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Impact of Umbilical Cord Cleansing With 4.0% Chlorhexidine on Time to Cord Separation Among Newborns in Southern Nepal: A Cluster-Randomized, Community-Based Trial

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Abstract

OBJECTIVE—Within a community-based, cluster-randomized study of the effects of 4.0% chlorhexidine on omphalitis and mortality risk, we aimed to describe the distribution of times to separation and the impact of topical chlorhexidine treatment on cord-separation times.

METHODS—Between November 2002 and March 2005, 15 123 infants were assigned randomly within communities in southern Nepal to receive 1 of the following 3 cord-care regimens: cleansing with 4.0% chlorhexidine, cleansing with soap and water, or dry cord care. In intervention clusters, field workers cleansed the cord in the home on days 1, 2, 3, 4, 6, 8, and 10 after birth. Newborns were monitored throughout the newborn period for signs of omphalitis, and the time to cord separation was noted. Separation times were compared across treatment groups. Cord infection risk and a range of infant and household characteristics were assessed for their relationships to separation time.

RESULTS—The mean separation time was shorter in dry cord care (4.24 days) and soap/water (4.25 days) clusters than in chlorhexidine clusters (5.32 days; mean difference: 1.08 days). Cords of infants who received chlorhexidine were 3.6 times more likely to separate after 7 days. Separation time was not associated with omphalitis. Home-delivered topical antiseptics, facility-based birth, and birth attendant hand-washing were associated with greater likelihoods of cord separation after 7 days of age.

CONCLUSIONS—In this setting, the umbilical cord separated more rapidly than observed in hospital-based studies, and the impact of chlorhexidine cleansing on separation times was negligible. Increased cord-separation time attributable to topical chlorhexidine treatment should not be considered a factor in decision-making in settings where the baseline risk of omphalitis is high and chlorhexidine might reduce infection and mortality risks significantly.

Keywords

umbilical cord; omphalitis; cord separation; chlorhexidine; antisepsis; antiseptic; Nepal

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UMBILICAL CORD INFECTION contributes to neonatal mortality and morbidity risk in developing countries. Reliable data from low-resource settings have been largely lacking but are necessary to guide appropriately recommendations for optimal umbilical cord-care practices for newborns. Current World Health Organization recommendations[1] for cord care in low-resource settings are based largely on incomplete information from developed countries,[2,3] where the risk of infection and exposure of the umbilical cord stump to infectious pathogens differ substantially.

Topical antiseptic regimens for umbilical cord care were implemented widely in past decades, despite a lack of conclusive evidence that these regimens can reduce infection rates.[2] Most studies were conducted in settings where overall infection risk was low, and the main focuses of randomized trials comparing antiseptics and nonantiseptics were secondary outcomes such as cord-separation time. It has been well established in many studies[4–9] that application of a variety of topical antiseptics (as with any action that delays colonization of the stump and leukocyte infiltration of the site[10]) increases the time to separation of the cord, relative to protocols promoting dry cord care or nonantiseptic treatment. Combined with ambiguous results from inadequately powered studies, this consistent characteristic of cord antisepsis, which may contribute to maternal dissatisfaction and economic concerns, has prompted a movement toward dry cord care.[11–15] This trend is reflected in current World Health Organization recommendations for developing countries,[1] which promote dry cord care under routine circumstances but acknowledge that antiseptics may be helpful when harmful, unhygienic, traditional practices place newborns at increased risk for omphalitis.

We reported recently that topical antisepsis with 4.0% chlorhexidine reduced infection risk markedly among neonates in rural Nepal.[16] Furthermore, if the cleansing intervention was initiated in the first 1 day of life, then the risk of death among neonates was reduced significantly. These results, given the importance of these outcomes relative to secondary outcomes emphasized more commonly in developed countries, are likely to renew debate regarding the use of topical antiseptics in developing countries.

Because cord-separation time has evolved as an important justification for recommending against the use of topical antiseptics, it is important to evaluate the effect of antiseptics on this outcome in settings where the risk of infection is high and the promotion of chlorhexidine may have a substantial public health impact. In such settings, many infants are born in the home under unhygienic conditions and bacterial colonization of the cord occurs rapidly, which suggests that baseline separation times may be comparatively short. Traditional practices, which often include applying substances such as chalk, herbs, ash, or household oils,[17–19] may affect separation times but have not been studied in a prospective manner. Our randomized trial of the impact of 4.0% chlorhexidine cleansing of the cord on omphalitis and mortality rates[16] in rural Nepal provided us with an opportunity to (1) evaluate the role of topical antiseptics on time to umbilical cord separation, (2) examine infant characteristics and behavioral practices related to separation time, and (3) assess the relationship between cord-separation time and umbilical cord infection.

METHODS

Study Population and Design

The data on umbilical cord cleansing, infection, and time to separation were collected within a community-based trial of the impact of umbilical cord cleansing with chlorhexidine on neonatal mortality and morbidity risk in Sarlahi District, Nepal. The study site was divided into 413 clusters, based on the population that 1 local female worker could monitor (• 40−50 households). The population, recruitment and randomization procedures, cord treatment regimens and cleansing procedures, and follow-up activities were reported previously.[16]

Briefly, a computer-generated randomization sequence assigned all infants within clusters to 1 of 3 cord-care regimens (umbilical stump cleansing with 4.0% chlorhexidine, cleansing with soap and water, or dry cord care only). Investigators, field workers, and participants were masked with respect to the chlorhexidine and soap/ water treatment groups. Pregnant women were identified in the community by local female project workers, the study was explained, and oral informed consent was obtained. All women were provided with 400 mg of albendazole, iron-folate supplementation (90 days), a locally manufactured clean delivery kit, tetanus toxoid immunization, and basic educational messages regarding hygienic umbilical cord care during delivery and the postnatal period.

Data Collection

Infants who were born between November 18, 2002, and March 8, 2005, and were alive at • 1 home visit before 10 days of age were eligible for enrollment. Enrolled newborns were visited up to 11 times during the neonatal period (days 1−4, 6, 8, 10, 12, 14, 21, and 28) for evaluation of the umbilical cord for signs of infection (pus, redness, or swelling). This schedule for home visits was designed to maximize both the coverage of the intervention and the detection of cases of omphalitis. In intervention clusters, workers cleansed the cord stump gently with the assigned solution (4.0% chlorhexidine or soap and water) during home visits before day 12. On the basis of a validation exercise described previously,[20] cord infection was defined as the presence of pus with redness of the skin around the cord stump or severe redness (extending • 2 cm) with or without pus.

Cord-Separation Time

At each visit, the worker assessed the cord-separation status and recorded the date and time of the visit. The cord was defined as fully separated if all visible signs of the necrotized cord had fallen from the stump. For infants who were assessed • 1 time both before and after the cord had separated (92.1%), the cord-separation time was defined as the age of the infant at the midpoint between the last visit before and the first visit after cord separation was noted. For infants whose visits all occurred after the cord had fallen off (6.4%), the cord-separation time was defined as one half the age of the infant at the first visit. Infants who were met only before the cord separated (1.6%) were excluded from the primary analyses, but the time under observation contributed to the time-to-event analysis.

Sample Size

These data were collected within a trial with primary outcomes of infection and death; therefore, the sample size was predicated on the number of participants in that trial. The final sample size of 14 887 infants provided • 99% power to detect a mean difference between treatment groups in the age at the time of cord separation of • 5 hours.

Analyses

Baseline infant, maternal, and household characteristics of enrolled infants were compared across the 3 treatment groups. Linear regression models were used to examine the difference in time to cord separation between any 2 cord regimen groups and included adjustment for variables that did not achieve balance across treatment groups. Associations between infant and behavioral characteristics were assessed with bivariate and multivariate regression models, with adjustment for treatment group. A Poisson regression model with robust variance estimation[21] was constructed to assess the relationship between the incidence of umbilical cord infection and time to separation, with adjustment for cord care received. All models examining associations across treatment allocation were estimated by using generalized estimating equations to account for the cluster-randomized design of the trial.[22] The impact of excluding right-censored infants (*n* • 236 [1.6%]) was assessed by estimating the Kaplan-

Meier time-to-event function according to treatment group and comparing the area under the curve (mean separation time) with the means estimated from the restricted data set. Analyses followed an intention-to-treat approach.

All analyses were conducted with Stata 9.0 (Stata Corp, College Station, TX). The Nepal Health Research Council (Kathmandu, Nepal) and the Committee on Human Research of the Johns Hopkins Bloomberg School of Public Health (Baltimore, MD) approved the protocol. This trial is registered at ClinicalTrials.gov (study NCT00109616).

RESULTS

Participants

Infants eligible for this analysis included a subset of those enrolled in the main trial of the effects of chlorhexidine cleansing on cord infection and mortality risk. A total of 15 123 infants were enrolled in that trial; analyses here were restricted to 14 887 (98.4%) of those infants, for whom specific information on time to cord separation was collected. There were 4853, 5037, and 4999 infants in the 4% chlorhexidine, soap and water, and dry cord care clusters, respectively (Fig 1). Among enrolled infants, only 29 mothers (0.2%) refused • 1 household visit during the intervention period; most of those mothers (*n* • 23 [79%]) were in the nonchlorhexidine clusters (relative risk [RR]: 1.81; 95% confidence interval [CI]: 0.70 to 4.70). No adverse events in response to the intervention were reported for any of the groups.

Baseline Comparison

Infant, maternal, and newborn care behaviors were generally well balanced across the groups (Table 1). In the intervention groups, maternal literacy was slightly higher and more infants were born to families originating from the hills (Pahadi), compared with the plains region of Nepal (Madeshi). The most commonly reported nonstudy application to the cord was mustard oil; this was applied more frequently in the dry cord care group. A range of other substances (such as mud, ash, herbs, spices, or breast milk; 4.6%) and nonstudy antiseptics (7.5%) were applied less commonly, and there was less exposure to nonstudy antiseptics in the chlorhexidine group. The overall prevalence of low birth weight (• 2500 g) was 29.9%, and rates were equal across the treatment groups.

Time to Cord Separation

The overall mean • SD and median times to cord separation were 4.60 • 2.0 days and 4.33 days (interquartile range: 3.29−5.13 days), respectively. If infants with estimated cord-separation times (6.4%) were excluded, then the mean time to infection was only 0.1 day (2.4 hours) greater; therefore, the entire sample was used. The umbilical cord separated fully within the first 1 week of life for 13 658 infants (91.7%). Cord-separation times varied significantly across the treatment groups. Among infants who received chlorhexidine cleansing, the mean time to separation was 5.32 • 2.4 days, whereas the mean ages at cord separation for infants in the soap/ water and dry cord care groups were 4.25 • 1.6 days and 4.24 • 1.6 days, respectively. The cord-separation time was significantly longer (1.08 days; 95% CI: 0.99 to 1.16 days) in the chlorhexidine clusters, compared with the nonchlorhexidine groups combined. This estimate did not change substantially after adjustment for ethnic group, maternal literacy, and home-delivered applications to the cord (1.05 days; 95% CI: 0.96 to 1.14 days). Approximately 65% (n • 802) of the 1229 infants whose cord separation was delayed past 7 days were in the chlorhexidine group (RR: 3.64; 95% CI: 3.09 to 4.28).

The Kaplan-Meier time-to-event functions according to treatment group, including the 236 right-censored infants, are shown in Fig 2. The restricted mean and exponentially extended

mean for each of these curves were identical within treatment groups and were not different from the mean separation times estimated when the censored observations were excluded.

Factors Associated With Cord-Separation Time

The mean cord-separation time and risk of delayed (• 7 days) separation, stratified according to various factors and adjusted for cord care treatment group, are shown in Table 2. Given the large sample size, even small differences in the mean time to separation were statistically significant. The stratum-specific time to separation differed by • 0.25 days (• 6 hours) only for home-delivered applications of antiseptics, ethnic group, maternal literacy, and place of birth. Furthermore, in a multivariate model of separation time, including factors listed in Table 2, the stratum-specific adjusted difference in time to separation exceeded 0.25 days only for ethnic group (0.41 days; 95% CI: 0.32 to 0.50 days). A range of characteristics were associated with delayed (• 7 days) separation time. In a multivariate model, the most important factors included male gender (RR: 1.15; 95% CI: 1.03 to 1.28), birth weight of • 2500 g (RR: 1.15; 95% CI: 1.01 to 1.31), Pahadi ethnic group (RR: 1.56; 95% CI: 1.36 to 1.80), facility-based birth (RR: 1.26; 95% CI: 1.01 to 1.57), and home-delivered antiseptics (RR: 1.34; 95% CI: 1.09 to 1.66).

Cord-Separation Time and Infection

There were 742 incident cases of omphalitis in the cord cleansing trial, and the risk varied significantly according to treatment group.[16] We collected cord-separation time information for 737 (99%) of these cases. The mean time to separation among cases (4.43 days) was slightly less than that among noncases (4.60 days) but, after adjustment for treatment received and ethnic group, this difference was not significant (• 0.01 days; 95% CI: • 0.15 to 0.13 days).

We restricted analysis of the association between separation time and infection to infants in the nonchlorhexidine groups, given the strong correlation between this treatment and both separation time and infection risk. In a Poisson regression model with the time to separation as a continuous independent variable and adjustment for ethnic group, there was a decreased risk of infection of 3% for each additional day the cord did not separate, although this was not statistically significant (RR: 0.97; 95% CI: 0.92 to 1.03). Among infants whose cord separated after the first 1 week of life, the incidence of infection was 4.5 cases per 100 neonatal periods, compared with 5.9 cases per 100 neonatal periods among infants whose cord separated before the seventh day (Fig 3). This difference was not statistically significant (RR: 0.73; 95% CI: 0.48 to 1.17), and the comparative risk estimate was diminished in magnitude after adjustment for variables potentially associated with infection status, such as ethnic group, birth assistant hand-washing, and home-delivered applications to the cord (RR: 0.83; 95% CI: 0.52 to 1.33).

DISCUSSION

Many studies examining the time to separation of the umbilical cord have concluded that topical antiseptics delay separation of the cord. There are, however, no published reports from prospective studies conducted in communities in developing countries examining the time to cord separation, the impact of topical antiseptics on this separation time, or the relationship between separation time and risk of infection. This study of 15 000 infants in rural Nepal, where • 90% of infants are born in the home without trained assistance, contrasts sharply with data available from developed settings. These data demonstrate that the umbilical cord separates considerably earlier among rural newborn infants in Nepal than among infants in tertiary care institutions in developed[2,23,24] or developing[25–27] countries and that rapid separation time is a consistent characteristic, regardless of the use of topical antiseptics.

There is considerable variation in times to cord separation in developed countries, depending on the care provided.[6,8,24,28] With or without topical antiseptics, the observed mean time to

separation is generally • 10 days, and mean separation times of • 7 days have been reported only rarely.[18,29,30] Monu and Okolo[17] suggested that a traditional concoction of chalk and herbs with desiccating properties might lead to the cord stump falling off within 2 days after birth in communities of Nigeria, but no specific data were presented. The results from our study confirm this observation and suggest that cord separation is rapid in communities in developing countries where infants are exposed to unhygienic practices.

The time to cord separation was • 1 day longer among infants who received chlorhexidine, compared with those who received soap/water cleansings or dry cord care, which represents a 25% relative increase. Furthermore, the treated infants were also 3.6 times more likely to have delayed (• 7 days) separation. Relative mean increases of this magnitude and an increased likelihood of delayed separation have been observed in developed countries; in some cases, this decreased maternal satisfaction and raised economic concerns.[11–13] In such settings, a recommendation against chlorhexidine or other topical antiseptics may be justified. In this setting, however, where the risk of serious infection is high, the benefits of chlorhexidine cleansing of the cord[16] outweigh greatly any concerns related to increased separation time. The absolute difference in mean time to separation according to treatment was only 24 hours, and these data provide evidence that delayed cord separation is not associated with increased risk of infection. Newborn infants whose cord separated later (• 7 days) were at slightly less risk of infection, but there seems to be no causal relationship; the difference was not significant, and almost all infections in this setting occurred during the first 1 week of life (Fig 3).

In this setting, we did not attempt to measure directly maternal satisfaction with the protocol. The level of early withdrawal from the study, however, was very low (0.2%), which suggests that maternal dissatisfaction was also low. Because the mean increase in separation time was only 24 hours, it is possible that any slight delay in separation, relative to previous nonparticipating children, went unnoticed for many mothers.

There are consistencies between data presented here and previous reports from hospital-based studies regarding factors associated with cord separation. Hygienic behaviors or procedures that reduce the overall exposure of the cord to bacterial colonization (such as cesarean section[31]) tend to increase cord-separation times. In this study, facility-based birth, hand-washing with soap by birth attendants, and the use of home-delivered antiseptics all were associated with increased likelihood of cord separation after 7 days. Separation time was 17% more likely to occur before 7 days for female subjects, compared with male subjects, as suggested previously,[32] but this difference has not been observed consistently.[25–27]

None of these factors, however, or more distal factors (such as ethnic group or maternal literacy) that were associated statistically with differences in cord-separation time represents an increase of any practical significance. Furthermore, all had substantially less impact on separation time than was seen with cord-cleansing treatment. Among infants who were not treated with chlorhexidine, increased cord-separation time was not associated with increased infection risk. In communities of developing countries in which many infants are born at home and hygienic conditions during the perinatal period are difficult to achieve, the potential for delayed cord separation as a result of topical antiseptic treatment seems to be negligible. Where baseline risks of omphalitis are high, early topical cleansing of the cord with chlorhexidine should be promoted widely.

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Abbreviations

CI, confidence interval; RR, relative risk.

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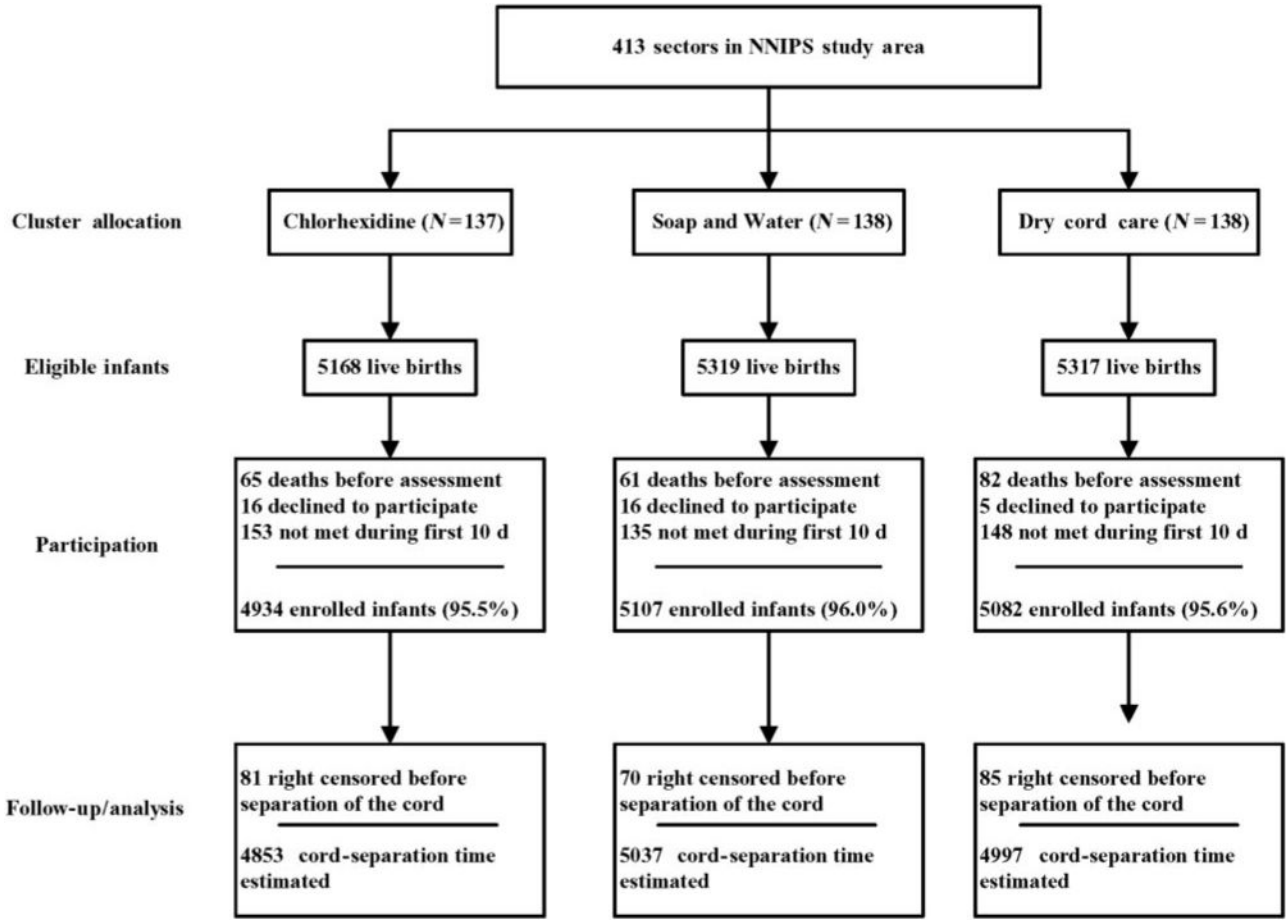

FIGURE 1.
Study participants flow diagram. NNIPS indicates Nepal Nutrition Intervention Project, Sarlahi.

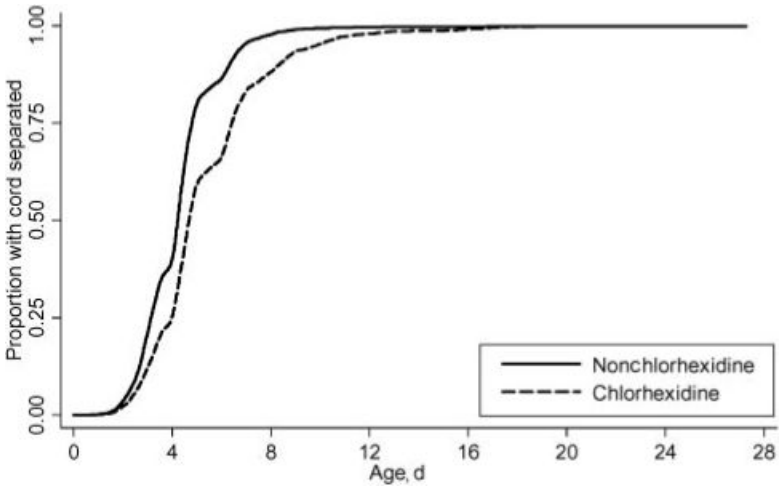

FIGURE 2.
Kaplan-Meier curves for times to cord separation for chlorhexidine versus nonchlorhexidine groups. The soap/water and dry cord care groups were combined.

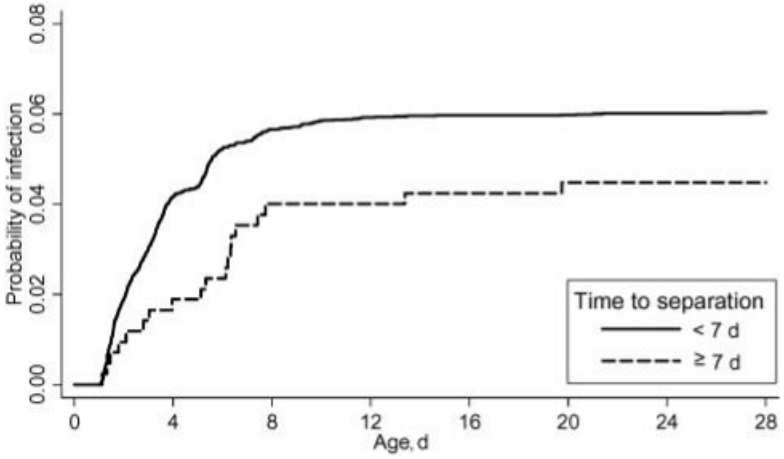

FIGURE 3.

Time to cord infection according to cord-separation status (• 7 vs • 7 days). The analysis was restricted to infants in the nonchlorhexidine groups.

TABLE 1

Baseline Characteristics According to Treatment Group

Variable	Chlorhexidine	Soap/Water	Dry Cord Care
No. of clusters (%)	137 (100.0)	138 (100.0)	138 (100.0)
No. of infants per cluster, mean	35.4	36.5	36.2
Total No. of infants (%)	4853 (100.0)	5037 (100.0)	4999 (100.0)
No. of home visits per infant, mean • SD	9.5 • 1.8	9.5 • 1.8	9.5 • 1.8
Gender, n (%)			
Female	2342 (48.3)	2497 (49.6)	2433 (48.7)
Male	2511 (51.7)	2540 (50.4)	2564 (51.3)
Birth weight, n (%)			
• 2500 g	1376 (28.7)	1487 (30.0)	1482 (30.0)
• 2500 g	3419 (71.3)	3462 (70.0)	3450 (70.0)
Ethnic group, n (%)			
Plains (Madeshi)	3160 (66.4)	3453 (70.2)	3655 (74.5)
Hills (Pahadi)	1618 (33.6)	1486 (29.8)	1264 (25.5)
Maternal literacy, n (%)			
No	3540 (73.0)	3746 (74.4)	3732 (74.7)
Yes	1309 (27.0)	1288 (25.6)	1263 (25.3)
Delivery place, n (%)			
Nonfacility	4314 (92.0)	4423 (90.5)	4479 (92.1)
Facility	376 (8.0)	462 (9.5)	383 (7.9)
Birth assistant washed hands, n (%)			
No	1715 (38.4)	1805 (38.7)	1786 (38.4)
Yes	2751 (61.6)	2854 (61.3)	2866 (61.6)
Mother/infant skin-to-skin care, n (%)			
No	4198 (95.6)	4284 (95.0)	4320 (96.2)
Yes	193 (4.4)	225 (5.0)	173 (3.1)
Home applications to cord, n (%)			
Mustard oil			
No	2510 (51.7)	2664 (52.9)	2316 (46.4)
Yes	2343 (48.3)	2373 (47.1)	2681 (53.6)
Home antiseptics			
No	4527 (93.3)	4638 (92.1)	4606 (92.2)
Yes	326 (6.7)	399 (7.9)	391 (7.8)
Other (mud, ash, herbs, or spices)			
No	4626 (95.3)	4826 (95.8)	4755 (95.2)
Yes	227 (4.7)	211 (4.2)	242 (4.8)

TABLE 2

Cord-Separation Times According to Infant, Maternal, and Household Characteristics

Variable	n	Cord-Separation Time, Mean• SD, d	Difference (95% Cl), d	RR for Cord-Separation Time of• 7 d (95% Cl)
Gender				
Female	7272	4.53• 1.9		
Male	7615	4.66• 2.0	0.12 (0.06 to 0.19)	1.17 (1.05 to 1.30)
Birth weight				
• 2500 g	4345	4.49• 1.9		
• 2500 g	10 331	4.65• 2.0	0.12 (0.05 to 0.19)	1.21 (1.07 to 1.36)
Ethnic group				
Plains (Madeshi)	10 406	4.42• 1.9		
Hills (Pahadi)	4368	5.01• 2.1	0.53 (0.46 to 0.60)	1.62 (1.45 to 1.82)
Maternal literacy				
No	11 018	4.48• 1.9		
Yes	3860	4.94• 2.2	0.41 (0.34 to 0.48)	1.41 (1.26 to 1.58)
Delivery place				
Nonfacility	13 216	4.57• 1.9		
Facility	1221	5.21• 2.5	0.62 (0.51 to 0.74)	1.89 (1.62 to 2.16)
Birth assistant washed hands				
No	5306	4.52• 1.9		
Yes	8471	4.65• 2.0	0.12 (0.06 to 0.19)	1.16 (1.03 to 1.30)
Mother/infant skin-to-skin care				
No	12 802	4.60• 2.0		
Yes	591	4.48• 1.9	• 0.06 (• 0.22 to 0.10)	0.98 (0.75 to 1.29)
Home applications to cord				
Mustard oil				
No	7490	4.50• 2.0		
Yes	7397	4.69• 1.9	0.19 (0.13 to 0.25)	1.09 (0.98 to 1.22)
Home antiseptics				
No	13 771	4.55• 1.9		
Yes	1116	5.17• 2.4	0.61 (0.50 to 0.73)	1.86 (1.60 to 2.17)
Other (mud, ash, herbs, or spices)				
No	14 207	4.60• 2.0		
Yes	680	4.53• 2.0	• 0.07 (• 0.22 to 0.08)	0.94 (0.73 to 1.22)