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## **Feasibility and acceptability of clean birth kits containing misoprostol for self-administration to prevent postpartum hemorrhage in rural Papua New Guinea**

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## ABSTRACT

*Objective:* To determine the feasibility and acceptability of providing clean birth kits (CBKs) containing misoprostol for self-administration in a rural setting in Papua New Guinea.

*Methods:* A prospective intervention study was conducted between April 8, 2013, and October 24, 2014. Eligible participants were women in the third trimester of pregnancy who attended a prenatal clinic in Unggai Bena. Participants received individual instruction and were then given a CBK containing 600 µg misoprostol tablets for self-administration following an unsupervised birth if they could demonstrate their understanding of correct use of items in the CBK. Data regarding the use and acceptability of the CBK and misoprostol were collected during postpartum follow-up.

*Results:* Among 200 participants, 106 (53.0%) had an unsupervised birth, and 99 (93.4%) of these women used the CBK. All would use the CBK again and would recommend it to others. Among these 99 women, misoprostol was self-administered by 98 (99.0%), all of whom would take the drug again and would recommend it to others.

*Conclusion:* The findings strengthen the case for community-based use of misoprostol to prevent postpartum hemorrhage in remote communities. Large-scale interventions should be planned to further evaluate impact and acceptability.

## 1. Introduction

Most maternal deaths occur in low-resource settings [1], primarily in remote and rural communities when births are not assisted by skilled attendants. Globally, postpartum hemorrhage (PPH) is the leading cause of maternal mortality [1], but this complication can be prevented by the use of uterotonic agents, such as oxytocin [2]. However, oxytocin requires intramuscular administration and refrigerated storage, making this potentially life-saving intervention unavailable for the millions of women who experience unsupervised delivery.

Misoprostol has been suggested as a substitute to oxytocin in low-resource settings [3,4]. The safety and efficacy of 600 µg orally administered misoprostol to prevent PPH in community settings has been documented in several countries [3,5–14]. Distribution of misoprostol has been undertaken by community health workers, including traditional birth attendants [5–8,13]. In some settings, this drug has been distributed to women for self-administration [9–12,14]. Such distribution is frequently undertaken in conjunction with training and education about birth preparedness, the importance of supervised births, recognizing danger signs (including PPH), the correct timing for taking misoprostol, and common adverse effects [3,6,8–12,14].

In 2012, in recognition of the limited evidence to support distribution of self-administered misoprostol, WHO and the International Federation of Gynecology and Obstetrics called for research to evaluate the inclusion of misoprostol in effective, locally appropriate, and comprehensive community-based interventions [15]. The distribution of clean birth kits (CBKs) to support hygienic birth practices is one such intervention that has been frequently used in low-resource settings [16]. The potential benefit of including additional items in these kits, such as misoprostol, has been suggested [17], although this advice has not been formally evaluated in such settings.

Papua New Guinea (PNG) is a low-to-middle-income country in the Asia–Pacific region. Access to skilled health care in this country is limited as a result of geographic, infrastructure, and logistical challenges. The majority (87%) of the 7.2 million residents of PNG live in rural areas [18]. Furthermore, PNG has one of the highest maternal mortality ratios in the world, with 594–733 maternal deaths per 100 000 live births [1,19]. Although 78% of women in PNG attend a prenatal clinic at least once during their pregnancy, only 44% experience supervised delivery within a health facility [20]. Many women give birth in the community, either alone or with a female relative to support them. In PNG—as in many low-resource settings—PPH and sepsis are the leading causes of maternal mortality [21].

The aim of the present study was to evaluate the distribution of misoprostol as part of a comprehensive community-based strategy to prevent PPH and to describe the feasibility and acceptability of CBKs and misoprostol among participants in a remote rural setting in PNG.

## 2. Materials and methods

A prospective community-based intervention study was conducted between April 8, 2013, and October 24, 2014. Women in the third trimester of pregnancy (on the basis of clinical assessment) who attended a prenatal clinic at government health

facilities in Unggai Bena were eligible to participate. The eligibility criteria limited the time between receiving the intervention and the estimated delivery date. Exclusion criteria were a history of mental illness and age younger than 16 years. Ethical approval was provided by the Institutional Review Board of the PNG Institute of Medical Research, Goroka; the Medical Research Advisory Committee, PNG National Department of Health, Port Moresby; and the Human Research Ethics Committee, University of Queensland, Brisbane, QLD, Australia. Women willing to participate completed written informed consent procedures. For women unable to sign owing to illiteracy, a witness signature confirmed that the participant had understood the consent process and was providing informed consent. All women were assigned a unique study identity number.

The study was conducted within Unggai Bena, one of eight administrative districts in the Eastern Highlands Province of PNG. Coverage of maternal health care in this predominantly rural area is low, with only 68% of women attending a prenatal clinic on at least one occasion; the supervised birth rate is just 38% [20]. The present study site of Upper Bena is accessible by one unsurfaced road, often impassable after heavy rain. Many villages are located in steep mountainous terrain and accessible only by bush tracks. Four government health facilities in the area (three aid posts and one health center) offer a range of preventive and curative services, including weekly prenatal clinics. The health center is equipped to manage uncomplicated births, which are conducted primarily by nurses. There is one midwife at the health center.

Review of the available provincial-level maternal health data for 2012 (the year in which the present study was planned) indicated a supervised birth rate at the study site of approximately 7%. The proportion of women who attend the provincial hospital, or other facilities, for a supervised birth is not systematically recorded; however, previous research in the area suggested that most women give birth unsupervised in the community, either alone or supported by family [19,22].

Visual teaching aids were designed using nationally available safe motherhood teaching aids and messages, and piloted by a research team from the PNG Institute of Medical Research, Goroka. The research team comprised a health extension officer (E.W.) (a professional health worker with 4 years of formal training), a midwife (P.H.), and two community liaison officers (M.M. and M.T.), supported by the principal investigator (L.M.V.). All team members were experienced in the conduct of community-based field research. The teaching aids, which highlighted key messages relating to birth preparedness (Box 1), were used to disseminate information through community sessions at both informal and formal gatherings, including at village markets, after church services, and at participating prenatal clinics.

Pictorial flipcharts for the CBKs and misoprostol, including correct use of each item, were also designed and piloted. Each CBK contained a piece of soap, a pair of gloves (non-sterile), a plastic sheet, a scalpel blade, two cord ties, and a sealed packet containing three misoprostol tablets (600 µg in total) to be taken orally after delivery. The misoprostol tablets were repackaged by the research team and labeled “safer afterbirth” tablets before inclusion in the CBK to comply with a requirement

from the ethics committees in PNG following concerns that misoprostol could be used inappropriately (e.g. to induce abortion).

At enrollment, women received one-to-one education using the pictorial flip charts, before being provided with the CBK. Educational activities were undertaken by the health extension officer or research midwife. Women were advised about the risks of taking the misoprostol tablets too soon (i.e. before delivery) and about common minor adverse effects. Using a study-specific checklist, participants were required to demonstrate their understanding of the correct use of each item in the CBK, specifically the use of misoprostol, before the CBK was provided. Women who did not demonstrate the correct knowledge did not receive the CBK at enrollment. These women were asked to return to the prenatal clinic the following week to receive further instruction and to be reassessed regarding their knowledge before provision of the CBK. A pictorial insert on the use of each item (Figure 1) and a birth notification card (to enable postpartum follow-up) were also included in the CBK.

Sociodemographic data and obstetric history were collected using a study-specific case record form that had previously been tested in this setting (unpublished data). Locator information, including distance from health facility and road access, was collected to enable the research team to visit participants in their villages, communicate key messages to their community (Box 1), and to facilitate postnatal follow-up.

Participants were visited in the community by the research team during the postpartum period. A semi-structured questionnaire was used to collect information relating to birth experience (including location of birth) and the use of each item in the CBK. Probing questions were used where necessary. Unused CBKs, including misoprostol tablets, were collected by the research team and disposed of in accordance with study-specific standard operating procedures.

All individual prenatal information sessions and postpartum interviews took place in quiet, private areas at the health facility or in the woman's home, unless she requested otherwise. All community information sessions and individual interviews were conducted in Tok Pisin, one of three official national languages in PNG.

The data were analyzed using STATA version 10.0 (StataCorp, College Station, TX, USA). All women enrolled in the study were included in the analysis irrespective of whether they received the CBK. Data were summarized as frequencies and percentages. Bivariate analysis and the  $\chi^2$  test were performed to identify associations between unsupervised versus supervised births, sociodemographic and obstetric history, and use of CBK and misoprostol. The Fisher exact test was used to compare differences in proportions when small numbers were recorded.  $P < 0.05$  was considered statistically significant.

### **3. Results**

A total of 200 women were recruited and underwent postpartum follow-up (Figure 2). A CBK was given to 195 (97.5%) women; 5 (2.5%) were unable to demonstrate knowledge of the safe use of the CBK items at enrollment and did not return to the prenatal clinic as requested before giving birth, so they were not issued with a CBK.

Every village from which a woman was enrolled was visited at least once by the research team to disseminate the key messages (Box 1).

Location of birth and sociodemographic characteristics are outlined in Table 1. Unsupervised births were recorded among 106 (53.0%) participants, of whom 43 (40.6%) either chose to give birth in the community or were told to give birth there by their husbands (data not shown). Compared with women who had a supervised birth, women who experienced unsupervised birth were more likely to have no or limited formal education ( $P=0.017$ ) and to be married ( $P=0.037$ ) (Table 1). No statistically significant between-group differences were found for age, employment status, or religious denomination.

Women giving birth for the first time were more likely to have a supervised birth than were multiparous women ( $P=0.002$ ) (Table 2). No maternal deaths occurred among the study participants. Two infants were stillborn; both were supervised births.

Overall, all or part of the CBK was used by 115 (59.0%) of the 195 who received one. Among all 106 women who had an unsupervised birth, most used the CBK (Table 3). Two (1.9%) of the 106 women who had an unsupervised birth did not use the CBK because they did not have it with them at the onset of labor. The other five women who had unsupervised births and did not use the CBK had not been given one.

All items were employed as instructed among the majority of the 115 women who used their CBK (Table 3). Of the 99 women who gave birth unsupervised and used the CBK, all but one used the scalpel blade to cut the umbilical cord (Table 3). The one exception used scissors, stating that she had forgotten that the scalpel was provided. Among the 16 women who had a supervised birth and used the CBK, the most frequently used items were the gloves and clean plastic sheet (Table 3).

Among the 115 women who used their CBK, 112 (97.4%) self-administered the misoprostol. Among these, 89 (79.5%) women correctly took the misoprostol immediately following the birth of the infant; 18 (16.0%) took their misoprostol after expulsion of the placenta; and three women (2.6%) took it later than instructed. Two women did not state when it was taken (Table 3). Among those who did not use the misoprostol, one woman stated that she did not take it, as she felt she was not bleeding “too much”.

Responses to questions relating to acceptability suggested that the majority of women who used a CBK would use it again and recommend its use to others (Table 3). Additionally, almost all the women who self-administered misoprostol said that they would take it again and that they would recommend it to other women in their community (Table 3).

All 200 women were asked about problems experienced after delivery, specifically regarding six symptoms associated with the use of misoprostol (shivering, fever, nausea, dizziness, vomiting, and diarrhea). Overall, 164 (82.0%) of the 200 participants reported at least one symptom after delivery, with shivering the most frequently reported event (Table 4). No significant differences in shivering, nausea, or dizziness were reported among women who took misoprostol versus those who

did not. None of the women reported vomiting or diarrhea. Excessive bleeding after delivery (defined as more than two cups of blood) was reported more frequently by women who did not take misoprostol than by women who did take this drug ( $P < 0.001$ ) (Table 4).

#### 4. Discussion

The present study demonstrated that a CBK containing misoprostol for self-administration to prevent PPH was acceptable, feasible, and appropriately used in a remote low-resource rural setting. High acceptability and adherence of self-administered misoprostol have previously been reported in other settings [9,11,13,14], but to our knowledge, the present study represents the first time a package of interventions, including community-based birth preparedness education and the addition of misoprostol within CBKs, has been evaluated in a rural low-resource context. Additionally, the present study identified a few women who found the CBK and misoprostol both useful and acceptable when attending a health facility for a supervised birth. These women, who were uncertain that they had received injectable oxytocin and were afraid of bleeding, self-administered their misoprostol. Whether they informed their care providers at the health facility was unknown.

Through providing communities and women attending prenatal clinics with key messages relating to birth preparedness, the present study sought to encourage women to undergo supervised births while also providing them with an intervention to promote hygienic and safe delivery should they experience an unsupervised birth. Constraints on the available data precluded estimates of change in coverage of supervised births at a health facility; however, review of provincial-level data and health facility records by the present study team for the period 2012–2014 indicated a steady increase in new attenders for prenatal care and supervised births in the present study area. This increase could reflect the present study intervention; an earlier pregnancy study conducted in the same area by the present study team; or external factors. Most importantly, the intervention did not lead to an increase in unsupervised home births, which had been a concern among some stakeholders.

More than half the women in the present study underwent unsupervised birth in their village owing to difficulties with transport, distance, and decision making, a finding in line with previous research in the same location [22] and elsewhere [23]. While women continue to give birth unsupervised—either through choice or circumstances—they remain at risk. The present study highlights the importance of using prenatal clinic visits to provide women with birth preparedness messages, including promotion of supervised births, and to make CBKs available for those who, despite this encouragement, will undergo unsupervised births because of the sociocultural and structural constraints within which they live.

Misoprostol is currently available for use in health centers and hospitals throughout PNG. The present study demonstrated the potential use of misoprostol when combined as a package with other community-based interventions. Several safeguards were included to ensure the misoprostol was used as intended. First, the present study enrolled only women in late pregnancy—as others have done [14]—to reduce the chance that misoprostol was misused in early pregnancy. Second, the misoprostol provided in the intervention was re-labeled and packaged with a very specific indication. Finally, the CBKs and misoprostol were only distributed to women

who could correctly recall key messages on usage. This last safeguard did result in five women undergoing unsupervised birth in the community without a CBK. Fortunately, all these women had a safe outcome; however, this finding does illustrate the balance of risks involved in imposing such safeguards. Packing the misoprostol within the CBK also helped ensure the safe storage and management of the tablets. The postnatal follow-up visits enabled collection of any unused misoprostol tablets, thereby minimizing the risk of inappropriate use.

Although there is limited evidence that the use of CBKs reduces maternal sepsis [17], earlier work in PNG highlighted that many women give birth in extremely unclean circumstances (e.g. in coffee gardens or on riverbanks) [22,24]. Hence, promoting clean and hygienic births in this setting was considered a priority.

The present study was not designed to evaluate the effectiveness of misoprostol for the prevention of PPH. Nevertheless, the women who took this drug were substantially less likely to report excessive bleeding than were those who did not take it.

Several limitations of the present study should be considered. Through only enrolling at prenatal clinics in the last trimester of pregnancy, the opportunity was missed to provide some women with the intervention. In addition, some women who were enrolled did not receive the intervention package owing to inaccurate knowledge regarding use of the CBK and misoprostol.

In conclusion, the present study found that provision of a CBK and misoprostol for self-administration was a feasible and highly acceptable intervention. Given the large number of unsupervised births and the high maternal mortality ratio recorded in PNG, the present study (despite some limitations) provided evidence for a community-based strategy and intervention that could provide a short-term solution to improve maternal health outcomes in this setting.

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### **Conflict of interest**

The authors have no conflicts of interest.



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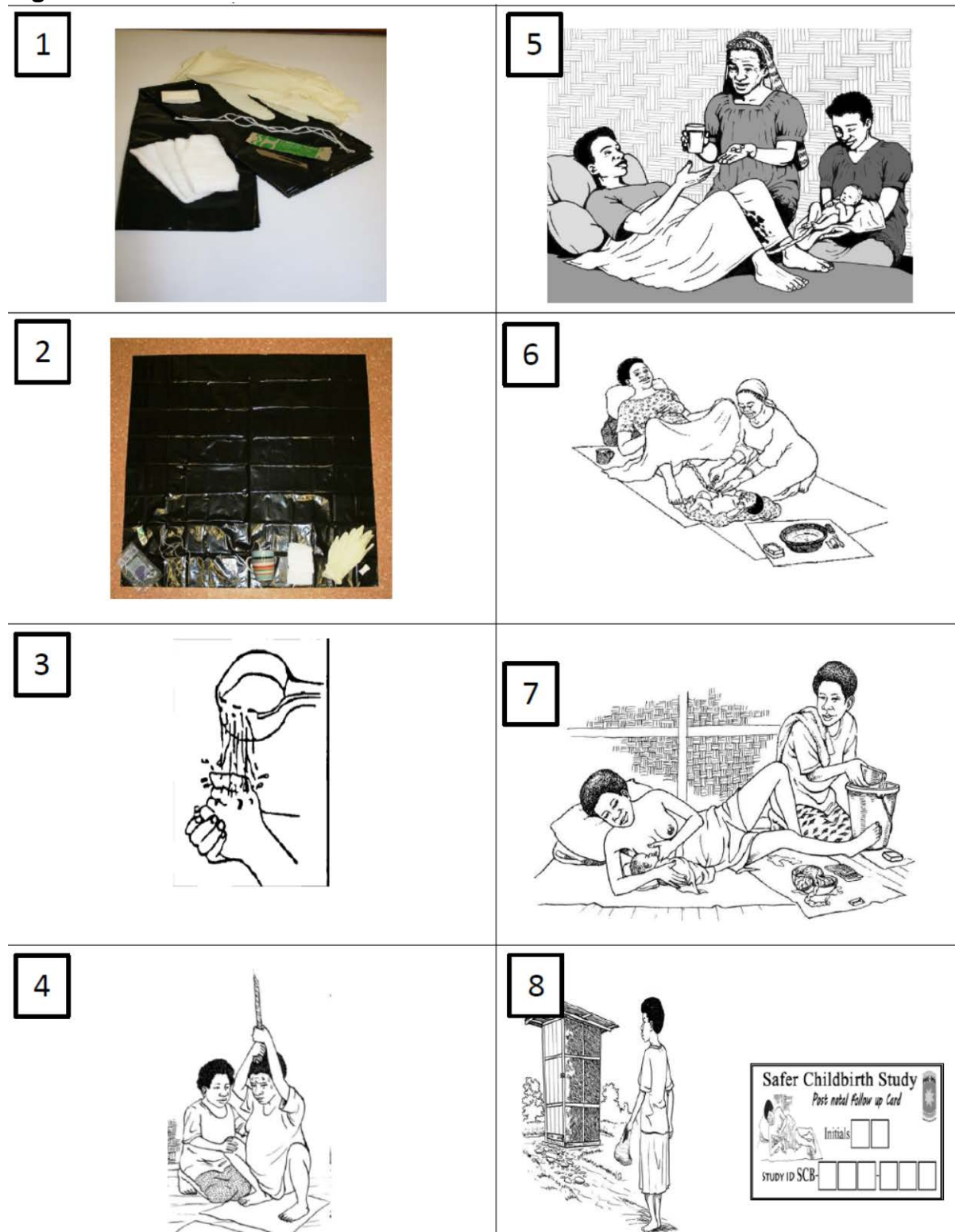
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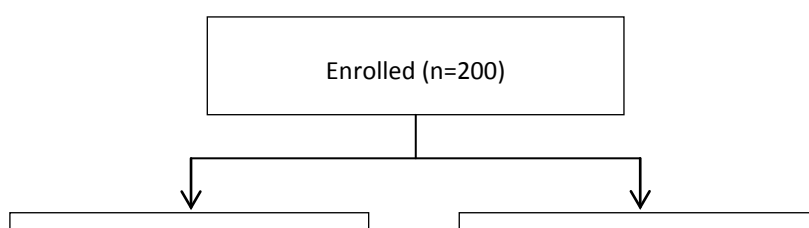
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**Figure 1** The clean birth kit insert



**Figure 2** Supervision of births and CBK use among study participants. Abbreviation: CBK, clean birth kit.



**Box 1** Key messages communicated during community information sessions.**Part 1: Normal process of safe childbirth**

- Childbirth can be dangerous
- Planning for safe childbirth
- Recognize the signs of labor
- Help a woman when she is in labor
- Recognize when the child is ready to be born
- Care for the mother immediately after childbirth
- Care of the mother and newborn from birth to 6 weeks
- Plan for and space pregnancies

**Part 2: Danger signs in mothers and newborns**

- Know the danger signs and act quickly
- Danger signs in labor
- Danger signs in the mother after childbirth
- Danger signs in the newborn
- Be prepared and plan for a supervised birth

**Table 1** Location of birth and sociodemographic characteristics.<sup>a</sup>

Characteristic	All women (n=200)	Unsupervised birth (n=106)	Supervised birth (n=94)	<i>P</i> value
Birth location				NA
Birthing house	19 (9.5)	19 (17.9)	NA	
Bush or garden	3 (1.5)	3 (2.8)	NA	
Riverside	15 (7.5)	15 (14.2)	NA	
Roadside	3 (1.5)	3 (2.8)	NA	
Coffee garden	7 (3.5)	7 (6.6)	NA	
Garden house	3 (1.5)	3 (2.8)	NA	
Own home	51 (25.5)	51 (48.1)	NA	
Others home	1 (0.5)	1 (0.9)	NA	
Other or missing data	4 (2.0)	4 (3.8)	NA	
Health center	56 (28.0)	NA	56 (59.6)	
Hospital	38 (19.0)	NA	38 (40.4)	
Age, y				0.329
<20	33 (16.5)	10 (9.4)	23 (24.5)	
20–24	65 (32.5)	38 (35.8)	27 (28.7)	
25–29	43 (21.5)	24 (22.6)	19 (20.2)	
30–34	40 (20.0)	25 (23.6)	15 (16.0)	
35–39	15 (7.5)	7 (6.6)	8 (8.5)	
≥40	4 (2.0)	2 (1.9)	2 (2.1)	
Marital status				0.037
Not married	7 (3.5)	1 (0.9)	6 (6.4)	
Married	193 (96.5)	105 (99.1)	88 (93.6)	
Employment status				0.150
Household duties and/or farmer	192 (96.0)	104 (98.1)	88 (93.6)	
Employed or student	8 (4.0)	2 (1.9)	6 (6.4)	
Education level				0.017
No formal education	84 (42.0)	49 (46.2)	35 (37.2)	
Year 1–6	78 (39.0)	45 (42.5)	33 (35.1)	
Year 7–12	31 (15.5)	12 (11.3)	19 (20.2)	
Tertiary level	5 (2.5)	0	5 (5.3)	
Unknown	2 (1.0)	0	2 (2.1)	
Religion				0.219
Seventh-day Adventist	123 (61.5)	71 (67.0)	52 (55.3)	
Foursquare	42 (21.0)	20 (18.9)	22 (23.4)	
Other	35 (17.5)	15 (14.2)	20 (21.3)	

Abbreviation: NA, not applicable.

<sup>a</sup> Values given as number (percentage) unless indicated otherwise.

**Table 2** Obstetric and pregnancy history.<sup>a</sup>

Characteristic	All women (n=200)	Unsupervised birth (n=106)	Supervised birth (n=94)	<i>P</i> value
Parity				0.002
0	52 (26.0)	18 (17.0)	34 (36.2)	
1	45 (22.5)	26 (24.5)	19 (20.2)	
2	35 (17.5)	21 (19.8)	14 (14.9)	
3	30 (15.0)	20 (18.9)	10 (10.6)	
4	28 (14.0)	15 (14.2)	13 (13.8)	
≥5	10 (5.0)	6 (5.7)	4 (4.3)	
Length of pregnancy at first prenatal care visit, wk				0.918
<26	50 (25.0)	27 (25.5)	23 (24.5)	
26 up to 32	74 (37.0)	37 (34.9)	37 (39.4)	
≥32 up to 36	52 (26.0)	30 (28.3)	22 (23.4)	
≥36	24 (12.0)	12 (11.3)	12 (12.8)	
Total no. of prenatal care visits				0.583
1	72 (36.0)	37 (34.9)	35 (37.2)	
2–3	99 (49.5)	56 (52.8)	43 (45.7)	
≥4	29 (14.5)	13 (12.3)	16 (17.0)	
Length of pregnancy at enrolment, wk				0.366
≥26 to <32	103 (51.5)	52 (49.1)	51 (54.3)	
≥32 to <36	45 (22.5)	29 (27.4)	16 (17.0)	
≥36	52 (26.0)	25 (23.6)	27 (28.7)	
Birth outcome				0.131
Live birth	198 (99.0)	106 (100.0)	92 (97.9)	
Stillbirth	2 (1.0)	0	2 (2.1)	

<sup>a</sup> Values given as number (percentage) unless indicated otherwise.

**Table 3** Use and acceptability of the intervention<sup>a</sup>

Outcome	All women (n=200)	Unsupervised birth (n=106)	Supervised birth (n=94)	P value
<b>Used CBK</b>				
No	85 (42.5) <sup>b</sup>	7 (6.6) <sup>b</sup>	78 (83.0)	
Yes	115 (57.5)	99 (93.4)	16 (17.0)	<0.001
Washing of hands	109 (94.8)	96 (97.0)	13 (81.3)	<0.001
Washing of hands with soap	109 (94.8)	97 (98.0)	12 (75.0)	<0.001
Using gloves at birth	115 (100.0)	99 (100.0)	16 (100.0)	<0.001
Using plastic sheet at birth	114 (99.1)	99 (100.0)	15 (93.8)	<0.001
Neonate delivered onto plastic sheet	115 (100.0)	99 (100.0)	16 (100.0)	<0.001
Using cord ties	107 (93.0)	99 (100.0)	8 (50.0)	<0.001
1 cord tie used	3 (2.8)	3 (3.0)	0	
2 cord ties used	104 (97.2)	96 (97.0)	8 (50.0)	
Using a scalpel blade to cut the cord	106 (92.1)	98 (99.0)	8 (50.0)	<0.001
Self-administered misoprostol	112 (97.4)	98 (99.0)	14 (87.5)	<0.001
Taken immediately after delivery	89 (79.5)	80 (81.6)	9 (64.3)	
Taken after expulsion of the placenta	18 (16.1)	15 (15.3)	3 (21.4)	
Taken after wash and/or rest	2 (1.8)	2 (2.0)	0	
Taken the next day	1 (0.9)	1 (1.0)	0	
Not specified when taken	2 (1.8)	0	2 (14.3)	
<b>Acceptability of the intervention</b>				
<b>Would use CBK again</b>				
Yes	111/115 (96.5)	99/99 (100.0)	12/16 (75.0)	<0.001
Missing data	4/115 (3.5)	0/99	4/16 (25.0)	
<b>Would recommend CBK to others</b>				
Yes	111/115 (96.5)	99/99 (100.0)	12/16 (75.0)	<0.001
Missing data	4/115 (3.5)	0/99	4/16 (25.0)	
<b>Would take misoprostol again</b>				
Yes	109/112 (97.3)	98/98 (100.0)	11/14 (78.6)	<0.001
Missing data	3/112 (2.7)	0/98 (0.0)	3/14 (21.4)	
<b>Would recommend misoprostol to others</b>				
Yes	109/112 (97.3)	98/98 (100.0)	11/14 (78.6)	<0.001
Missing data	3/112 (2.7)	0/98	3/14 (21.4)	

Abbreviation: CBK, clean birth kit.

<sup>a</sup> Values given as number (percentage) or number/total number (percentage), unless indicated otherwise.<sup>b</sup> Includes 5 women who were not provided with a CBK at enrolment.

**Table 4** Symptoms reported immediately after childbirth.<sup>a</sup>

Symptom	All women (n=200)	Took misoprostol (n=112)	Did not take misoprostol (n=88)	<i>P</i> value
Any symptom	164 (82.0)	90 (80.4)	74 (84.1)	0.495
Shivering	127 (63.5)	70 (62.5)	57 (64.8)	0.740
Nausea	13 (6.5)	7 (6.3)	6 (6.8)	0.871
Dizziness	30 (15.0)	14 (12.5)	16 (18.2)	0.264
Fever	17 (8.5)	11 (9.8)	6 (6.8)	0.450
Excessive bleeding <sup>b</sup>	48 (24.0)	15 (13.4)	33 (37.5)	<0.001

<sup>a</sup> Values are given as number (percentage) unless indicated otherwise.

<sup>b</sup> Self-reported; >2 cups of blood.