dirty cloths on the cord stump at the time of the interview (53%), while those with trained attendants were the least likely (42%). Babies delivered by trained and untrained kit non-users were equally likely to have a dirty cloth on the cord stump (47%). Among trained attendants slightly more kit users washed their hands before cutting the cord (96% vs. 90%), but among untrained attendants many more kit users than non-users washed their hands
(91% vs. 76%; $p < .001$). Untrained attendants in both user and non-user cohorts were more likely than trained attendants to wash their hands only after cutting the cord.

Table 6. Birth practices possibly related to infection, by cohort

		Kit User, Trained (Col %)	Kit User, Untrained (Col %)	Kit Non-user, Trained (Col %)	Kit Non-user, Untrained (Col %)
Put on cord just after	Nothing	67.1	75.9	68.8	72.6
	Ash	5.7	12.1	9.9	14.2
	Dettol	11.2	6.5	9.9	1.8
	Mustard oil	1.9	2.5	3.5	5.0
	Antibiotic	2.1	0.5	2.0	0.5
	Herbal	2.1	1.0	0.5	3.4
	Other	0.7	0.5	0.7	0.9
	Don't know	9.0	1.0	4.7	1.6
Put on cord later	Nothing	32.1	26.4	29.0	37.9
	Mustard oil	57.6	66.2	56.2	55.3
	Herbal	4.3	3.0	10.9	1.8
	Antibiotic	3.8	2.5	3.0	1.4
	Don't know	0.5	0	0.2	0.2
	Other	1.7	1.8	0.7	3.4
Cord covering	Clean	56.3	45.7	48.7	49.0
	No cloth	1.5	1.8	4.3	3.8
	Dirty cloth	42.3	52.5	47.0	47.1
Wash hands					
- at all	Yes	98.3	90.6	95.4	75.9
-before cord cut	Yes	95.8	73.5	89.8	64.9
-only after cord cut	Yes	2.4	16.1	5.0	9.4

Definition of Infection

The determination of cord infection was based on both the mother's report during the interview (including selection of a photo from an array of color photos of cords) and the interviewer's observation of the umbilicus at the time of the interview. It is clear from Table 7 that those defined as having "likely" or "possible" infection were substantially different from those defined as not infected. Cord-specific questions differentiate better than general baby symptoms like fever or poor sucking. "Foul smell" was weakly correlated with discharge (r=.323), photo (r=.328) and interviewer observation (r=.296), but discharge and photo were strongly correlated with interviewer observation (r=.521 and .655) and with diagnosis of likely infection (r=.602 and .737). The factor most strongly correlated with diagnosis of likely cord infection was interviewer observation of signs of infection (r=.839).

Table 7. Defining features of infection cases

	LIKELY CORD INFECTION		POSSIBLE CORD INFECTION	
	None Col % (n=1389)	Likely Col % (n=271)	None Col % (n=1300)	Possible Col % (n=360)
Mother's report:				
Cord:				
Foul smell	2.0	32.9	0.9	28.7
Blood or pus discharge	3.0	55.0	0.5	51.4
Infected (using photo)	5.1	80.8	0.8	77.5
Baby symptoms:				
None	76.3	63.5	76.7	65.9
Fever	7.2	8.2	7.2	7.8
Spasm, stiff	3.1	9.5	3.1	7.8
Poor suck	6.6	6.9	6.9	6.0
Interviewer observation:				
Slight redness	3.0	10.0	1.2	14.9
Infection, red, swollen	1.0	78.1	0.0	62.6

Definition of Comparison Groups within Kit Non-users

Since so many kit non-users actually used new or boiled blades, it is necessary to define comparison groups that distinguish those using components similar to the kit from those who are not. The strongest associations between various kit components and infection were with the blade used for cutting and the cutting surface. Table 8 shows the infection rates associated with various combinations of blade and surface. There is relatively little difference between those using an old coin or nothing in each blade group (e.g., lightly shaded block for new blade), but the infection is considerably higher if some other cutting

surface is used (brick or iron were the most common ones mentioned). The rate for "boiled blade/other surface" is similar to all "other blade" users, so they were grouped together as one comparison group (darker shading). The final categories for analysis are kit users (n=818, although 2 were missing in Table 8 because one had missing data on blade and one on cutting surface), new blade/coin-or-nothing (n=454), new blade/other (n=22), boiled blade/coin-or-nothing (n=267), and boiled/other and other blade/all (n=79). The infection rates for kit users and the respective comparison groups were: kit users - 18.3%, new blade with coin or nothing - 9.9%, new blade with other cutting surface - 18.2%, boiled blade with coin or nothing - 16.9%, and other - 31.6%.

Table 8. Infection rates for different blade and cutting surface combinations

	CORD CUTTING SURFACE				
	CHDK coin	**Coin**	**Nothing**	**Other**	**Total**
CHDK blade	**18.5** (147/794)	**27.3** (3/11)	**0** (0/5)	**0** (0)	**18.5** (150/810)
New blade	**0** (0/2)	**10.1** (42/417)	**8.1** (3/37)	**18.2** (4/22)	**10.3** (49/478)
Boiled blade	**0** (0/3)	**17.1** (44/257)	**10.0** (1/10)	**25.0** (5/20)	**17.2** (50/290)
Other	**0** (0/1)	**37.1** (13/35)	**33.3** (4/12)	**25.0** (3/12)	**33.3** (20/60)
Total	18.4 (147/800)	14.2 (102/720)	12.5 (8/64)	22.2 (12/54)	16.4 (269/1638)

Confounders

Several factors related to cord infection were distributed unevenly between kit users and non-users. All factors that were significantly associated ($p<.05$) both with cohort and infection were tested in the logistic regression model as confounders. Only those found to be true confounders (i.e., they had a significant independent effect on outcome and altered the odds ratio associated with kit use when included in the model) are discussed here in more detail. Such factors can distort or *confound* the true relationship between kit use and cord infection. Table 9 shows the four factors which were found to be true confounders in the model and their distribution among the cohorts, while Table 10 shows the infection rates associated with each of the factors.

Table 9. Key confounding factors, by cohort

		Kit User, Trained (Col %)	Kit User, Untrained (Col %)	Kit Non-user, Trained (Col %)	Kit Non-user, Untrained (Col %)
Interview week	2	49.9	43.7	42.1	36.3
	3	22.7	30.9	27.0	25.6
	4	27.4	25.4	30.9	38.1
Month	July	11.2	9.8	18.8	44.7
	August	12.4	7.3	11.9	45.2
	September	14.5	13.1	13.1	9.6
	October	25.2	27.6	21.0	0.2
	November	36.7	42.2	35.1	0.2
District	Siraha	32.6	14.6	43.1	28.1
	Morang	31.4	35.4	31.4	42.9
	Sunsari	36.0	50.0	25.5	29.0
Interviewer	11	11.7	4.0	10.9	15.5
	12	9.3	6.5	19.8	12.6
	21	21.7	24.1	23.8	22.1
	22	10.0	13.3	15.1	21.0
	31	15.0	16.6	11.1	14.6
	32	32.4	35.4	19.3	14.2
Washed hands before delivery	No	5.4	34.8	16.1	56.2

Interview week. Interviews were conducted during the second to fourth weeks after birth. Kit users, especially those with trained birth attendants, were much more likely than kit non-users (50% vs. 36-42%) to have been interviewed during the second week after birth when the signs of infection would still be apparent and memories would be fresher. Infection rates were higher in the second week for all cohorts. Kit non-users with untrained attendants were much more likely to have been interviewed in the fourth week (38% vs. 25-27%), when infection rates were lower.

Month. In three of the four cohorts, infection rose from their lowest rates in July to nearly double in October (Table 10). In the other cohort (untrained kit non-user) there was a similar but less pronounced rise that was cut short by the completion of enrollment early in the study. Approximately 90% of kit non-users with untrained attendants were enrolled in July and August (vs. only 10-11% of kit users), months when infection rates were low for all cohorts. They were the easiest group to find, so the quota for that cohort was filled early. Kit users (especially those with untrained attendants) were much more likely to be enrolled in October and November (62-70%), when rates of infection were at their highest (regardless of kit use or not).

District. Many more kit non-users were enrolled in Siraha district, where lower infection rates were seen in both groups. On the other hand, somewhat more non-users with untrained attendants were enrolled in Morang, the district with the highest infection rate.

Siraha has had an active program of non-government organization (NGO) training related to Safe Motherhood, which may have contributed to the lower rates of infection there.

Interviewers. The interviewers had widely different rates of infection detected and were unevenly distributed with regard to enrollments in the four cohorts. Since interviewers were assigned primarily (but not exclusively) to one district, it is hard to know how much the different rates observed were due to the district where she worked and how much to the individual. The differences were seen in the way mothers responded to questions and not only in the interviewer observations. Since interviewers working in the same districts had similar rates (11 and 12 in Siraha, 21 and 22 in Morang, 31 and 32 in Sunsari), real differences in infection rates in each district seem to be the stronger factor. Interviewer 21 had the highest infection detection rate and also did the greatest number of interviews. Three interviewers detected higher infection rates among kit non-users, while three found higher rates among kit users.

Regardless of why these relationships occurred, they clearly had the potential to distort the association between kit use and cord infection and were, therefore, included in the multiple logistic regression models.

Table 10. Infection rates by confounders and cohorts

		CORD INFECTION RATES				
		Kit User, Trained	Kit User, Untrained	Kit Non-user, Trained	Kit Non-user, Untrained	Total
Interview Week	2	23.0	25.9	22.4	14.5	21.6
	3	15.8	19.5	12.8	8.9	14.4
	4	5.2	11.9	12.0	12.6	10.6
Month	July	10.6	12.8	5.3	10.7	9.8
	August	11.5	24.1	14.6	13.6	14.4
	September	16.4	19.2	17.0	14.3	16.8
	October	20.8	24.5	22.4	0.0	22.5
	November	16.9	19.0	19.7	0.0	18.5
District	Siraha	10.2	6.9	13.2	1.6	8.7
	Morang	31.1	31.2	23.6	21.3	26.4
	Sunsari	9.3	16.6	13.6	9.4	12.6
Interviewer	**11**	**8.2**	**6.3**	**9.1**	**1.5**	**5.6**
	Count	(4/49)	(1/16)	(4/44)	(1/68)	(10/177)
	12	**2.6**	**3.8**	**6.3**	**1.8**	**4.0**
	Count	(1/39)	(1/26)	(5/80)	(1/55)	(8/200)
	21	**34.1**	**32.3**	**21.9**	**22.7**	**27.6**
	Count	(31/91)	(31/96)	(21/96)	(22/97)	(105/380)
	22	**31.0**	**18.9**	**14.8**	**19.6**	**20.2**
	Count	(13/42)	(10/53)	(9/61)	(18/92)	(50/248)
	31	**1.6**	**18.2**	**13.3**	**15.6**	**12.2**
	Count	(1/63)	(12/66)	(6/45)	(10/64)	(29/238)
	32	**14.0**	**18.4**	**28.2**	**3.2**	**16.5**
	Count	(19/136)	(26/141)	(22/78)	(2/62)	(69/417)

Kit Use and Other Factors Related to Infection

There were 271 cases identified as likely infection (16.3% of all births). The highest *unadjusted* infection rate was among kit users with untrained attendants (20%), followed by kit users and non-users with trained attendants (16%, 17%) and then non-users with untrained attendants (12%). There were 28 newborn deaths (1.7% of eligible births), of which two were thought to be likely infections. Maternal health was similar between the user and non-user groups, with about 85% of mothers healthy at the time of interview, 7-8% ill previously but well at interview, 7-8% ill at the interview, and less than 1% very ill at interview.

A multiple logistic regression analysis was undertaken to estimate relative risks associated with kit use and other factors related to infection and to control for the confounding factors identified above. Relative risk is the increased risk of the outcome (e.g., cord infection) over the risk associated the specified reference action or condition,

regardless of what the absolute rate is in the specific setting is. The relative risk is more useful for general analysis, since the underlying rates may be affected by many other factors and vary widely from one setting to another. All factors which had a significant relationship with both kit use and cord infection were initially included in the logistic regression models. Only those factors which had significant independent risks in the model (i.e., whose 95% confidence intervals did not include 1.0) were retained in the final model. For example, DISTRICT was no longer significant when INTERVIEWER was included in the model and was, therefore, dropped from the model. Similarly, a variable that grouped birth attendants into four categories (trained TBA, untrained TBA, family or neighbor, health worker) was initially included in the model. There were no real differences among the first three groups (once other more specific variables were accounted for), and the elevated infection risk associated with health workers (RR=1.6, 95% C.I. of 0.78-3.4) was not statistically significant. The relative risks, as adjusted for the confounding factors of week of interview, month, and interviewer, are shown in Table 11.

Table 11. Kit use and other risk factors for cord infection

Risk Factor	Relative Risk[1]	95% Confidence Interval
Kit vs. new blade, coin/nothing	1.3	(0.81, 1.9)
Kit vs. new blade, other surface	0.74	(0.22, 2.5)
Kit vs. boiled blade, coin/nothing	0.96	(0.63, 1.5)
Kit vs. boiled blade, other surface; other blade, any surface[2]	0.45	(0.25, 0.81)
Put on cord just after (vs. nothing):		
Mustard oil	0.31	(0.07, 1.3)
Ash	1.4	(0.90, 2.2)
Herbals	0.78	(0.22, 2.8)
Dettol	0.67	(0.35, 1.3)
Antibiotic	0.93	(0.25, 3.4)
Other	3.8	(0.96, 15.1)
Don't know	0.56	(0.24, 1.3)
Clean or no cloth vs. Dirty one[2]	0.60	(0.43, 0.82)
Hands washed with soap before cutting cord vs. not washed[2]	0.58	(0.40, 0.84)
Hands washed with water before cutting cord vs. not washed	0.78	(0.44, 1.4)

[1]Adjusted for interview week, month, and interviewer.
[2]$p<.05$

Kit use has no particular advantage when compared with using a new or boiled blade to cut the cord and a coin-or-nothing as the cutting surface; however, compared with those using a boiled blade with another surface or using some other cutter with any cutting surface, kit users had less than half (OR=0.45) the infection risk of kit non-users. While they were not quite statistically significant, putting ash (n=168) or other substances (such as gauze, dung, talcum powder, n=12) on the cord soon after cutting was associated with

elevated risk of infection, while mustard oil (n=54) seems to offer some protective value (although not statistically significant). Dettol and herbals also appear to be somewhat protective, but this could be due to chance (since the numbers are relatively small and the confidence intervals are large). As expected, a clean cloth or no covering on the umbilicus at the time of the interview was significantly associated with reduced infection (by 40%), when compared with a dirty cloth. Infection is reduced by about 40% (OR=0.58) when the birth attendant washes her hands with soap before cutting the cord. Those who washed with water but no soap (n=183) had some reduction in risk compared to those who did not wash at all (OR=0.78), but it is not significant. In families where they did not know whether the attendant washed her hands or not, the difference in risk is not statistically significant (OR=0.84; 95% C.I. of 0.47-1.5).

Based on these relative risks and the prevalence of the various practices among the population, an unclean blade and cutting surface accounted for about 8% of the infection among kit non-users (population attributable risk percent), the dirty cloth accounted for about 24%, not washing hands before cutting accounted for about 11%, putting ash on the cord accounted for about 4%, and putting other substances on the cord accounted for about 2% of the infections.

Table 12. Kit use and other risk factors for cord infection, by district

Risk Factor	SIRAHA		MORANG		SUNSARI	
	Rel.Risk[1]	95% C.I.	Rel.Risk[1]	95% C.I.	Rel.Risk[1]	95% C.I.
Kit vs. new blade, coin/nothing	0.64	(0.27, 1.5)	2.9	(1.5, 5.9)	0.73	(0.29, 1.9)
Kit vs. new blade, other surface	0	0.00	2.8	(0.53, 14.9)	**0.02**[2]	(0, 0.48)
Kit vs. boiled blade, coin/nothing	**0.20**[2]	(0.06, 0.63)	1.5	(0.81, 2.8)	0.96	(0.45, 2.0)
Kit vs. boiled blade, other surface; other blade, any surface	0.41	(0.04, 4.3)	0.70	(0.32, 1.6)	0.81	(0.20, 3.4)
Put on cord just after (vs. nothing):						
Mustard oil	0	0.00	0.81	(0.07, 9.3)	0.18	(0.02, 1.7)
Ash	1.9	(0.62, 5.8)	2.0	(1.1, 3.9)	0.88	(0.36, 2.1)
Herbals	1.2	(0.19, 7.5)	0.05	0	1.0	(0.09, 10.8)
Dettol	1.0	(0.30, 3.4)	0.31	(0.06, 1.6)	0.71	(0.29, 1.7)
Antibiotic	0	0.00	2.6	(0.38, 17.2)	0.76	(0.08, 7.2)
Other	0	0.00	**13.9**[2]	(1.6, 120.4)	3.7	(0.47, 29.3)
Don't know	1.4	(0.25, 8.0)	0.65	(0.20, 2.1)	0.31	(0.04, 2.4)
Clean or no cloth vs. Dirty one	0.71	(0.30, 1.7)	**0.60**[2]	(0.38, 0.95)	0.65	(0.36, 1.2)
Hands washed with soap before cutting cord vs. not washed	0.86	(0.20, 3.7)	**0.46**[2]	(0.27, 0.78)	0.73	(0.36, 1.5)
Hands washed with water before cutting cord vs. not washed	0.38	(0.06, 2.4)	0.84	(0.40, 1.8)	0.96	(0.26, 3.5)

[1] Adjusted for interview week, month, and interviewer.
[2] p<.05

This final logistic model was also applied to each district separately (Table 12). Because the numbers are smaller, the confidence intervals for the relative risk estimates are wider and the statistical certainty is reduced. However, the associations are generally in the same directions as described above and are consistent across districts (except where numbers are especially small). For example, the reduced risk associated with kits as compared to boiled blade and coin-or-nothing in Siraha is based on just 28 births, while the strong protective effect associated with kits as compared to new blade and other surface in Sunsari is based on just 3 births. Mustard and Dettol are still somewhat protective while ash and "other" are still associated with increased risk, but the numbers are too small for this to be more than suggestive. A clean cloth covering the umbilicus and hand washing are still associated with reduced infection risk in all three districts.

Kit Pictorial Instructions

The value of the pictorial instructions was to be measured by reported practices in compliance with key messages and by maternal recollection. When actual reported

behavior is considered (as in Table 13), it appears that kit users are significantly more likely to practice the desired behavior, especially when related to the use of kit contents like the plastic, the blade and the cord ties. Washing hands was not universal among kit users but was higher among users than among kit non-users (as was use of soap). Neither group wrapped the baby promptly, with 87% in each group waiting until after bathing the baby, but kit users were a little more likely to wrap the baby early. Similarly, neither group had a high proportion beginning breastfeeding in the first hour after birth, but kit users were slightly more likely to start within the first day (39% vs. 31%).

Table 13. Actual practice of behaviors related to pictorial instructions

Recommended behavior	Reported by Kit User %	Reported by Kit Non-user %
Use plastic for delivery surface[1]	89.0	11.1
Use new blade to cut cord[1]	99.1	58.5
Wash hands before delivery[1]	80.7	63.8
Wash hands before cutting cord[1]	80.4	67.8
Tie cord with new thread[1]	99.3	62.1
Wrap baby right after delivery	10.7	7.4
Begin breastfeeding immediately (<1 hour)	15.8	13.5
Begin breastfeeding immediately first day[2]	38.6	31.2

[1] $p<.001$
[2] $p<.01$

Unfortunately, the interviewers misunderstood the protocol and showed the respondents the pictures one by one, so the data on maternal recall probably greatly over-estimated the true levels. More than 90% recognized the messages about washing hands before the delivery and beginning breastfeeding immediately after delivery. About 75-80% recognized the messages about washing hands before cutting the cord, using the three clean ties, cutting with the kit blade, and burying the kit afterwards. Wrapping the baby immediately and using the plastic were the least recognized messages (59-72%), even when the pictures were shown.

Kit Disposal

Disposal practices varied by district (Table 14), with families in Siraha generally more likely to throw kit components away or bury them. About 90% of those is Siraha buried or threw away the blade, while only 72-74% did in other districts. Only 26% of families in Siraha reused the plastic tarp, while 58-61% did in the other two districts. Soap was reused by 61% of families in Siraha, as compared with 81-84% in the other districts. Even the plastic coin was kept by 14-17% of families in Morang and Sunsari, while 95% disposed of it in Siraha.

Table 14. Disposal of kit contents, by district

		DISTRICT							
		Siraha		Morang		Sunsari		Total	
		Count	Col %	Count	Col %	Count	Col %	Count	Col %
Blade	Buried	143	76.1	151	59.2	168	54.2	462	61.4
	Thrown away	26	13.8	37	14.5	55	17.7	118	15.7
	Washed & reused	13	6.9	45	17.6	40	12.9	98	13.0
	Boiled & reused	1	0.5	2	0.8	5	1.6	8	1.1
	Kept	1	0.5	18	7.1	40	12.9	59	7.8
	Other	4	2.1	2	0.8	2	0.6	8	1.0
	Total	**188**	**100**	**255**	**100**	**310**	**100**	**753**	**100**
Plastic	Washed & reused	49	25.8	153	57.5	204	61.3	406	51.5
	Buried	126	66.3	103	38.7	122	36.6	351	44.5
	Thrown away	8	4.2	1	0.4	3	0.9	12	1.5
	Other	7	3.7	9	3.4	4	1.2	20	2.5
	Total	**190**	**100**	**266**	**100**	**333**	**100**	**789**	**100**
Soap	Reused	115	60.8	216	84.0	276	80.5	607	76.9
	Thrown away	69	36.5	40	15.6	67	19.5	176	22.3
	Other	5	2.6	1	0.4	0	0.0	6	0.7
	Total	**189**	**100**	**257**	**100**	**343**	**100**	**789**	**100**
Plastic coin	Buried	127	67.6	135	54.0	122	38.9	384	51.1
	Thrown away	52	27.7	81	32.4	137	43.6	270	35.9
	Kept	1	0.5	15	6.0	33	10.5	49	6.5
	Reused	5	2.7	16	6.4	21	6.7	42	5.6
	Other	3	1.6	3	1.2	1	0.3	7	0.9
	Total	**188**	**100**	**250**	**100**	**314**	**100**	**752**	**100**

Kit Purchase and Satisfaction

Information about kit purchase, sources of publicity, and consumer satisfaction were gathered to help MCH Products Pvt., Ltd. evaluate its marketing needs and efforts to date. The results varied considerably by district (Table 15). For example, people in Siraha were least likely to be aware of the kit (49% vs. 24-30%). However, of those who had heard of the kit, those in Siraha were most likely to know where to get it (86% vs. 32-42% in other districts). Distance to a source of kits was not much of a problem in any district. Of those few who knew of the kit but did not use it for the current delivery, the most common reason given was "no time" (40-48%). In Siraha, "high price" was the next most common reason (16%), while in Morang not knowing where to get it (21%) was the next most common reason.

Table 15. Kit awareness and decision to buy, by district

		DISTRICT							
		Siraha		Morang		Sunsari		Total	
		Count	Col %	Count	Col %	Count	Col %	Count	Col %
Ever see or hear of kit	No	242	49.2	175	29.8	141	24.3	558	33.6
	Yes, seen	227	46.1	290	49.3	341	58.8	858	51.7
	Yes, heard	23	4.7	123	20.9	98	16.9	244	14.7
	Total	**492**	**100**	**588**	**100**	**580**	**100**	**1660**	**100**
Know place to get kit	No	30	12.0	272	65.9	243	55.6	545	49.5
	Yes	214	85.6	133	32.2	184	42.1	531	48.3
	Yes, but not near	6	2.4	8	1.9	10	2.3	24	2.2
	Total	**250**	**100**	**413**	**100**	**437**	**100**	**1100**	**100**
Reason for not using kit	No time	22	40.0	66	47.1	42	48.3	130	46.1
	Don't know where to get	5	9.1	30	21.4	10	11.5	45	16.0
	Not tradition	3	5.5	23	16.4	9	10.3	35	12.4
	TBA didn't bring	7	12.7	5	3.6	11	12.6	23	8.2
	Not near	8	14.5	12	8.6	11	12.6	31	11.0
	Too expensive	9	16.4	4	2.9	2	2.3	15	5.3
	Other	1	1.8	0	0.0	2	2.3	3	1.1
	Total	**55**	—	**140**	—	**87**	—	**282**	—
Learn about kit from	Health worker	102	40.8	196	47.6	223	51.0	521	47.4
	Radio/TV	13	5.2	122	29.6	103	23.6	238	21.7
	TBA	70	28	78	18.9	86	19.7	234	21.3
	Family member	46	18.4	7	1.7	10	2.3	63	5.7
	Neighbor, friends	24	9.6	14	3.4	24	5.5	62	5.6
	Total	**255**	—	**417**	—	**446**	—	**1118**	—
Who advised to get kit	TBA, trained	78	40.0	127	46.5	182	52.3	387	47.4
	TBA, untrained	4	2.1	12	4.4	5	1.4	21	2.6
	Immediate family	29	14.9	6	2.2	5	1.4	40	4.9
	Relatives/friends	23	11.8	19	7.0	25	7.2	67	8.2
	Self	18	9.2	3	1.1	4	1.1	25	3.1
	HP/SHP/PHCC	0	0.0	11	4.0	8	2.3	19	2.3
	Depot holder/RC	8	4.1	0	0.0	5	1.4	13	1.6
	HW/SCF staff	35	17.9	95	34.8	114	32.8	244	29.9
	Total	**195**	—	**273**	—	**348**	—	**816**	—

Health workers were the most common source of information about kits in all three districts (41-51%), with radio or television next in Morang and Sunsari and family next

most common in Siraha. The trained TBA was the most frequent one to recommend kit use in all three districts (40-52%), with health workers or
Save the Children U.S. staff next (especially in Morang and Sunsari). Those who attended antenatal care were much more likely to have seen or heard of the kit
(76% vs. 55%). Of those who actually used a kit, though, there was no difference between antenatal care attenders and non-attenders as to who advised them to use the kit. In Morang and Sunsari, the trained TBA was the one most likely to have purchased the kit used, followed by the woman herself (Table 16). In Siraha, trained TBAs and family members were about equally likely to have purchased the kit. This was greatly influenced by who attended the delivery. Among those attended by a trained TBA, 61% were bought by the TBA herself, followed by the husband, and then the woman herself as the next most common purchasers. Among those with an untrained TBA, the woman herself was the most likely purchaser (25%), followed by health workers, relatives, and husbands. Among those attended by family or neighbors, 37% of kits were bought by the woman herself, followed by health workers, family members, and trained TBAs as the next most common purchasers. When the birth was attended by a health worker, the health worker purchased the kit half the time and the woman herself was the next most common purchaser.

In Morang and Sunsari, the kit was commonly purchased directly from the TBA (with no information as to where she got it), while in Siraha the pharmacy was the most common source. Very few were bought in retail shops. Again, it was influenced by who attended the delivery. Of those with a trained TBA, 56% bought their kit directly from the TBA. Those with an untrained TBA were equally likely to get their kit from a TBA, a female community health volunteer (FCHV) or a pharmacy. Those attended by family or a neighbor or friend were most likely to get the kit from a FCHV or health post. Those attended by a health worker were most likely to get the kit from the health post or from a TBA.

In Morang and Sunsari, kits were most commonly bought one to three weeks before the birth, while in Siraha almost half waited until less than a week before the delivery to buy the kit. In all three districts, about a quarter were brought by the attendant at the time of labor.

The price paid for kits varied considerably both within and between districts. In Siraha, 74% paid Rs.20 or more for their kit, vs. only 31-33% elsewhere. Morang had the most free or subsidized kits (28% vs. 13-14%).

Table 16. Kit purchase, by district

		DISTRICT							
		Siraha		Morang		Sunsari		Total	
		Count	Col %	Count	Col %	Count	Col %	Count	Col %
Who obtained	TBA, trained	63	32.3	96	35.2	131	37.8	290	35.6
	Family member	64	33.3	20	7.3	29	8.4	114	14.0
	Relatives/friends	24	12.3	37	13.6	44	12.7	105	12.9
	Self	16	8.2	63	23.1	89	25.6	168	20.6
	CHDK project	2	1.0	3	1.1	3	0.9	8	1.0
	Depot holder/RC	4	2.1	0	0.0	0	0.0	4	0.5
	HW/SCF staff	19	9.7	53	19.4	47	13.5	119	14.6
	Other	2	1.0	1	0.4	4	1.2	7	0.8
	Total	**194**	**100**	**273**	**100.1**	**347**	**100.1**	**815**	**100**
Where obtained	TBA	52	26.7	106	38.8	155	44.5	313	38.4
	FCHV	30	15.4	54	19.8	50	14.4	134	16.4
	Pharmacy	63	32.3	20	7.3	20	5.7	103	12.6
	Shop	4	2.1	4	1.5	2	0.6	10	1.2
	HP/SHP/PHCC	14	7.2	52	19.0	63	18.1	129	15.8
	Depot holder/RC	16	8.2	0	0.0	12	3.4	28	3.4
	HW/SCF staff	10	5.1	29	10.6	41	11.8	80	9.8
	Other	6	3.0	8	2.9	5	1.5	19	2.4
	Total	**195**	**100**	**273**	**99.9**	**348**	**100**	**816**	**100**
When obtained	>2 months before	5	2.6	4	1.5	9	2.6	18	2.2
	1-2 months before	13	6.7	60	22	62	17.9	135	16.6
	1-3 weeks before	39	20.2	95	34.8	117	33.7	251	30.9
	<1 week before	88	45.6	61	22.3	69	19.9	218	26.8
	attendant brought	48	24.9	53	19.4	90	25.9	191	23.5
	Total	**193**	**100**	**273**	**100**	**347**	**100**	**813**	**100**
Price	Free	7	3.6	17	6.2	10	2.9	34	4.2
	Rs 1-9	5	2.6	37	13.6	21	6	63	7.7
	Rs 10-14	13	6.7	22	8.1	13	3.7	48	5.9
	Rs 15-19	25	12.8	108	39.6	195	56	328	40.2
	Rs 20-24	73	37.4	29	10.6	42	12.1	144	17.6
	Rs 25+	72	36.9	60	22.0	67	19.3	199	24.4
	Total	**195**	**100**	**273**	**100.1**	**348**	**100**	**816**	**100**

Kit users were quite satisfied with the kits, with more than 90% saying they would buy them again (Table 17). In Siraha and Morang, ease of use was the primary reason for planning to use the kit in the future, with safety as the next most commonly given reason. In Sunsari, "safe" and "healthy" were mentioned equally often. When asked what they liked most about the kit, the blade and the plastic tarp were most often mentioned (58-

83%). Few mentioned any negatives when asked, except 11% in Siraha disliked the high price they paid.

Table 17. Kit satisfaction, by district

		DISTRICT							
		Siraha		Morang		Sunsari		Total	
		Count	Col %	Count	Col %	Count	Col %	Count	Col %
Used kit before	Yes	33	13.2	16	3.9	23	5.3	72	6.5
Would use again	Yes	191	76.4	336	81.4	342	78.3	869	79.0
	Maybe	37	14.8	63	15.3	53	12.1	153	13.9
Would buy again	Yes	185	98.4	268	98.9	320	92.5	773	96.0
Reason for using kit in future	Easy	104	55.9	140	52.4	110	32.2	354	44.5
	Safe	68	36.6	87	32.6	175	51.2	330	41.5
	Healthy	61	32.8	73	27.3	177	51.8	311	39.1
	Inexpensive	4	2.2	8	3.0	0	0	12	1.5
	Useful	5	2.7	5	1.9	7	2.0	17	2.1
Like most	Plastic, blade	136	70.1	224	82.7	201	57.8	561	69.0
	Easy to use	19	9.8	28	10.3	28	8.0	75	9.2
	Complete	19	9.8	13	4.8	16	4.6	48	5.9
	Safe	18	9.3	17	6.3	61	17.5	96	11.8
	Clean, healthy	7	3.6	22	8.1	92	26.4	121	14.9
	Prevents diseases	18	9.3	3	1.1	66	19.0	87	10.7
Like least	None	128	75.3	248	95.4	308	97.8	684	91.8
	Expensive	18	10.6	0	0.0	1	0.3	19	2.6
	Soap not good	6	3.5	8	3.1	2	0.6	16	2.1

Validation of Data

A total of 46 TBAs (6% of the 772 births attended by TBAs) were identified and interviewed within a few weeks after the original household interview. In general there was good concurrence between the information given by the household and the TBA. On a set of 14 items about events during the delivery itself, agreement was better than 80% on all items except when the baby was wrapped (which may have been after the TBA left) and what was put on the cord after (79.5% agreed). Answers on whether or not the kit was used were in accord in all but two cases when the family seems not to have known that the kit was used. Agreement on whether the attendant washed her hands was also quite high (95%). As to disposal of the kit, there was good agreement about the plastic but less about the blade and soap. It was not possible to compute Kappa values on most items because of the small numbers and multiple categories (resulting in rows or columns with zero values).

V. DISCUSSION

Immediate Impact

Use of the clean home delivery kit was clearly protective (with half the infection risk) when compared with births in which a new or boiled blade and a clean cutting surface were not used. Discussions with field interviewers revealed that the coin traditionally used as a cutting surface is often boiled before use in this area and is generally reserved for special use during birthing. Where a new or boiled blade is already in wide use and few harmful practices regarding the cutting surface are used, as was the case in the study districts, the kit may not add much (as was seen with the low proportion of infection attributed to unclean cutting). That this was so suggests that the clean cutting of the cord is perhaps the most important element of any kit, as far as infection is concerned. In areas where new or boiled blades are not widely used, kit use can be expected to result in a substantial reduction in infection. Similarly, hand washing with soap before cutting the cord (much more common among kit users) also contributed to significantly reduced infection. As expected, it was not possible to detect any impact on newborn mortality or maternal morbidity (because of small numbers of such events). It was not possible (or appropriate) to compare absolute (crude) rates of infection directly, because of the powerful influence of confounding factors.

Intermediate Impact on Behaviors and Attitudes

A major behavioral impact was the increase in hand washing among kit users, and the more frequent use of soap (especially among untrained attendants). It is difficult to know the extent to which the increased washing among kit users is due to the presence of soap in the kit or the pictorial messages encouraging hand washing or to predisposition towards hygiene among those who choose to buy kits. Tying of the cord was already widespread in this population, so it could not be affected much by kit use. However, use of the plastic tarp greatly reduced the number of women who might otherwise have delivered on a dirt floor (almost 30% of kit non-users).

Pictorial messages promoting prompter wrapping of the newborn and initiation of breastfeeding on the day of birth seemed to have only modest effect. It is necessary to explore more thoroughly what people thought about the pictures, what they did with them afterwards, and how interpretation differed with different attendants.

The important effect that substances put on the cord stump can have (either harmful or protective) and the harmful effect of leaving a dirty cloth on the umbilicus raise the question of whether the pictorial insert could help promote healthier practices like use of mustard oil or local herbs and leaving the cord uncovered. As with prompt wrapping and early breastfeeding, it is unlikely they can have a dramatic effect in themselves; but if public health messages were standardized and spread in the community, the pictorial insert might play a reinforcing role.

It was not clear from these data whether it would be worthwhile to include antimicrobials (antiseptics or antibiotics) in the kit to prevent infection. A study in Pakistan (Bennett et al, 1997) showed a significant protective effect against neonatal tetanus when antimicrobials were used both initially and in subsequent days, even when compared with a dry cord stump to which nothing had been applied. A similar study in Bangladesh (Parashar et al, 1998) found that only antibiotics (not antiseptics) applied at delivery were significantly protective against neonatal tetanus. There were not enough families using such substances in the current study to achieve statistically significant results, but Dettol and herbal treatments (mostly "harro") had some protective effect. Antibiotics (used only by 17 households) showed no protective value (RR=1.1). There are not sufficient data here to support adding topical antimicrobials to the kit. It would be difficult to use the kit or the pictorial insert to promote the idea of putting nothing on the stump—leaving it uncovered.

Disposal of the kit was generally done safely, with nearly 80% disposing of the blade and less than 8% keeping it without at least washing it. There should be little risk associated with reusing the plastic tarp (as about half the households did) since it was washed. About 77% kept and reused the soap, which may contribute to improved personal hygiene in the home. It may be necessary to caution people against using the soap on the newborns, since the field interviewers reported anecdotally that some families complained the soap was too harsh for babies.

It is not possible to tell from these data if the high level of use of new or boiled blades among kit non-users was related in any way to publicity about the kit or to general public education efforts about clean delivery. More information on how non-users knew to use a clean blade could be useful in developing awareness campaigns in other places not yet so well informed.

Factors Related to Kit Use or Infection

There were few major demographic differences between kit users and non-users, and neither demographic nor socioeconomic factors were strongly related to infection. This is consistent with the results of the 1996 Nepal Family Health Survey (Luther, Thapa, Westley, 1999), which found a limited effect of socioeconomic factors on neonatal mortality. Attendance at antenatal care seems to have contributed to increased kit use by giving people the opportunity to hear about kits from health workers. Although TT immunization was also correlated with antenatal care, it was not related to protection against simple cord infection (which fits with what would be expected).

Although trained and untrained TBAs had differences in their practices, such as what they put on the cord after and whether they washed their hands before the delivery, both groups used a clean blade and cutting surface most of the time, and there were no significant differences in infection rates between them once these specific factors were controlled for. The higher rate of infection associated with health workers, although not quite statistically significant, deserves further investigation. It is not explained by hand

washing (they had the highest proportion of hand washing and were the most likely to use soap), and it was true for kit users and non-users alike.

Access and Acceptability

The low level of awareness of the kit, especially in Siraha, points up the need for greater publicity about it. In Morang and Sunsari, the publicity should address the issue of where to get the kit. Health workers were an important source of information about the kit, but radio seems to have contributed to the higher levels of awareness in Morang and Sunsari. Trained TBAs represent an important distribution channel (especially in Morang and Sunsari) which should be relatively easy to strengthen. FCHVs and health posts also offer good opportunities; inquiries in other regions will be needed to see if this pattern is typical elsewhere. If it is, it could guide MCH Products Pvt., Ltd. as to where it should put its marketing and distribution efforts.

The high level of satisfaction with the kit and the nearly universal intention to buy again are encouraging. The perception of the kit as easy, safe, and healthy suggests themes for future marketing and indicates that these are features valued by consumers. The price seems to be reasonably pegged, except in Siraha, where prices were indeed much higher than the recommended price. Since the wholesale price is less than Rs. 20, the fact that about 75% of kits in Siraha were sold for at least Rs.20 (while only 30% were in Morang and Sunsari) suggests that there should be room for price competition in Siraha. The sensitivity to even slightly higher prices also suggests that any additions to the kit (and therefore the cost) should be undertaken only if there is good evidence to support the utility and acceptability of the items.

The issue of the timing of kit purchase needs further study, since it was the main reason given in all three districts for not having bought a kit. It is probably related to cultural issues, such as “tempting fate” by taking direct action related to the delivery.

Strengths and Limitations of the Study

The unexpectedly high number of kit non-users who used a new or boiled blade greatly reduced the power of the study to detect a statistically significant difference in infection. Despite this, a twofold increase in infection risk associated with use of a boiled (rather than new) blade and unclean cutting surface or of any cutting instrument other than a new or boiled blade was statistically significant. The strong correlation between all items in the kit made it difficult to evaluate the individual components of the kit, such as the plastic tarp or the cord ties.

The unexpected and unexplained rise in infection rates in the later months of the study, along with the maldistribution of cohort enrollment over time, severely confounded the study, making the crude infection rates for the cohorts nearly meaningless for direct comparison. Although it is not clear why the infection rates for all cohorts were higher in the later months, it was suggested by several of the field interviewers that it might have

been related in some way to the hotter temperatures after the monsoon and/or to the presence of additional visitors in the household during the September holidays.

The lack of a clear explanation of the variability in infection detection rates among interviewers and the differences among the three districts raises unanswerable questions about inter-rater reliability. The fact that infection as determined by mothers' responses to standardized questions (assisted by photos) was similar to the interviewers' observations and that interviewers in the same districts had similar detection rates suggest that the variability was due more to district differences than to individual idiosyncrasies.

The study raises several questions that can only be answered with more qualitative research, such as:

1) why so many kit non-users already knew to use a clean or boiled blade;
2) how the pictorial insert was perceived and why it had little impact on wrapping and breastfeeding;
3) which factors determine whether and when attendants wash their hands and use soap;
4) what actual beliefs and practices are with regard to the coin (e.g., is it boiled) and whether a plastic substitute is needed in the kit at all; and
5) what the issues are that underlie the delay in purchasing kits.

Several features of the study give it an advantage over other studies of this type. The use of both maternal recall (aided by photos) and direct interviewer observation of the baby as well as review by a neonatologist should enhance the likelihood of effective detection of infection. The high degree of correlation between the various signs and symptoms lend support to this contention. The short time period for maternal recall (no more than three weeks since the time when infection would have occurred) makes this study more reliable that those which rely on recall going back a year or more (as in Parashar et al, 1998; Traverso et al, 1989; Bennett et al, 1997). Since the mother, not the birth attendant, was the respondent, there was less incentive to report "desirable" behavior; however, there may also have been more possibility that the mother missed some details of the attendant's behavior. The sub-study of 45 TBAs showed there were some disagreements on details, but these were generally not on major points.

VI. CONCLUSION

The study supports the notion (which is already accepted on an intuitive basis) that use of a clean delivery kit will reduce simple cord infection (and by extension, since the route of infection is the same, neonatal tetanus and sepsis), when compared with deliveries done using unclean instruments for cutting the cord and unclean cutting surfaces. In addition to providing clean cutting materials, it may also promote better hand washing practices. Although it is not possible to separate out the specific effect of the plastic coin, the data suggest its role in the kit should be reconsidered, as it may not be contributing much (as

long as the traditional coin is boiled). Clearly, women liked the convenience of the kit as a package with blade, plastic tarp and ties in one place, and they are willing to pay a reasonable price for it.

The opportunity to put educational messages directly in the home of the newborn at a time when families are particularly poised and well motivated to heed them warrants careful thought and further investigation as to the role of any insert in a kit. The study was not able to adequately address this issue, although it did show a high level of compliance with the behaviors regarding kit components as shown in the pictorial messages. The pictorial messages were clearly less successful in changing behaviors that were not directly related to kit components (such as early breastfeeding and wrapping).

Where unhygienic practices are widespread, inexpensive clean delivery kits designed to suit local needs and tastes can contribute to a reduction in infection, but not in isolation. Although management of cord cutting is a critical step, what is put on the cord afterwards in terms of foreign substances or cloth dressings is also important. The kit can provide the necessary components to make compliance with hygiene messages easier, but its value can be negated if it is not part of a comprehensive strategy to reduce obstetric and newborn complications.

To the extent that the Terai differs from other places, the results from this study may not be true for other parts of Nepal or other countries, but some recommendations for program managers can be suggested from the findings.

- If use of a clean (new or boiled) implement for cutting the cord is already widespread, introduction of a specially designed kit may not greatly reduce infection.
- Where use of a clean implement is not well established and soap is not universally available, sale of a clean delivery kit can provide a convenient way for families to get appropriate supplies while utilizing the private sector to do the promotion of clean deliveries. Promoting the use of clean or boiled blades may achieve a similar effect.
- A kit (or clean supplies) will not work in isolation, without addressing other practices such as topical substances put on the stump afterwards and leaving dirty cloths on as dressings.
- This study does not provide sufficient evidence for changes to the current kit components, but suggests that the plastic disk may not be necessary. The study was not designed to provide information on new components like gloves or antimicrobials. The sensitivity to kit cost expressed by users, though, suggests that any additions to the kit should be weighed carefully against the effect of increasing the cost.
- While pictorial instructions were effective in ensuring correct use of kit components, they were much less effective in promoting other behaviors.

REFERENCES

Bennett J, Macia J, Traverso H et al. (1997) Protective effects of topical antimicrobials against neonatal tetanus. *International Journal of Epidemiology* 26: 897-903.

Garner P, Lai D, Baea M et al. (1994) Avoiding neonatal death: An intervention study of umbilical cord care. *Journal of Tropical Pediatrics* 40:24-8.

Luther NY, Thapa S, Westley SB. (1999) Nepal survey shows that "Family planning saves lives". *Asia-Pacific Population & Policy* No.49:1-4.

Parashar UD, Bennett JV, Boring JR et al. (1998) Topical antimicrobials applied to the umbilical cord stump: A new intervention against neonatal tetanus. *International Journal of Epidemiology* 27:904-8.

Smith J and Fortney J. (1996) Birth kits: An assessment. Paper prepared for UNICEF.

Traverso HP, Bennett JV, Kahn, AJ et al. (1989) Ghee applications to the umbilical cord: A risk factor for neonatal tetanus. *Lancet* 1(8636):486-88.

WHO. (1998) *Care of the umbilical cord: A review of the evidence.* Geneva, WHO (document WHO/RHT/MSM/98.4).

VTRP14744.doc