



# Final Research Report

Evaluation of a clean  
delivery kit intervention in  
preventing cord infection  
and puerperal sepsis in  
Mwanza, Tanzania

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**Final Research Report**

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**Submitted by:  
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## List of Acronyms

ACO	Assistant Clinical Officer
AMO	Assistant Medical Officer
CO	Clinical Officer
LSHTM	London School of Hygiene & Tropical Medicine
MCHA	Maternal and Child Health Aide
MOH	Ministry of Health
NIMR	National Institute for Medical Research
PATH	Program for Appropriate Technology in Health
UNFPA	United Nations Population Fund
VHW	Village Health Worker
WHO	World Health Organization

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## **I. Executive Summary**

Umbilical cord infection contributes significantly to newborn infection and subsequent neonatal death, particularly among infants delivered at home without a skilled birth attendant or under unhygienic conditions.<sup>1</sup> Similarly, puerperal sepsis, or genital tract infection following childbirth, is among the leading causes of preventable maternal death and is particularly prevalent in countries where home delivery and unhygienic births are common.<sup>2</sup> In Tanzania, 53% of all deliveries take place at home, and rates of cord infection and puerperal sepsis are crucial health concerns.

Program for Appropriate Technology in Health (PATH) worked with the Ministry of Health, National Institute of Medical Research, and London School of Hygiene & Tropical Medicine to investigate a low-cost option to reduce cord infection in newborns and puerperal sepsis in mothers in rural Tanzania using a clean delivery kit supplied by the United Nations Population Fund. The study was funded by the U.S. Agency for International Development under the HealthTech program managed by PATH. The performance and acceptability of a clean delivery kit in a low-resource setting such as Tanzania had not been evaluated previously.

The main objectives of the study were to (1) determine the effectiveness of clean delivery kits in preventing cord infection in newborns, (2) determine the effectiveness of clean delivery kits in preventing puerperal sepsis in mothers, and (3) gather qualitative information from kit users and kit non-users in the community on the acceptability, correct use, and appropriateness of the kits.

The study was conducted in surveillance sites across two rural districts of Mwanza Region. A total of 3,262 women between the ages of 17 to 45 were enrolled in the study, of which 1,935 (59%) used the delivery kit and 1,327 (41%) did not use the kit. For analytical purposes, in the analysis for cord infection a total of 59% of women had used the kit, and in the analysis of puerperal sepsis a total of 56% of women had used the kit.

A total of 58% of women delivered at home and 38% delivered at a medical facility. Of the 1,886 women who delivered at home, 1,182 (63%) used the delivery kit. Of the 1,251 women who delivered in a medical facility, 689 (55%) used the kit. Fifty-six percent of the 90 women who delivered somewhere else (i.e., on the way to the medical facility) used the delivery kit.

Pregnant women received the clean delivery kits at the local health center as part of on-going antenatal education. Health aides explained to pregnant women how to use the kit components and gave the pregnant women health education about clean birth. Village health workers administered structured questionnaires to the mothers five days postpartum and inspected the child's umbilical cord stump for signs of possible infection. Suspected cases of infection were referred to a local health facility for diagnosis.

### **Results**

Multiple logistic regression was conducted with variables that were significantly associated with both kit use and either infection. Results indicated that use of the clean delivery kit had a positive effect on reducing both cord infection and puerperal sepsis. The effect of the kit on reducing cord infection was much greater than on puerperal sepsis, but both were significant.

After adjusting for whether a mother had a bath before delivery, where the delivery took place, and whether any substances were put on the cord stump, **an infant whose mother used the delivery kit was about 13 times less likely to develop cord infection than an infant whose mother did not use the delivery kit.** A newborn of a woman who bathed before delivery was also about three times less likely to develop cord infection than a newborn of a woman who did not bathe before delivery.

After adjusting for whether a woman had a bath or shaved before delivery, where delivery took place, and duration of labor, **a woman who used the kit for delivery was about three times less likely to develop puerperal sepsis than a woman who did not use the delivery kit.** A woman who bathed before delivery was also about three times less likely to develop puerperal sepsis than a woman who did not bathe.

The results of this cross-sectional observation study should be interpreted conservatively, as they do not reflect the same level of evidence that would have been obtained if a randomized-control trial design were used.

## **Qualitative Research**

In addition to the quantitative study, qualitative research was carried out to gather information about kit use and acceptability. A total of 18 in-depth interviews were conducted with kit users and non-users selected randomly across the ten study clusters. The interviews were designed to collect information about use of the delivery kit (e.g., decision to use, where the mother got it), description of delivery (e.g., where, who attended, cord cutting, cord dressing, hand washing, use of soap), overall feelings about the kit (likes/dislikes, recommendations to improve/change, use and non-use of kit components), pictorial instructions (understanding, suggestions to improve), and effect of pictorial instructions on hand washing and understanding “clean delivery.”

Respondents who used the kit found it acceptable, were able to use it correctly, and reported satisfaction with the way the kit contributed to a clean delivery. All respondents said they would be willing to pay between 200 and 500 Tanzanian shillings (US\$0.20-\$0.50) for the kit. Kit-user respondents did not report difficulties in using the kit, and they recommended it be used by other women. Recommendations regarding cord care and pretesting of pictorial instructions are detailed in this report. Women who did not use the kit said they would have used the kit if it had been made available to them.

## **Recommendations and Conclusions**

The use of a clean delivery kit coupled with an educational intervention about the “six cleans” recognized by World Health Organization (i.e., clean hands, clean perineum, clean delivery surface, clean cord cutting and tying instruments, and clean cutting surface) was strongly and significantly associated with a lower incidence of cord infection and puerperal sepsis among women enrolled in the study. In low-resource settings where home birth is common and clean delivery supplies are scarce, disposable kits can be made available through government health clinics, markets, pharmacies, or other channels such as small shops to help reduce rates of infection.

Birth attendants, mothers, and family members should be advised about clean birth, hand washing, and how to correctly use the contents of the kit during antenatal visits at clinics or wherever the kits are sold. In addition, birth attendants and pregnant women should be educated to recognize signs and symptoms of cord infection and puerperal sepsis and to report to a health facility for treatment as soon as possible when symptoms are identified.

The qualitative research indicates that clean delivery kits are viewed as acceptable, appropriate, and useful items, and that women may be willing to pay a small fee for them. The instructions for kit use should be simple, include explanatory pictures as well as simple written instructions in the national and, where feasible, other major local languages, and should be carefully pretested to ensure that they are well understood by nonliterate or women with low levels of literacy and appropriate for the local culture. Training health care workers may be an effective way of educating women about the usefulness of clean delivery kits. Comprehensive maternal and newborn health programs that include training of skilled birth attendants may be particularly appropriate venues in which to introduce clean delivery kits.

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<sup>1</sup> World Health Organization. Essential newborn care: report of a technical working group. WHO/FRH/MSM/96.13. Geneva, 1996.

<sup>2</sup> Chisembele, M. The global incidence of puerperal sepsis. Geneva Foundation for Medical Education and Research. Geneva 2004.

## II. Background

Tetanus and other infections are leading causes of neonatal deaths. Worldwide some 500,000 infants die each year of neonatal tetanus, and a further 460,000 die as a consequence of severe bacterial infection.<sup>1</sup> Cord infections contribute significantly to neonatal infection. A study in India found that in 47% of infants hospitalized with sepsis, cord infection was the source; and 21% of infants admitted for other reasons had cord infection.<sup>2</sup>

The reasons for the high incidence of cord infection in the developing world are the high proportion of home deliveries, unhygienic cutting of the cord, application of unclean substances to the cord stump, and covering the stump with unclean fabric. Strategies to reduce the risk of neonatal tetanus and cord infection include promoting clean delivery and clean cord care as well as increasing tetanus toxoid immunization.<sup>2</sup>

At least 75,000 maternal deaths, mostly in developing countries, are caused every year by puerperal sepsis.<sup>3</sup> This type of infection is responsible for 15% of all maternal deaths worldwide<sup>4</sup> and causes the loss of more than one-third of healthy years of life.<sup>5</sup> In sub-Saharan Africa, puerperal sepsis is among the leading causes of preventable maternal death. A study in an urban hospital in Nairobi, Kenya, in 1987 found the incidence to be 20%,<sup>6</sup> and in Mwanza Region of Tanzania puerperal sepsis caused 17% of all maternal deaths in 1999.<sup>7</sup> A study in Anambra, Nigeria, in 1988 showed that sepsis was the fourth leading cause of death and contributed 12% to maternal deaths.<sup>8,9</sup> Unhygienic delivery has been identified as a major cause of puerperal sepsis.<sup>10</sup> In Tanzania, 53% of all deliveries take place at home, many of these under unhygienic conditions.<sup>11</sup> During home deliveries in Tanzania, unclean substances are often introduced into the vagina (unclean hands, local herbs, etc.), an unclean delivery surface is often used, and unclean cloth is used to cover the vagina after delivery. Likewise, the cord is frequently cut by unclean instruments and unclean substances are put on the cord.<sup>10</sup> These practices increase the likelihood of microorganisms entering the birth canal of the woman or the cord stump of the neonate, causing puerperal sepsis or cord infection, respectively.

Although the government has made available a network of dispensaries and health centers throughout Tanzania (more than 85% of the population live less than 5 km from a health facility) and has insisted that all pregnant women should deliver in health facilities, still more than half of women deliver at home under conditions where they are at risk of puerperal sepsis for themselves and cord infection in their neonates.

For this reason the Ministry of Health (MOH), National Institute of Medical Research (NIMR) Program for Appropriate Technology in Health (PATH), and London School of Hygiene & Tropical Medicine (LSHTM) decided to investigate a low-cost option to reduce puerperal sepsis and cord infection in rural Tanzania using a clean delivery kit. The study was supported by the U.S. Agency for International Development through the HealthTech program managed by PATH. The performance, acceptability, and effectiveness of a clean delivery kit in the socio-cultural context and poor human, infrastructure, and economic resources in rural areas of Africa had not been evaluated previously.

### III. Objectives

The main objectives of the study were:

1. To determine the effectiveness of clean delivery kits in preventing cord infection.
2. To determine the effectiveness of clean delivery kits in preventing puerperal sepsis.
3. To gather qualitative information from kit users and kit non-users in the community on the acceptability, correct use, and appropriateness of single-use, clean delivery kits.

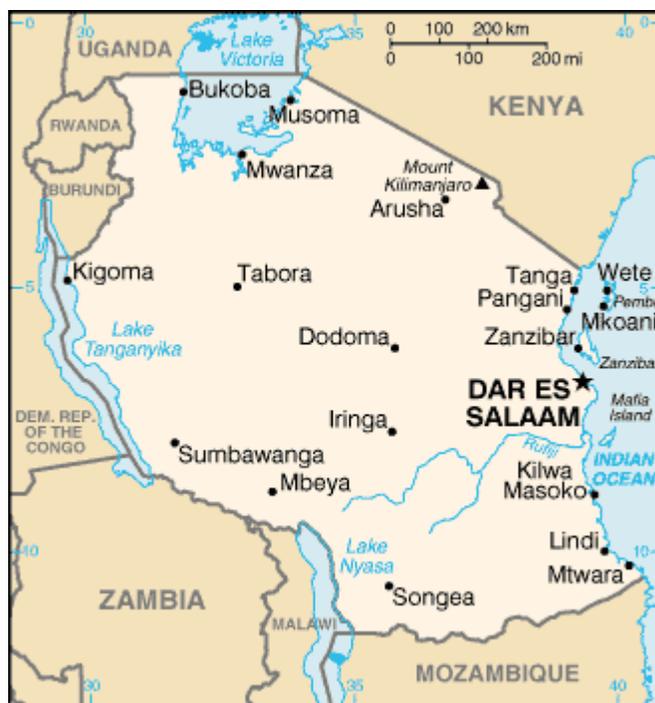
### IV. Methodology

#### Study Site

Mwanza Region is situated on the southern shore of Lake Victoria in Tanzania. It has a population of 3,009,422 and is divided into seven districts.

This area was purposely selected due to the presence of an active community-based maternal and perinatal health care surveillance system managed by CARE International. The surveillance system started in January 2000 and involved all 32 villages. Key components of the system included registration of pregnant women starting as early as 22-weeks gestation, community-based registration of all pregnancy outcomes, three home consultations for birth planning, and at least three postpartum consultations by trained health volunteers. The system was implemented by four village health workers (VHWs), village government, and women's community groups. The system was supervised by CARE and district-level health officials through monthly site visits and semiannual data reviews and refresher trainings.

According to the 1996 Demographic and Health Survey, more than 97% of pregnant women in Mwanza Region made at least one antenatal care visit. The crude birth rate was estimated to be 46/1,000 in 1999. Despite the high proportion of pregnant women attending antenatal services, only 44% of all births in rural areas occur at a health facility, while up to 56% of births take place outside of a health facility.<sup>11</sup>



Map of Tanzania

## Study Participants

This study was implemented among pregnant women age 17 to 45 in eight wards in Kwimba and Missungwi Districts as shown in Table 1.

**Table 1: Demographic information of proposed study area**

	<b>Kwimba District “Malya Surveillance Site”</b>	<b>Missungwi District “Mbarika Surveillance Site”</b>
Population*	54,778	51,610
Women 17 to 45 years	12,051	11,354
Health facilities with antenatal care	4	6
Number of villages	16	16
Main ethnic group	Sukuma	
Major religions	Roman Catholic, Africa Inland Church of Tanzania, Islamic, Seventh Day Adventist	

\*Estimated 2001 population based on 1988 census with 2.7% annual growth.

The study population consisted of pregnant women in the study area who met the following criteria:

- Age 17 to 45 and listed in community pregnancy registers.
- Delivered in the study area (at the health facility in the study area or in communities in the service areas).

Only pregnant women of reproductive age who reside in Kwimba and Missungwi Districts in Mwanza Region were eligible to participate in this evaluation.

All deliveries in the study area, whether they took place at home, in dispensaries, or in health centers, were included in the study. This was because the peripheral health facilities did not always have adequate materials to provide clean deliveries. In the delivery kit intervention population, the maternal and child health aide (MCHA) assigned to the health facility provided pregnant mothers with a clean delivery kit at their first antenatal visit.

## Study Clusters

The study was conducted in the surveillance sites described above across the districts of Kwimba and Missungwi. The sites were sectioned into ten clusters; each cluster was defined as a dispensary or health center providing antenatal care to its service population.

The ten clusters included in the study (eight dispensaries and two health centers plus their service areas) were based on an implementation schedule of one new cluster every six weeks to allow for logistics, training, close monitoring, and refinements before advancing. The order of the cluster implementation schedule was randomized. This approach allowed for facilitation of careful implementation and introduction of all participating clusters to the intervention before the end of the study.

**Table 2: Implementation schedule for disposable clean kits**

Cluster	Week 1	Week 6	Week 12	Week 18	Week 24	Week 30	Week 36	Week 42	Week 48	Week 54
Cluster 1										
Cluster 2										
Cluster 3										
Cluster 4										
Cluster 5										
Cluster 6										
Cluster 7										
Cluster 8										
Cluster 9										
Cluster 10										

## Ethical Considerations

No incentives were offered to women to participate in the evaluation. Ethics and research clearance for the study was obtained initially from the Mwanza Centre Scientific Committee and thereafter from the Tanzanian National Medical Research Coordinating Committee. This committee acts as the national ethics and research clearance body for all medical research in Tanzania. The ethics committee at the LSHTM and the PATH Human Subjects Protection Committee also provided review and approval.

## Informed Consent Process

A standard written consent procedure was utilized in this evaluation. Written consent for participation in the study was obtained by the VHW during initial registration of the pregnant woman. She or he verbally explained the study objectives to each potential participant, and an informed consent statement was read and signed by the client. An information sheet was posted at all participating health facilities and village government offices. In the case of low- or non-literate women, the information sheet was read aloud in its entirety, and the woman stamped her thumbprint in the designated box on the consent form to signify her consent. Another person present acted as witness to this act and signed the informed consent form accordingly. In most cases, the witness was another household member.

All members of the local development committees were informed of the study and requested to provide voluntary consent for implementation of the study in their communities. An information sheet that explains the study was provided to all community leaders.

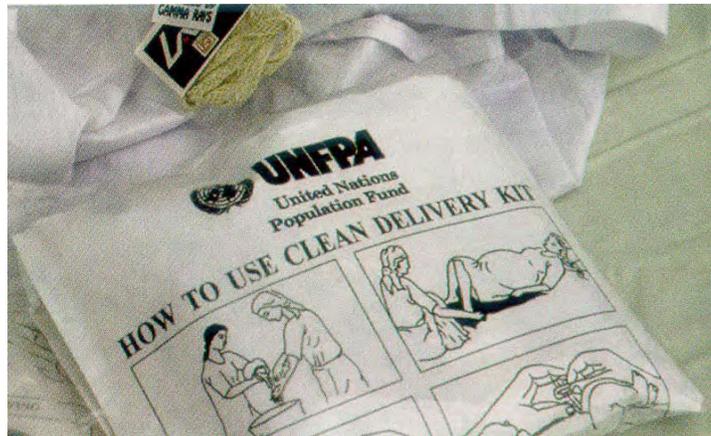
All mothers and infants diagnosed with puerperal sepsis and/or cord infection were treated at respective dispensaries and referred to the district hospitals for further treatment, where

necessary. Verbal consent for treatment procedures was obtained at the health facility as part of the routine counseling provided to each woman.

## V. Materials

Clean, disposable delivery kits were purchased from United Nations Population Fund (UNFPA). The clean delivery kit consisted of a plastic sheet (or mackintosh), a small piece of soap, a new razor blade for cutting the cord, two new cord ties, and user instructions. The kit items were packaged together in a sealed plastic bag. Women in all clusters received the clean delivery kit free of charge in accordance with the implementation schedule (see Table 2 above).

The MCHA explained how to use each of the kit components, with the aid of pictorial instructions included in the kit. She told the pregnant women to transmit this information to whomever assisted them during their delivery. The MCHA also gave the pregnant women health education based on the principles of the “six cleans” recognized by the World Health Organization (WHO) (i.e., clean hands, clean perineum, clean delivery surface, clean cord cutting and tying instruments, clean cutting surface).



UNFPA Clean Delivery Kit

## VI. Data Collection and Analysis

Data were collected by trained staff working at the peripheral health facilities (clinical officers [COs], MCHA, and VHWs) under the supervision of the NIMR field research leader and the MOH regional medical officer in Mwanza.

On the fifth day after giving birth, the VHWs visited the households of mothers who had recently delivered, irrespective of whether they had been supplied with a kit. The mean age of infants when cord infection appears is 3.2 days, and the primary symptom for puerperal sepsis is fever between birth and ten days postpartum. Most signs of puerperal or cord infection are visible by day five, and data were not collected after that.<sup>1</sup> During the postpartum visits, the trained VHW performed the following tasks (see Appendix 1 for data collection instruments):

- Check the mother and newborn for any complications/danger signs (mother: excessive bleeding, lower abdominal tenderness, fever, abnormal lochia; baby: hypothermia, cord infection, tetanus, poor suckling).
- Check mother's temperature using digital thermometer.
- Check mother for symptoms of puerperal sepsis.
- Check cord of infant to determine if infection is present, as defined in criteria.
- Update register.
- Escort mother and infant to health facility for medical diagnosis and treatment if suspected of having infection.

- Administer questionnaire about delivery to mother and birth attendant.

The VHW made a preliminary diagnosis of cord infection by directly observing if any one or more of the following were present during the day-five postpartum visit: erythema, tenderness of tissues surrounding the cord, pus discharge, or smelly or moist stump. VHWs showed the mother photographs of infected cords and asked the mother if the infant's cord resembled the photographs. This technique helped mothers recognize cord infection. The VHW made an independent assessment as to the presence of infection.



**Clinical Officer at Maligisu Dispensary**

The VHW made preliminary diagnosis of puerperal sepsis by determining if the following were present during the day-five postpartum visit: (1) a temperature reading of 38 °C or higher, or a complaint of *homa* or body hot to the touch; and (2) lower abdominal pain or foul lochia or both. *Homa* is a Kiswahili word that describes a state of fever (either a feeling of cold or hot and body malaise), well known in Tanzania.

Standardized questionnaires were administered to the mother and the delivery attendant (if one was present during delivery) by well-trained and supervised VHWs. During the visit, the VHW investigated whether the clean delivery kit was used or whether any clean delivery items separate from those in the kit were used (e.g., razor blade, gloves, soap, plastic sheet, cloth or gauze, cord tie).

### **Referral to Health Provider**

If the mother or baby was suspected of having infection, both mother and infant were escorted to the nearest health facility where a clinical officer reexamined them to provide an independent diagnosis. Transport was facilitated using the VHW's bicycle. Records from all confirmed cases of cord infection and puerperal sepsis were reviewed by the clinical officer who was designated to determine the final diagnosis. Clinical criteria for the diagnosis of puerperal sepsis included sublingual temperature of 38 °C or more, plus one or more of the following symptoms: lower abdominal pain, lower abdominal tenderness, or foul lochia. The health provider's diagnosis of cord infection was based on the same criteria as that of the VHW. Qualifying health providers included clinical officer, assistant clinical officer, nurse midwife, or MCHA.

The NIMR field research leader randomly reviewed ten diagnoses per month by reviewing all data, including visiting the individual client with suspected cord infection and/or puerperal sepsis to make a final confirmation of diagnosis.

## Data Analysis

Data forms were submitted to NIMR Mwanza where the data section team conducted monitoring, double entry, and verification of data in DBaseIV. The team performed data management including range and consistency checks in DBaseV and STATA 7.0. These preliminary data were used for monthly monitoring of the progress of the study. The NIMR data section gave feedback monthly on the data entry errors detected at each site and also supplied monthly frequency distributions to the study team. Statistical analysis for these data was done in STATA 7.0.



**Study Team at Maligisu Dispensary**

Univariate and multivariate analyses were conducted to determine the following:

- Incidence of cord infections among kit users and non-users.
- Incidence of puerperal sepsis among kit users and non-users.
- The strength of association between the incidence of cord infection, use of a clean delivery kit, and education.
- The strength of association between the incidence of puerperal sepsis, use of a clean delivery kit, and education.

Summary descriptive analysis and multivariate analysis using multiple logistic regression were carried out using STATA 7.0. Bivariate tests of association to investigate risk factors other than kit use that were associated with cord infection and puerperal sepsis were done using the Chi-square test. All risk factors that were significantly associated ( $p < 0.05$ ) with kit use and either type of infection were included in the logistic regression model as potential confounders.<sup>12</sup>

Multiple logistic regression was used to determine odds ratios and 95% confidence intervals to determine the association between risk factors and infection and to control for potential confounding factors. Clinical diagnoses of puerperal sepsis or cord infection were the dependent variables, and kit use was the main risk factor of interest. Continuous variables were grouped into categories. Only risk factors that altered the odds ratio associated with kit use when included in the model are discussed in detail, as these factors can confound (or distort) the true relationship between kit use and infection.

## Qualitative Data Collection and Analysis

In-depth interviews (IDIs) were conducted using a semistructured questionnaire among a random sample of kit users and non-users across clusters. Qualitative data were collected to determine the acceptability, correct use, and appropriateness of the kit as identified by kit users only (see Appendix 2 for in-depth interview guides). The following topics were explored:

1. Use of delivery kit (e.g., decision to use, where the mother got it).
2. Description of delivery (where, who attended, cord cutting, cord dressing, hand washing, use of soap, preparations for delivery).
3. Overall feelings about the kit (cultural acceptability, likes/dislikes, recommendations to improve/change, use and non-use of kit components, willingness and ability to pay, willingness of mothers to recommend the kit to friends).
4. Pictorial instructions (understanding, suggestions to improve).
5. Clarity and effect of pictorial instructions on hand washing and understanding “clean delivery.”

Two female research assistants were recruited and trained to conduct the IDI. Before starting the interviews, the research assistants informed the respondents of the purpose of the research, how long it would take, and assured them of confidentiality. The research assistants then sought verbal consent of the respondents to be interviewed. The research assistants took written notes during the interviews to record information provided by the respondents. Data were coded and organized thematically and analyzed manually.

## VII. Results

### Demographic Profile of Study Participants

A total of 3,262 women between the ages of 17 to 45 were enrolled in the study. About two-thirds (68%) of women were in monogamous marriages, 16% were in polygamous marriages, and another 12% were unmarried. The rates of kit use among these categories were about the same, ranging from 55% to 61%. Of the 3,262 study participants, 66% completed primary school (Standard 7), 16% had no school, and 13% went to primary school but did not complete Standard 7. The rate of kit use among women from these education levels was virtually the same, ranging from 59% to 61%.



**Study Participant and Baby in Maligisu**

Kit use is defined according to the elements that were used during delivery, as there were cases when a woman stated that she used the delivery kit but did not report using any of the elements in the kit. Conversely, there were cases when a woman indicated that she did not use a kit, but, in response to other questions, reported using a plastic sheet, razor, or cord tie obtained from the kit. If a woman reported using at least one of the items in the kit (i.e., the plastic sheet, cord tie, or razor blade), she was defined as having used a delivery kit (Table 3). A minority of women (303) reported kits that were not UNFPA kits; these women were dropped from the analysis as the study team could not verify the contents of these kits.

For **cord infection**, use of the relevant components of the kit was redefined as a woman having used either:

- The full kit (i.e., the plastic sheet, cord tie, or razor blade), or
- the plastic sheet and either the razor blade, cord tie, or both, or
- the razor blade and cord tie, or
- only the razor blade.

However, if a woman used only the plastic sheet, she was defined as a kit non-user in the analysis of cord infection, as use of the plastic sheet alone is not a kit component that would impact health of the umbilical cord.

For **puerperal sepsis**, kit use was defined as a woman having used the plastic sheet with or without any other components of the kit. This was because use of the sheet alone has a potential impact on preventing sepsis by providing a clean birthing surface. Women who used the razor blade or cord tie only were defined as kit non-users in this analysis.

**Table 3: Women who reported using the various components of the kit**

Items used from kit	Analysis of sepsis infection	Analysis of cord infection	Delivery kit used	Deliveries (%)
Plastic sheet, cord ties, razor blade	Y	Y	Y	1,775 (54.4%)
Plastic sheet, cord ties	Y	Y	Y	28 (0.9%)
Plastic sheet, razor blade	Y	Y	Y	22 (0.7%)
Plastic sheet	Y	N	Y	16 (0.5%)
Cord ties, razor blade	N	Y	Y	60 (1.8%)
Razor blade	N	Y	Y	15 (0.4%)
Cord ties	N	Y	Y	19 (0.6%)
None	N	N	N	1,327 (40.7%)
Total				3,262

Of the 3,262 women enrolled in the study, 1,935 (59%) used at least one component of the delivery kit. For the analysis of cord infection, a total of 59% of women used the relevant components of the kit according to the definition above; in the analysis of puerperal sepsis 56% of women used the relevant components of the kit (Table 4).

**Table 4: Total number of kit users per infection category**

	Kit Use	No Kit Use	Total
Cord Infection	1,919 (58.8%)	1,343 (41.2%)	3,262 (100%)
Puerperal Sepsis	1,841 (56.4%)	1,421 (43.6%)	3,262 (100%)

The number and percentage of deliveries and the number and percentage of delivery kit use in each cluster are detailed below. Each cluster accounts for between 8% and 11% of the total deliveries.

**Table 5: Total deliveries and delivery kit use by cluster**

<b>Cluster</b>	<b>No. of deliveries (%)</b>	<b>Delivery kit usage* (%)</b>
Buhunda	365 (11.2)	325 (89.0)
Maligisu	360 (11.0)	314 (87.2)
Shushi	267 (8.2)	206 (77.2)
Nyangomango	327 (10.0)	236 (72.2)
Mbarika	281 (8.6)	163 (58.0)
Lyoma	279 (8.6)	107 (38.4)
Lubili	372 (11.4)	139 (37.4)
Igongwa	304 (9.3)	97 (31.9)
Sumbugu	342 (10.5)	228 (66.7)
Malya	343 (10.5)	108 (31.5)
No info	22 (0.7)	12 (54.6)
<b>Total</b>	<b>3,262 (100)</b>	<b>1,935 (59.3)</b>

\*Kit used for puerperal sepsis or cord infection prevention or both.

### **Pregnancy Outcome for Mothers and Newborns**

A total of 3,143 (96%) of the mothers were in good health following their delivery. Five women (0.15%) died during delivery and four (0.12%) died within 48 hours after delivery. Causes of death included anemia, postpartum hemorrhage, and obstructed labor. Eight women (0.2%) experienced a perineal tear during the delivery. A total of 3,086 (96%) of the 3,262 newborns were healthy following birth, 46 (1.4%) infants were stillborn, 32 (0.98%) infants died within 48 hours after birth, and 38 (1.2%) infants were born prematurely.

There were 69 confirmed cases of puerperal sepsis in the mother (2.1%) and 53 confirmed cases of cord infection in the infants (1.7%). In 24 mother-infant pairs, both the mother and infant had the infections.

### **Impact of Kit Use on Incidence of Cord Infection**

The majority of women reported using razors to cut the cord. Of the 3,262 women enrolled in the study, 1,893 (58%) reported using a razor blade from the delivery kit, and 1,204 (37%) reported using a razor obtained elsewhere. After excluding the 78 infants who died within 48 hours of delivery and 126 (3.8%) with incomplete questionnaires, 3,058 infants were used for the analysis of cord infection. A total of 53 newborns (1.7%) developed cord infection, including 5 newborns (0.3%) of women who used the kit and 48 newborns (3.9%) of women who did not use the kit ( $\chi^2=57.62$ ,  $p<0.001$ ).

**Table 6: Cross-tabulation of delivery kit use and cord infection**

Cord infection	Delivery kit use		Total
	Yes	No	
No	1,815 (99.7)	1,190 (96.1)	3,005
Yes	5 (0.3)	48 (3.9)	53
Total	1,820	1,238	3,058

### Place of delivery and use of kit

There were no apparent differences in the number of newborns who experienced cord infection among the three delivery places: medical facility (1.7%), home (1.7%) or other places (2.5%). There were, however, significant differences in the percentage of women who used the delivery kit in the three delivery places: 63% of women who delivered at home, 54% of women who delivered in a medical facility, and 52% of women who delivered in other places used the kit ( $\chi^2_{(2)} = 26.32$ , p-value < 0.001).

The majority of the razor blades were disposed of by throwing them in the rubbish pile (56%), burying them in the ground (29%), or burning them in the fire (9%). Only 39 women (2%) reported that they boiled the razor blades for reuse.

### Factors influencing cord infection

Exploratory analysis of factors that could be associated with cord infection revealed that place of delivery, the reported condition of instrument used to cut the cord, substance put on cord after delivery, bathing before delivery, and shaving before delivery appeared to significantly influence the incidence of cord infection.

The reported condition of the instrument used to cut the cord was significantly associated with the incidence of cord infection ( $\chi^2 = 4.99$ , p-value = 0.026). Cord infection for neonates whose mother reported that their cord was cut with a clean razor blade was 1.6% compared to 4.5% among infants whose mother reported that the cord was cut with an old or used cutting instrument (Table 7).

**Table 7: Relationship of condition of instrument used to cut cord and cord infection**

Cord infection	Condition of instrument used to cut cord		Total
	New	Not new	
No	2,843 (98.3)	106 (95.5)	2,949
Yes	48 (1.7)	5 (4.5)	53
Total	2,891	111	3,002

Of the 2,820 infants whose mother indicated that they had not put (nor had anyone else put) any substances on the cord stump, 43 (1.5%) developed cord infection. Of the 223 infants whose

mother said that they put some substances on the cord stump, 11 (4.9%) developed cord infection ( $\chi^2_{(1)} = 13.77$ , p-value < 0.001). It was not known whether or not any substance had been put on the cord stump for the remaining 219 infants (unknown by mother or missing data). Cord infection was also four times lower among infants whose mothers who reported not having put any substances on the cord stump as it healed.

Factors associated with the incidence of cord infection included the newborn's mother bathing before delivery (washing the perineum with water and soap), and the newborn's mother shaving before delivery. Newborns whose mothers had bathed (1.3%) before delivery had significantly fewer cases of cord infection than women who did not bathe (5.6%) before delivery ( $\chi^2_{(1)} = 32.69$ , p-value < 0.001). In addition, newborns whose mothers shaved (1.6%) before delivery had significantly fewer cases of cord infection than women who did not shave (4.0%) before delivery ( $\chi^2_{(1)} = 7.31$ , p-value = 0.007).

### Results of logistic regression

Results from multiple regression analyses indicated that there was evidence of an independent association between cord infection and the use of the delivery kit (defined as use of at least the razor or cord tie), where the delivery took place, whether a mother bathed before delivery, and whether substances were put on the cord stump. To examine the independent effect of the use of the delivery kit in reducing cord infections, these potentially confounding factors were adjusted for. After adjusting for each factor individually, any change in the odds ratio for use of the kit of more than 10% was considered important (Table 8).<sup>12</sup> A change in the odds ratio of 1.0% was apparent for use of the kit after adjusting for bathing or shaving before delivery, where the delivery took place, or whether substances were put on the cord stump, but not the reported condition of the cutting instrument.

**Table 8: Summary of the odds ratio for kit use (UNFPA razor or cord tie) adjusting for other factors that are associated with cord infection**

Factor adjusted for	Odds ratio for kit use	p-value	CI for odds ratio
Unadjusted	12.19	<0.001	5.20, 28.58
Bath before delivery	13.18	<0.001	5.21, 33.28
Shave before delivery	14.00	<0.001	5.55, 35.35
Place of delivery	12.35	<0.001	5.26, 28.99
Condition of cutting instrument	12.19	<0.001	5.16, 28.73
Substances put on cord stump	11.41	<0.001	4.84, 26.87

In Table 9, the effect of kit use was adjusted for bathing before delivery, shaving before delivery, place of delivery, and whether substances were put on the cord stump. Adjusted odds ratios indicate that delivery kit use was the most important factor in predicting cord infection. An infant whose mother reported having used the relevant components of the delivery kit was about 13 times less likely to develop cord infection than an infant whose mother did not use the delivery kit. Bathing before delivery was also independently associated with fewer cord infections after adjusting for the other factors in Table 9. A newborn of a woman who bathed before delivery was about three times less likely to develop cord infection than a newborn of a woman who did not bathe before delivery after adjusting for the factors listed in Table 9.

**Table 9: Summary of the adjusted odds ratio of factors that are associated with cord infection**

Factor	Odds ratio	p-value	CI for odds ratio
<i>i) Kit use</i>			
Yes	1.0		
No	12.6	<0.001	4.96, 32.10
<i>ii) Bath before delivery</i>			
Yes	1.0		
No	3.4	<0.001	1.77, 6.53
<i>iii) Shaved before delivery</i>			
Yes	1.0		
No	0.96	0.923	0.42, 2.18
<i>iv) Place of delivery</i>			
Home	1.0		
Medical facility	1.0	0.890	0.58, 1.86
Other places	1.2	0.789	0.28, 5.40
<i>v) Substances put on cord</i>			
Nothing	1.0		
Some substance	1.6	0.201	0.78, 3.30

### Impact of Kit Use on Incidence of Puerperal Sepsis

After excluding the 9 women (0.3%) who died within 48 hours after delivery and 75 women (2.3%) who had incomplete questionnaires, 3,178 women were used for the analysis of puerperal sepsis.

As the following table indicates, there were only 19 (1.1%) cases of puerperal sepsis among women who were “puerperal” kit users, compared to 50 (3.6%) cases among those who did not report having used the relevant components of the kit. ( $\chi^2_{(1)} = 23.19$ , p-value < 0.001).

**Table 10: Relationship of delivery kit use and puerperal sepsis**

Puerperal Sepsis	Delivery kit used/ "puerperal"		Total
	Yes	No	
No	1,779 (98.9)	1,330 (96.4)	3,109
Yes	19 (1.1)	50 (3.6)	69
Total	1,798	1,380	3,178

### Place of delivery and use of kit

There was no significant difference in the incidence of puerperal sepsis between the three places of delivery: medical facilities (1.8%), home (2.3%), and other places (4.5%). Medical facilities include hospitals, health centers, and dispensaries, and the category of "other places" was most often en route to the medical facility. There were significant differences, however, in the percentages of women who used at least the plastic sheet from the delivery kit in the three delivery places: 61% of the women who delivered at home, 51% of the women who delivered in a medical facility, and 49% of the women who delivered in other places used the plastic sheet. ( $\chi^2_{(2)} = 28.73$ , p-value < 0.001).

### Factors influencing puerperal sepsis

Only 877 women (27%) reported that the birth attendant inserted his or her hands into the vagina, and 830 women (25%) reported that the attendant washed his or her hands before doing so. Of those 830 women, 816 (98%) reported that the attendant had used soap and water. Twelve (1.5%) of the 830 women who were attended by birth assistants who washed their hands developed puerperal sepsis, compared to two (8.0%) of the 25 women who reported that the birth attendant did not wash their hands before inserting them into the vagina ( $\chi^2_{(1)} =$ , p-value=0.012). In addition, 0.2% of deliveries by an attendant who wore new gloves developed puerperal sepsis, compared to 1.5% of deliveries by attendants who washed their hands only.

Several factors were significantly associated with the incidence of infection in a bivariate analysis. These included the woman bathing before delivery, shaving before delivery, and experiencing a long labor. A majority of women (85%) reported both bathing and shaving before delivery and only 4% of women reported neither bathing nor shaving before delivery. As noted in Table 11, women who bathed or shaved before delivery had significantly fewer cases of puerperal sepsis than women who did not bathe or shave before delivery ( $\chi^2_{(1)}=24.70$ , p-value= < 0.001 and  $\chi^2_{(1)}=9.71$ , p-value=0.002 respectively). Women who experienced labor for more than three hours had significantly more cases of puerperal sepsis than women who experienced labor lasting under three hours ( $\chi^2_{(2)}=14.32$ , p-value=0.001).

**Table 11: Summary of factors associated with puerperal sepsis**

Factor	Infection	No infection	p-value
<i>Bath before delivery</i>			
Yes	47 (1.7)*	2742 (98.3)	< 0.001
No	21 (5.7)	349 (94.3)	
<i>Shave before delivery</i>			
Yes	56 (1.9)	2862 (98.1)	=0.002
No	12 (4.9)	231 (95.1)	
<i>Duration of labor</i>			
0-3 hrs**	12 (1.5)	774 (98.5)	=0.001
3-6 hrs	29 (1.7)	1654 (98.3)	
> 6 hrs	28 (4.0)	681 (96.0)	

\*Values in parentheses are percentages.

\*\*0-179 minutes.

All 69 women with puerperal sepsis and 3,058 (98%) of women without puerperal sepsis indicated that they used clean items (sanitary pads, cotton, wool, or clean cloth) to cover the perineum after delivery. A total of 35 women reported inserting some substance into their vaginas after delivery. Substances included herbs (15 women), soil (4 women), and other substances (16 women). Only three women that developed puerperal sepsis reported that they inserted some substance in their vagina (herbs, soil, or an unknown substance) during the intrapartum period. Although there was a significant difference in the incidence of puerperal sepsis between women who inserted some substances in the vagina and those who did not, this practice was rare ( $\chi^2_{(1)} = 7.05$ , p-value < 0.001).

### Results of logistic regression

Results from multiple regression analyses indicated that there was evidence of an independent association between the use of at least the plastic sheet in the kit and where the delivery took place, or whether a woman had a bath or shaved before delivery, or the place of delivery or duration of labor. To examine the independent effect of the use of the kit in reducing puerperal sepsis, these potentially confounding factors were adjusted for. After adjusting for each factor individually, any change in the odds ratio for use of the kit of more than 10% was considered important (Table 12).<sup>12</sup> The change in the odds ratio for use of the kit after adjusting for these factors indicated an important change when kit use was adjusted for bath before delivery, place of delivery or duration of labor.

**Table 12: Summary of kit use adjusting for other factors that are associated with puerperal sepsis**

Factor adjusted for	Odds ratio for kit use	p-value	CI for odds ratio
Unadjusted	3.52	<0.001	2.06, 6.00
Bath before delivery	3.39	<0.001	1.96, 5.87
Shave before delivery	3.53	<0.001	2.04, 6.09
Place of delivery	3.61	<0.001	2.11, 6.16
Duration of labor	3.39	<0.001	1.99, 5.80

After adjusting for whether a woman had a bath before delivery, where delivery took place, and duration of labor, both kit use and bathing before delivery were strongly associated with the incidence of puerperal infection (Table 13). A woman who did not use at least the plastic sheet in the kit for delivery was about three times more likely to develop puerperal sepsis than a woman who used at least the plastic sheet in the kit. A woman who bathed before delivery was also about three times less likely to develop puerperal sepsis than a woman who did not bathe before delivery.

**Table 13: Summary of the adjusted odds ratio of factors that are associated with puerperal sepsis**

Factor	Odds ratio	p-value	CI for odds ratio
<i>i) Kit use</i>			
Yes	1.0		
No	3.4	<0.001	1.94, 5.86
<i>ii) Bath before delivery</i>			
Yes	1.0		
No	2.7	<0.001	1.59, 4.70
<i>iii) Place of delivery</i>			
Home	1.0		
Medical facility	0.7	0.169	0.40, 1.17
Other places	1.7	0.349	0.57, 4.87
<i>iv) Duration of labor</i>			
0-3 hrs*	1.0		
3-6 hrs	1.3	0.441	0.66, 2.61
> 6 hrs	2.7	0.004	1.37, 5.50

\* 0-179 minutes.

## **IIIX. Summary of Qualitative Research Findings**

A total of 18 in-depth interviews were carried out randomly across clusters. Ten were conducted with kit users (one had puerperal infection, nine had no infection) and eight were conducted with kit non-users (two had puerperal infection, one had cord infection, five had no infection).

### **Demographic Characteristics of the Respondents**

The age range of the 18 respondents was from 17 to 45 years, with half of the respondents between 20 and 35 years of age. Nine (50%) of the respondents had at least completed primary school education. Two had never attended school, and six had begun but did not complete primary school. One respondent who was a schoolteacher had completed secondary school education. The majority of the respondents were peasant farmers, and a few were engaged in small business such as operating food stalls. Half of the respondents were married. Only one respondent was having her first birth (primigravida).

### **Delivery Practices**

#### **Place of delivery**

Ten women reported that they delivered at home (eight kit users and two kit non-users). The remaining eight (three kit users and five kit non-users) delivered in local dispensaries or hospitals. Women who delivered at home gave reasons such as labor beginning late at night, labor beginning suddenly hence no time to go to dispensary, dispensary being far from their homes, and having no one to take them to the dispensary.

#### **Cord cutting practices**

The kit users reported that the cord was cut using the new razor blade included in the delivery kit. However, one respondent reported that she did not see how the nurse who helped her during delivery cut the cord, as she was very tired. Among the kit non-users, three reported using a razor blade to cut the cord, three reported health workers using a pair of scissors to cut the cord, one said she did not see what was used, and one did not respond to the question.

#### **Cord care**

The majority of respondents reported not putting anything on the cord until it healed. One kit user reported putting baby powder on the cord stump and two kit non-users reported putting salt on the cord stump to accelerate healing. One of the two respondents who put salt on their baby's cord said she did that on the second, third, and fourth day after delivery after being told so by her grandmother. The other respondent said her neighbor advised her to put salt mixed with baby oil three times a day for three days. The fourth respondent (kit non-user) used an antiseptic (Dettol) to clean her baby's cord on the sixth day after delivery. She said while cleaning her baby's cord, blood started coming out, and she then took her baby for treatment at a local dispensary as the baby had a cord infection. One kit user reported washing her child's cord twice a day using warm water as advised by a health worker in her local clinic.

## **Hand washing**

Most respondents (nine kit users and six kit non-users) reported that the people who assisted them during delivery washed their hands using soap. One kit non-user said the health worker who assisted her during delivery did not wash hands but did put on gloves. One respondent said that she delivered herself and she just had a bath before labor began.

## **Perineum care and puerperal infection**

All respondents reported that they washed their perineum using water and soap before and after delivery. The majority of respondents specifically said that they washed the perineum in order to avoid infection and also to be “clean.” A few respondents said that they were told by health workers to wash their perineum in order to avoid getting infection.

As indicated in the breakdown of the number of in-depth interviews conducted, three respondents had puerperal sepsis infection (one kit user and two kit non-users). The kit user who had puerperal infection, reported that she delivered at the local dispensary because she was experiencing abdominal pains before labor started. She also said she decided to deliver at the clinic so as to get help if anything went wrong. The respondent reported that she had bathed at home before the onset of labor because a health worker had taught her to be clean before delivery to avoid infection.

Among the two kit non-users who had puerperal sepsis infection, one reported delivering at home and the other one reported delivering at a local clinic. The respondent who delivered at home said she did so because her labor was shorter (only one day) than her previous labor experiences (normally two to three days). The respondent reported that her neighbor assisted her in delivery. The other kit non-user reported that she delivered at a local dispensary with the aid of the health worker in charge.

## **Disposal of kit items after use**

The vast majority of kit users stated that they disposed of the razor blade in a pit latrine. Most users also stated that they washed the soap and plastic sheet for reuse in their household.

## **Awareness and Appropriateness of Kit**

### **Awareness of the kit**

The eight kit non-users reported that they had heard about the delivery kit from health workers when they went to local dispensaries. The ten respondents who used the kit also reported that they first heard about the kit from the health workers in their local clinics.

### **Pictorial instructions**

A majority of respondents said they were able to understand the pictorial instructions included in the kit. Among the ten kit users, two said they did not understand the instructions because they could not read. One respondent did not use the pictorial instructions because she had no time to look at them after labor started. Three respondents said they did not use the instructions because the health workers who helped them during delivery had enough experience. One respondent

suggested that the instructions should be written in Kiswahili. One suggested that the pictures should be enlarged in order to make them easier to understand.

The pictorial instructions were introduced to the kit non-users during the interviews. Among the eight kit non-users, one could not interpret the instructions well, perhaps because she had never been to school. Three kit non-users suggested that the pictures should be enlarged, and one suggested that the instructions be in Kiswahili. Two suggested that the instructions should be on heavier paper, and one suggested using photographs instead of drawings.

## **Acceptability of the Delivery Kit**

### **Willingness to use**

The eight kit non-users said they would have been willing to use the delivery kit if it had been made available to them. The ten kit users said they liked using the kit, and they recommend it to other women.

### **Willingness and ability to pay**

All 18 respondents said they are willing to pay for the delivery kit for a price of between 200 and 500 Tanzanian shillings (US\$0.20-\$0.50). The majority of the respondents said they were willing to pay for the kit because it would ensure a safe and hygienic delivery, and therefore avoid infection. The ability to pay seems realistic as the majority of respondents reported that they had put aside between 500 and 20,000 Tanzanian shillings (US\$0.50-\$20) as preparation for their delivery. Only one respondent, a kit user, reported that she did not put aside any money in preparation for delivery, as she did not have any.

### **Overall feelings about the kit**

All the ten respondents who used the kit said they liked all the items included in it. They said that the items were useful in helping them deliver safely without infection. Two respondents said they liked the plastic sheet most because their babies are still using it for sleeping. In general, kit users appeared to be able to use all kit contents correctly.

## **Conclusions**

Respondents who used the kit found it acceptable and were able to use it correctly and reported satisfaction with the way the kit contributed to a clean delivery. All respondents showed willingness to pay for the delivery kit. Respondents did not report difficulties in using the kit, and they recommended it should be used by other women. Some harmful local beliefs about cord care (e.g., putting salt on the cord stump speeds up healing) need to be addressed. A possible time to address these issues may be during educational sessions when women are supplied with the kits. Future development of kit instructions should carefully consider whether text in a local language should accompany illustrations and thoroughly pretesting to ensure the instructions are understood by the target audience.

## IX. Discussion

### Impact of the Clean Delivery Kit on Cord Infection and Puerperal Sepsis

This study has shown a very substantial and statistically significant association between the reported use of the relevant components of a clean delivery kit containing a plastic sheet, soap, clean razor blade, cord ties, and user instructions in reducing the risk of cord infection (adjusted odds ratio= 12.6,  $p<0.001$ ) and puerperal sepsis (adjusted odds ratio= 3.4,  $p<0.001$ ). Infants whose mothers used the kit had substantially lower rates of cord infection and women who used the kit had substantially lower rates of puerperal sepsis. The effect of the kit on cord infection was much greater than on puerperal sepsis.

In addition, a woman who bathed before delivery was less likely to develop puerperal sepsis than a woman who did not bath before delivery, and a newborn of a woman who bathed before delivery was less likely to develop cord infection than a newborn of a woman who did not bathe before delivery. Taking a bath with soap and water before delivery likely decreases the incidence of puerperal sepsis and cord infection by reducing the number of exogenous organisms on the body surface, especially in the perineum and vulva area, that could be introduced in the birth canal before, during, or after delivery, or introduced into the cord during cutting. While bathing before delivery had about the same independent effect on puerperal sepsis as kit use, the added benefit of the kit is that it also helps reduce cord infection. Information about use of the soap in the kit by women to wash themselves before delivery was not collected. The presence of soap in the kit may have made it easier for women to bathe before delivery.

### Ensuring the “Six Cleans” During Delivery

The concept of “six cleans” as advocated by WHO reiterates the importance of clean hands, clean perineum (nothing unclean inserted into the vagina), clean delivery surface, clean cord cutting tool, clean cord tie, and clean cutting surface. Each one of the kit’s contents is selected to help ensure one of these “six cleans.” For example, the bar of soap provided the means of hygiene required to achieve clean hands and a clean perineum. The plastic sheet provided the means to achieve a clean delivery surface. The razor blade and cord ties in the delivery kit provide clean cord-cutting and cord-tying instruments.

Washing hands by birth attendants before the delivery and the use of new gloves were not found to be an important factors affecting rates of sepsis. While new gloves used by trained health workers reduce contamination, the technique of wearing gloves is not always easy for home birth attendants or family members to master and thus use of gloves does not guarantee sterility. Reuse of gloves could also potentially be a problem. Almost all women (99%) reported that they used clean materials to cover their perineum after delivery.

Longer labor (more than six hours) was also associated with increased risk of puerperal sepsis although it was not retained in the final logistic regression model. This was not unexpected as women with longer duration of labor are more likely to experience long hours between the rupture of membranes and delivery, more hours of uterine contraction, and an increase in ascending spread of endogenous and exogenous microorganisms that can cause upper genital tract infection.<sup>6,10</sup>

## Strengths and Limitations of the Study

The use of both maternal recall (aided by photos) and direct interviewer observation—coupled with confirmation from a clinician—improved the likelihood that the majority of all clinical cord and puerperal sepsis infections that occurred in the study population were identified. The short time for maternal recall due to the timely nature of health worker visits at five days after delivery helped ensure that information was reliable.

It should be noted, however, that the study was implemented in two districts where the nonprofit organization CARE has managed a system for active community-based maternal and perinatal surveillance for several years. It is possible that women living in these districts had more exposure to information about clean delivery than women in other areas of Tanzania. One component of CARE's surveillance system was to teach mothers about clean delivery and cord care. During the study, mothers were taught about WHO's "six cleans," and were given a clean delivery kit. This study showed that women who used the kit and had ancillary education had better outcomes than women who did not use the kit but still received ancillary education. Thus the delivery kit made the difference above and beyond the ancillary education. It is likely that the delivery kit plus ancillary education intervention would have shown an even greater effect in an area where the population was not exposed to an ancillary education intervention on the "six cleans." It is also possible that without this ancillary education, the impact of the use of clean delivery kits in preventing puerperal sepsis and cord infection may have been greater.

The design allowed for enrollment of respondents with minimal disruption to existing health services. In some cases, the close proximity of the clusters made it difficult to control for contamination effects. For example, there was a higher-than-expected percentage of kit use in Sumbugu (cluster 9). This cluster is a neighboring cluster to Mbarika (cluster 5) which has a large market and health facility. Mbarika cluster enrolled respondents six months prior to Sumbugu cluster. It is possible that women from Sumbugu cluster might have obtained the delivery kits (due to their popularity) in Mbarika and delivered in Sumbugu (their resident cluster), thereby giving women from this cluster more time to obtain and use the kit than anticipated.

This study was originally intended to be a two-armed cluster randomized trial, however the data analysis plan was altered to best utilize available data collected in the field. The study was analyzed as a cross-sectional study; thus an "intent to treat" analysis normally employed in a randomized cluster trial design was not undertaken.

As in any cross-sectional study, respondent and selection biases may have been present. Not all women who gave birth during the study period were included in the study. Furthermore, women who selected to use the clean delivery kit may have been different in some way from women who chose not to use the kit. Thus, the results of the study should be interpreted conservatively.

## X .Conclusions

The reported use of the relevant components of a clean delivery kit coupled with an educational intervention about the “six cleans” was associated with a substantially lower incidence of both cord infection and puerperal sepsis among women enrolled in the study. The strength of the association between reported kit use and cord infection was much greater than that for puerperal sepsis, but both were substantial and statistically significant. Results indicate that bathing before delivery was associated with a lower incidence of puerperal sepsis but not cord infection. As noted earlier, these results should be interpreted conservatively, as they do not reflect the same level of evidence that would have been obtained from a randomized controlled trial. The strong associations in this study support the need for a rigorously conducted cluster randomized controlled trial.

In low-resource settings where a high proportion of mothers give birth at home, supplies needed to conduct a clean delivery are often not available even in rural dispensaries and health centers. Making clean delivery kits available through government health clinics, markets, private pharmacies, or other commercial channels could likely help reduce rates of infection. The positive association between a woman bathing before delivery and a lower incidence of puerperal sepsis confirms the inclusion of this instruction in the advice given to a woman (and her birth attendants) during antenatal care. Although the encouragement of bathing before delivery could reduce puerperal sepsis nearly as much as the use of a clean delivery kit (odds ratio 2.7 vs. odds ratio 3.4), the reported use of the clean delivery kit was also associated with an independent reduction in cord infection.

A 2003 WHO review of evidence on the impact of newborn health interventions in less-developed countries identified attendant hand washing as a priority intervention to prevent infection during labor and delivery.<sup>13</sup> This review specified that having a skilled birth attendant can save lives and can reduce the risk of infection to mothers and newborns when the birth attendant keeps her or his hands and all contact with the neonate’s umbilical cord (especially cutting instruments and ties) clean. Ideally, mothers should be advised about clean birth, hand washing, and how to correctly use the contents of the kit during antenatal visits at clinics or wherever the kits are sold. Home birth attendants and family members can also learn about kit use to help ensure hygiene during the birth process. In addition, birth attendants and pregnant women should be educated to recognize signs and symptoms of cord infection and puerperal sepsis and to report to a health facility for treatment as soon as possible when symptoms are identified.

The qualitative research indicated that clean delivery kits are viewed as acceptable, appropriate, and useful items, and that women are willing to pay a small fee for them. The written instructions for kit use should be pictorial and/or printed in a local language, and should be carefully pretested to ensure that they are well understood by low-literate women and appropriate for the local culture. Kits should be made widely available at health facilities, pharmacies, and possibly small shops. Training health care workers may be an effective way of educating women about the usefulness of clean delivery kits. Comprehensive maternal and newborn health programs that include training of skilled birth attendants are particularly appropriate venues in which to introduce clean delivery kits.

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# Appendix 1: Post-Partum Reporting Tools for Village Health Workers, Clinical Officers/Assistant Clinical Officers, and Maternal and Child Health Aides

## A. GENERAL INFORMATION

Questionnaire ID#:			
Date of interview	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Name of interviewer:	
	Day Month		
Year			
Cluster:		Village:	
Mother's study ID # :		Mother's age: <input type="text"/> <input type="text"/>	
Ethnicity/Tribe:		Date of delivery: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
		Day Month Year	

1. Mother's marital status
  - a. married—monogamy
  - b. married—polygamy
  - c. divorced/widowed
  - d. single
  - e. unknown
  
2. Educational level completed
  - a. primary school only
  - b. secondary school
  - c. university or post-university
  - d. no school
  - e. literacy classes
  
3. Place of delivery
  - a. home
  - b. dispensary
  - c. health centre
  - d. hospital
  - e. BBA
  - f. unknown
  
4. Was a clean delivery kit used during this delivery?
  - a. yes
  - b. no  if **NO** ----- → Go to **Section III**.

## B. CLEAN DELIVERY KIT USE

5. What type of kit was used during this delivery?
  - a. disposable kit
  - b. TBA
  - c. self-made
  - d. none

## Post-Partum Reporting Tools for VHWs, COs/ACOs, and MCHAs

6. During what trimester did mother receive the kit?
- a. 0-3 months [ ]
- b. 4-6 months [ ]
- c. 7-9 months [ ]
- d. don't know [ ]

**C. INFORMATION ON DELIVERY ATTENDANT**

7. Attendant's code number	8. Attendant's age	<input type="text"/>	<input type="text"/>
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9. What training has attendant had?
- a. <2 weeks formal training [ ]
- b. >2 weeks formal training [ ]
- c. no training [ ]
- d. don't know [ ]

10. What is attendants relationship to the mother who just gave birth?
- a. neighbor [ ]
- b. family member [ ]
- c. other relative (specify: \_\_\_\_\_) [ ]
- d. TBA [ ]
- e. health facility worker [ ]

11. How many babies does attendant deliver each year? \_\_\_\_\_
- This year? \_\_\_\_\_
- Last year? \_\_\_\_\_

**D. DELIVERY PROCESS AND CORD CARE**

12. Was the mother bathed before delivery?
- a. yes [ ]
- b. no [ ]
13. Was the mother shaved before delivery?
- a. yes [ ]
- b. no [ ]
14. Onto what surface did the mother give birth?
- a. makintosh [ ]
- b. bed [ ]
- c. bare ground [ ]
- d. mat [ ]
- e. other: \_\_\_\_\_ [ ]
15. Did the attendant insert her hands into vagina?
- a. yes [ ]
- b. no [ ] *if NO ----- → go to question 19*
16. Did attendant wash her hands before inserting into vagina?
- a. yes [ ]
- b. no [ ] *if NO ----- → go to question 19*

## Post-Partum Reporting Tools for VHWs, COs/ACOs, and MCHAs

17. How did she wash her hands?
- a. water only [ ]
  - b. soap and water [ ]
  - c. antiseptic [ ] *if c ----- → go to question 19*
18. What was the source of water used to wash hands?
- a. well or pump [ ]
  - b. faucet [ ]
  - c. open source of standing water [ ]
  - d. other (specify: \_\_\_\_\_) [ ]
19. Did the attendant wear gloves?
- a. Yes – new pair [ ]
  - b. Yes – reused pair [ ]
  - c. No [ ]
  - d. Unknown [ ]
20. Were any substances inserted into vagina?
- a. herbs [ ]
  - b. soil [ ]
  - c. other \_\_\_\_\_ [ ]
  - d. none [ ]
21. What was used to cut the umbilical cord?
- a. razor from kit [ ]
  - b. knife/razor not from kit [ ]
  - c. boiled razor not from kit [ ]
  - d. other (specify: \_\_\_\_\_) [ ]
22. What was used to tie the umbilical cord?
- a. cord tie from kit [ ]
  - b. other cord tie or string [ ]
  - c. source of cord tie: \_\_\_\_\_ [ ]
23. What was placed on the cord stump?
- a. dung [ ]
  - b. soil [ ]
  - c. plants or herbs [ ]
  - d. nothing [ ]
  - e. other (specify: \_\_\_\_\_) [ ]
24. What was used to wrap the baby immediately after delivery?
- a. clean cloth [ ]
  - b. unclean cloth [ ]
  - c. nothing [ ]
  - d. other (specify: \_\_\_\_\_) [ ]
25. What was used to cover the mothers perineum?
- a. sanitary pad [ ]
  - b. clean cloth (new or recently washed) [ ]
  - c. unclean cloth [ ]
  - d. cotton wool [ ]
  - e. other (specify: \_\_\_\_\_) [ ]

## Post-Partum Reporting Tools for VHWs, COs/ACOs, and MCHAs

26. Is the baby breastfeeding now?  
 a. yes   
 b. no  *If NO ----- → go to question 28*
27. Is the baby having any problems breastfeeding?  
 c. yes  (specify problem: \_\_\_\_\_)  
 d. no
28. How was the used razor blade from the kit disposed of?  
 a. buried in the ground   
 b. thrown in rubbish pile   
 c. burned in fire   
 d. boiled for re-use   
 e. don't know   
 f. other (specify: \_\_\_\_\_)

**E. SCREENING OF CORD INFECTION**

29. Is there any redness of abdominal tissues near cord?  
 a. yes   
 b. no
30. Is there tenderness of abdominal tissues near the cord?  
 a. yes   
 b. no
31. Is there any pus discharge around cord or from tip of cord?  
 a. yes   
 b. no

**If any above signs are present, escort mother to nearest medical facility for diagnosis. See clinical screening questionnaire below.**

**F. SCREENING OF PUERPERAL SEPSIS**

32. Does the mother report having "homa" or a fever?  
 a. yes   
 b. no
33. How does the mother's body temperature feel to the touch (forehead)?  
 a. hot   
 b. normal/cold

34. Sublingual temperature of mother [record actual digital temperature]	<input type="text"/>	<input type="text"/>	<input type="text"/>
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35. Is the mother experiencing lower abdominal pain?  
 a. yes   
 b. no
36. Is the mother experiencing lower abdominal tenderness?  
 a. yes   
 b. no

## Post-Partum Reporting Tools for VHWs, COs/ACOs, and MCHAs

37. Does the mother report having foul-smelling vaginal discharge?
- a. yes [ ]
- b. no [ ]

**If any above signs are present, escort mother to nearest medical facility for diagnosis. See clinical questionnaire below.**

<b>G. CLINICIANS DIAGNOSIS</b>			
Facility ID:	<input type="text"/>	Date of visit: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	
<b>Clinician's Checklist for Puerperal Sepsis</b>		<b>Present</b>	<b>Absent</b>
Sublingual temperature (record actual in Centigrade)	<input type="text"/> High fever >38°C?		
	Abnormal lochia?		
	Lower abdominal pain?		
	Lower abdominal tenderness?		
<b>Clinician's Checklist for Cord Infection</b>			
	Erythema?		
	Tenderness or swelling of cord?		
	Tenderness or swelling of abdominal tissue near cord?		
	Pus discharge around cord?		
	Smelly or moist stump?		

### **H. RECORDING OF SCREENED PATIENTS FOR PUERPERAL SEPSIS AND CORD INFECTION**

Register books retained at participating health facilities during course of the study. A sample is as follows.

ID#	Village	Type Mother or child	Sex Male or female	Suspected problem	Clinical diagnosis	Signature of clinician

## Appendix 2: In-Depth Interview Topic Guide

### Topic Guide for Kit Users

#### *Introduction*

“We are trying to learn more about the health of women and birth practices in Mwanza. We want to talk with you about your practices during the delivery of your baby. The information you give us will help us understand how we might be able to make giving birth a safer experience for mothers and babies.

If you agree to talk with us, the interview will take less than one hour. No harm will come to you or your baby as a result of our visit. We know some of these questions are sensitive, and we will make sure your answers are confidential. Your participation is voluntary, and you may stop the interview at any time if you do not wish to continue.”

Date of interview: \_\_\_\_\_

Name of community: \_\_\_\_\_

Date of birth of baby: \_\_\_\_\_ day \_\_\_\_\_ month \_\_\_\_\_ year

Mother’s study identification #: \_\_\_\_\_

Approximate age of mother: \_\_\_\_\_

Number of children: \_\_\_\_\_

#### ***PREPARATIONS FOR DELIVERY***

##### **1. What preparations did you make before delivery, while you were pregnant?**

Probe:

- What preparations did you make before the onset of labor?
- Did you put aside money, food or clothes during pregnancy?

#### ***KIT USE***

##### **2. I understand that you used a Delivery Kit during your latest delivery. Could you please tell me about your decision to use the kit?**

Probe:

- Have you ever used the kit in the past?
- How did you learn or hear about the kit?
- Who advised you to use the kit?
- What did they say that convinced you the kit would be helpful?

**3. Where did you get the kit?***Probe:*

- If you wanted to buy a kit in the future, where (from whom) would you like to buy it?
  - shop
  - pharmacy
  - clinic or hospital
  - mothers' group
  - community distribution center or community-based organization
  - TBA
  - other: \_\_\_\_\_
- How much would you pay for this kit?

**DESCRIPTION OF DELIVERY****4. Where did you give birth? Who assisted you during delivery?***Probe:*

- What preparations did you or the birth attendant make just before delivering the baby?
- Did the attendant put anything underneath you?
- Did the attendant wash the perineum?
- Did the attendant wash their hands? Was soap used?

**5. Who actually cut the cord of your baby, and how was it done?***Probe:*

- What item was used to cut the cord?
- What was the cord cut on (cutting surface)?
- What preparation, if any, was done to the instrument used to cut the cord?
- What, if anything, was put on the cord? after cutting (cloth, oil/Vaseline, powder, dung, herbs)?
- What is the substance that was put on the cord supposed to do?
- How long was the substance left on the cord?

**6. How were items used during the delivery disposed of?**Items were:  burned or  buried or  other (specify): \_\_\_\_\_*Probe:*

- Why were the items disposed of in this way?
- Were any of the items in the kit re-used? If so, which ones?
- How were items cleaned before they were re-used?

**7. How do you feel about washing your hands with soap during delivery?***Probe:*

- Is washing your hands with soap during delivery important? If so, why?
- At what times during delivery did the person assisting you wash their your hands? Why?

## In-Depth Interview Topic Guide

- Did the person assisting you during delivery to give birth wash their hands before delivering the baby? Why?
- Did they wash their hands before cutting the cord? Why?

**8. How was the baby taken care of immediately after birth?**

*Probe:*

- Who wrapped the baby and when? What was baby wrapped in?
- How soon after birth did you begin to breastfeed your baby?
- What other kinds of food/drink were given to the newborn baby?

**OVERALL FEELINGS ABOUT THE KIT**

**9. List two characteristics you liked *most* about the kit.**

*Probe:*

- What item or items in the kit were most helpful to you and why?
- How were they helpful?

**10. List two characteristics you liked *least* about the kit.**

*Probe:*

- What items in the kit were least helpful (or not used) and why?
- Can you explain what it is about them was not helpful?

**11. Would you buy a kit for future deliveries or recommend it to another woman?**

Please explain.

If *yes*, **why?** (*don't read, just check any of the responses cited by the mother*)

- kit is easy to use
- kit is convenient
- feels that use of the kit ensures a healthy delivery
- kit is affordable
- kit is useful

If *no*, **why not?** (*don't read*)

- kit not easily available
- kit too much work
- kit not useful (probe: why not?)
- kit not useful

**PICTORIAL INSTRUCTIONS**

**12. In the kit, there is a piece of paper with illustrations and some writing (*show the pictorial insert to the respondent*). What did you think the purpose of this paper was, and what did you do with it?**

**13. What, if anything, did you learn from the pictures?** [*Show the entire pictorial insert and tick any messages mentioned spontaneously. After each, ask “Anything else?”*]

- Attendant should wash hands
- Use plastic sheet underneath mother
- Wrap baby right after delivery
- Wash hands with soap before tying cord
- Use cord ties
- Cut with the clean razor blade
- Bury everything in a hole after delivery
- Begin breastfeeding right after birth
- Nothing
- Don't remember
- Other, please specify: \_\_\_\_\_
  - How would you suggest improving the illustrations?

**14. Did the instructions in the delivery kit help you to learn or remember something about how to do a delivery?**

*Probe: if yes,*

- What, if anything, have you heard about “clean delivery”?
- wash hands washed with soap (clean hands)
- use cord ties (clean cord care)
- use plastic sheet (clean delivery surface)
- use razor blade (clean cord cutting instrument)

*Probe: if no:- if no,*

- Please tell us why these instructions were not helpful when you used the kit
- Were you not accustomed to using written instructions?
- Was it difficult for you to understand the instructions?
- Were the drawings not clear?

**15. Did the information in the delivery kit have an effect on you regarding washing hands with soap?**

*Probe: if yes,*

- Did the kit remind you to wash your hands or ask your birth attendant to wash their hands more than before?
- What about the kit influenced you (or ask birth attendant) to wash your hands with soap?

*Probe: - if no, please help us understand why the kit had no effect on hand washing.*

**Thank you for helping us understand more about how to make delivery safer for all women and children.**

## Topic Guide for Kit Non-users

### *Introduction*

“We are trying to learn more about the health of women and birth practices in Mwanza. We want to talk with you about your practices during the delivery of your baby. The information you give us will help us understand how we might be able to make giving birth a safer experience for mothers and babies.

If you agree to talk with us, the interview will take less than one hour. No harm will come to you or your baby as a result of our visit. We know some of these questions are sensitive, and we will make sure your answers are confidential. Your participation is voluntary, and you may stop the interview at any time if you do not wish to continue.”

Date of interview: \_\_\_\_\_  
 Name of community: \_\_\_\_\_  
 Date of birth of baby: \_\_\_\_\_ day \_\_\_\_\_ month \_\_\_\_\_ year  
 Mother’s study identification #: \_\_\_\_\_  
 Approximate age of mother: \_\_\_\_\_  
 Number of children: \_\_\_\_\_

### **PREPARATIONS FOR DELIVERY**

#### **1. What preparations did you make before delivery, while you were pregnant?**

*Probe:*

- What preparations did you make before the onset of labor?
- Did you put aside money, food or clothes during pregnancy?

### **DESCRIPTION OF DELIVERY**

#### **2. Where did you give birth? Who assisted you during delivery?**

*Probe:*

- What preparations did you or the birth attendant make just before delivering the baby?
- Did the attendant put anything underneath you?
- Did the attendant wash the perineum?
- Did the attendant wash their hands? Was soap used?

#### **3. Who actually cut the cord of your baby, and how was it done?**

*Probe:*

- What item was used to cut the cord?
- What was the cord cut on (cutting surface)?
- What preparation, if any, was done to the instrument used to cut the cord?
- What, if anything, was put on the cord (cloth, mustard oil, ghee, herbs)?
- What is the substance that was put on the cord supposed to do?
- How long was the substance left on the cord?

4. *How were items used during the delivery disposed of?*

Items were  burned or  buried or  other (specify): \_\_\_\_\_

*Probe:*

- Why were the items disposed of in this way?
- Were any of the items in the kit re-used? If so, which ones?
- How were items cleaned before they were re-used?

5. *How do you feel about washing your hands with soap during delivery?*

*Probe:*

- Is washing hands with soap during delivery important? If so, why?
- At what times during delivery did the person assisting you wash their hands? Why?
- Did the person assisting you during delivery wash their hands before delivering the baby? Why? Did they use soap?
- Did they wash their hands before cutting the cord? Why?

6. *How was the baby taken care of immediately after birth?*

*Probe:*

- Who wrapped the baby and when? What was the baby wrapped in?
- How soon after birth did you begin to breastfeed your baby?
- What other kinds of food/drink were given to the newborn baby?

### **KNOWLEDGE OF DELIVERY KIT**

7. **Have you ever heard of a clean delivery kit?**

- What do you know about the kit?
- Have you ever used the kit in the past?
- How did you learn or hear about the kit?

8. **Why didn't you use a clean delivery kit for your most recent pregnancy?**

9. **Would you buy a kit for future deliveries or recommend it to another woman?**

Please explain.

If yes, **why?**

- kit is easy to use
- kit is convenient
- feels that use of the kit ensures a healthy delivery
- kit is affordable
- kit is useful

If no, **why not?**

- kit not easily available
- kit too much work
- kit not useful (probe: why not?)
- kit not necessary

**PICTORIAL INSTRUCTIONS****10. In the kit, there is a piece of paper with illustrations and some writing.**

*Show the pictorial insert to the respondent.*

- What do you think is the purpose of this paper? What would you do with it?
- What, if anything, do you learn from the pictures?

*[Show the entire pictorial insert and tick any messages mentioned spontaneously.*

*After each, ask "Anything else?"]*

- Attendant should wash hands
- Use plastic sheet underneath mother
- Wrap baby right after delivery
- Wash hands with soap before tying cord
- Use cord ties
- Cut with the clean razor blade
- Bury everything in a hole after delivery
- Begin breastfeeding right after birth
- Nothing
- Don't remember
- Other, please specify: \_\_\_\_\_
- How would you suggest improving the illustrations?

**Thank you for helping us understand more about how to make delivery safer for all women and children.**