ORIGINAL RESEARCH ARTICLE

Community-level Distribution of Misoprostol to Prevent Postpartum Hemorrhage at Home Births in Northern Nigeria

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Abstract

In Nigeria, most deaths due to postpartum hemorrhage (PPH) occur in the absence of skilled birth attendants. A study using community mobilization and the training of community drug keepers to increase access to misoprostol for PPH prevention was conducted in five communities around Zaria in Kaduna State, Nigeria. Community-oriented resource persons (CORPs) and traditional birth attendants (TBAs) recruited and counseled pregnant women on bleeding after delivery, the importance of delivery at a health facility, and the role of misoprostol. Drug keepers stored and dispensed misoprostol during a woman's third trimester of pregnancy. TBAs and CORPs enrolled 1,875 women from January through December 2009. These results are based on 1,577 completed postpartum interviews. Almost all women delivered at home (95%) and skilled attendance at delivery was low (7%). The availability of misoprostol protected 83% of women who delivered at home against PPH who otherwise would not have been protected. Policymakers working in similar contexts should consider utilizing commuity-level distribution models to reach women with this life-saving intervention. *Afr J Reprod Health 2014; 18[2]: 166-175).*

Keywords: misoprostol, community-level distribution, Nigeria, maternal mortality

Résumé

Au Nigeria, la plupart des décès dus à une hémorragie du post-partum (HPP) se produisent en l'absence d'accoucheuses qualifiées. Une étude à travers la mobilisation communautaire et la formation des gardiens de drogues dans la communauté pour améliorer l'accès à misoprostol pour la prévention de l'HPP a été menée dans cinq communautés à l'alentour de Zaria dans l'État de Kaduna, au Nigeria. Les experts orientés vers les communautés (EOVC) et les accoucheuses traditionnelles (AT) ont été recrutés et ont conseillés aux femmes enceintes sur les saignements après l'accouchement, l'importance de l'accouchement dans un établissement de santé, et le rôle de misoprostol. Les gardiens de médicaments ont stocké et distribué misoprostol au cours du troisième trimestre de la grossesse de la femme. Les et les accoucheuses traditionnelles et les EOVC ont inscrit 1875 femmes de janvier à décembre 2009. Ces résultats sont basés sur 1 577 entrevues post-partum déjà terminées. Presque toutes les femmes ont accouché à domicile (95%) et l'assistance à l'accouchement par le personnel qualifié était faible (7%). La disponibilité de misoprostol a protégé 83% des femmes qui ont accouché à domicile contre l'HPP qui, autrement, n'auraient pas été protégées. Les décideurs qui travaillent dans des contextes similaires devraient envisager d'utiliser des modèles de distribution au niveau de la communauté pour atteindre les femmes à travers cette intervention de sauvetage. *Afr J Reprod Health 2014; 18[2]: 166-175).*

Mots clés: misoprostol, distribution au niveau de la communauté, Nigeria, mortalité maternelle

Introduction

Despite a global commitment to improving maternal health, the Millennium Development Goal of reducing maternal mortality by three quarters between 1990 and 2015 appears unattainable at the current rate of progress. Evidence suggests that worldwide, there are approximately 358,000 maternal deaths per year[1], with 14% of these deaths occurring in Nigeria. Post-partum hemorrhage (PPH) is the leading cause of maternal deaths in Nigeria and is estimated to account for 23% of the maternal mortality burden in the country[2]. Generally, PPH

is reported as being more common among poor, rural women of low economic status who deliver at home[3]. In Nigeria, as in other developing countries, most maternal deaths due to PPH occur in places where there are no skilled birth attendants or because skilled birth attendants lack the required skills or resources to manage PPH and the attendant haemorrhagic shock[4]. The risk of PPH can be significantly reduced by prophylactic use of a uterotonic drug, and oxytocin is recognized as the first-line uterotonic for PPH prevention. However, oxytocin requires both administration by injection and refrigeration, rendering it infeasible in communities such as those in rural Nigeria where the majority of women deliver at home without a skilled provider.

Misoprostol is a proven uterotonic increasingly used in obstetrical and gynecological practice for the prevention and treatment of PPH[5,6]. In 2007, the International Journal of Gynecology and Obstetrics published a special section entitled "Misoprostol in Obstetrics and Gynecology" which included a recommendation of 600 micrograms oral misoprostol for prevention of PPH[7]. The International Federation of Gynecologists and Obstetricians and the International Confederation of Midwives (FIGO/ICM) jointly recommended that in home births without a skilled attendant, misoprostol may be the only available technology to control PPH[4], and the World Health Organization's (WHO's) 18th Expert Committee on the Selection and Use of Essential Medicines added misoprostol to the WHO Essential Medicines List "for the prevention of [postpartum hemorrhage] in settings where injectable uterotonics are not available or feasible"[8]. Additionally, the WHO recommends that misoprostol can be used by trained community health care workers and lay-health workers for PPH prevention when skilled birth attendants are not present[9]. In January 2006, the Nigerian National Agency for Food and Drug Administration and Control approved the distribution of misoprostol for the prevention and treatment of PPH[10] and in 2010 Nigeria's Federal Ministry of Health approved the inclusion of misoprostol on the Essential Drug List (EDL).

Injectable uterotonics are not currently available outside of health facilities. However, every year an estimated 60 million women give birth outside health facilities, mainly at home, and 52 million births occur without skilled birth attendance[11]. Although it has been suggested that focusing on health centre intrapartum interventions would be the most effective strategy for reducing maternal mortality[12], this type of strategy is costly and will take time to implement. As such, numerous researchers have raised the question: "What should be done in the meantime, for the 52 million women in the world who deliver without skilled attendance at birth[13,14]"? In response to this question, there has been an increase in calls from maternal and child health experts for community-level interventions that can make home births safer[15-24].

There is a growing body of evidence to support community-level distribution of misoprostol as a low-cost strategy to reduce maternal deaths at home births. In rural areas of Ethiopia, Pakistan and The Gambia, traditional birth attendants (TBAs) have successfully administered misoprostol for PPH prevention[14,25,26]. Similarly, findings from rural Afghanistan and West Java, Indonesia, demonstrate that distribution of misoprostol by Community Health Workers (CHWs) is an effective strategy for prevention of PPH[27,28].

Given this evidence, there is a clear imperative to further explore the feasibility, safety and acceptability of community-level distribution of misoprostol to protect women who deliver either by themselves or with family members and TBAs. In particular, evidence is needed to demonstrate the potential impact of misoprostol distribution for PPH prevention in areas where it is difficult to reach women with health interventions, such as very rural areas and settings where women are secluded. The purpose of this paper is to report on the results of an intervention in northern Nigeria designed to examine the safety, feasibility, and acceptability of community-level distribution of misoprostol for use in home births to prevent PPH.

Goal and objectives

The goal of this study was to provide empirical evidence to inform policymakers on the administration of misoprostol to prevent PPH, the

leading cause of maternal deaths, at home births in Nigeria.

The specific objectives were:

1. To determine effective distribution outlets and persons to administer misoprostol to parturient women at the community level;
2. To document any symptoms that may be associated with the use of misoprostol for the prevention of PPH;
3. To determine the acceptability and uptake of misoprostol as a prophylactic drug for PPH; and
4. To explore issues relating to the sustainability of community-level distribution of misoprostol for the prevention of PPH.

Methods

The Study Setting

The study was conducted in five communities in Zaria, Kaduna State, in the North West geo-political zone of Nigeria from January to December 2009. The five study communities (Tsibiri, Hayin Ojo, Yakawada, Dakace, and Unguwan Godo) have a combined population of around 21,000 and Hausa/Fulani and Islam are the dominant ethnic group and religion, respectively. The population is young, with 48% aged less than 15 years in three of the five communities[29]. The majority of women live in *purdah*, defined as "the elaborate codes of seclusion and feminine modesty used to protect and control the lives of women"[30]. The mean age at marriage for females is 15 years, the total fertility rate is 8.2 children per woman, and contraceptive use is very low[29]. Even though each of the communities has at least one health facility where antenatal care is provided, health facility delivery services are provided in only two of the communities; consequently, deliveries in health facilities are very low[29]. The North West zone has the highest percentage of home deliveries in Nigeria, with 92% of women delivering at home and only 10% of deliveries supervised by a skilled attendant[31]. Most women deliver alone, with a TBA, or with family members[32].

The Intervention

A community-based participatory approach was used to: 1) develop a community awareness campaign to educate communities on PPH and the use of misoprostol for PPH prevention, including where to get the drug; 2) establish community drug keepers to act as community-level misoprostol distribution points; and 3) train TBAs to administer misoprostol for PPH prevention during deliveries, assess excessive blood loss, and treat PPH with misoprostol when blood loss after delivery exceeded 500ml.

Community Awareness Campaign: Before commencing the study, the research team conducted 18 community dialogues with a total of 1,800 people, both male and female. The purpose of these community dialogues was to find a means of identifying excessive blood loss after delivery. A local rubber cup used for fetching water, called *moda*, was found to hold exactly 500 ml of water. Similarly, two yards of cotton material was found to hold exactly 500 ml of water when soaked. These provided clear visual representations for the community to understand when a woman had lost too much blood after delivery and was facing a life-threatening emergency.

Further, the community dialogues identified the need for a new cadre of community-level health workers who could educate their communities on pregnancy-related health promotion messages, especially PPH and its prevention with misoprostol, and act as a liaison between the community and the health care system by informing midwives of pregnant women and deliveries in their communities. Community-oriented resource persons (CORPs) were introduced for this study, and 29 CORPs were trained in counseling skills, educating pregnant women on safe delivery messages and misoprostol use, as well as documentation of their activities[33].

Community drug keepers as community-level misoprostol distribution points: Drug keepers were the community-level distribution points and they dispensed misoprostol to TBAs and pregnant women and their families during the third trimester of pregnancy (Figure 1).

The drug keepers were literate and trusted community members and the group included either male or female patent medicine vendors, TBAs, teachers and village leaders. They were selected on the recommendation of the community members during the community dialogues. Twenty-seven drug keepers were trained for three days on: safe keeping of misoprostol; how to secure informed consent and provide education on correct use of misoprostol at the time of distribution; distributing three misoprostol tablets (600 micrograms) to pregnant women and/or their family members during the third trimester of pregnancy; and documentation of dispensing of the drug.

The tablets were monitored by study physicians and nurses throughout the course of the project. Each drug keeper had a log, in which they noted when, to whom and how many misoprostol tablets they distributed. Every two weeks, when the study monitors visited the drug keepers, they checked this log to see how many misoprostol tablets had been dispensed. They resupplied the drug keepers as needed.

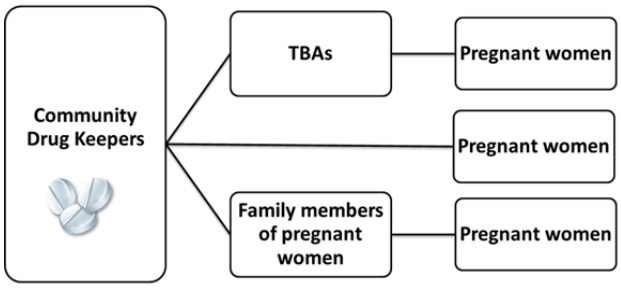

Figure 1: Community-level misoprostol distribution system

All pregnant women who delivered in the five communities during the study period were eligible to participate in the study, given certain eligibility criteria.

When drug keepers distributed misoprostol, they obtained informed consent for recruitment into the study. When the beneficiary of the drug did not come herself for collection of the drug, the consent form was given to the person collecting the drug, who then took it to the beneficiary with instructions to have a literate person read it to her and have her provide her thumbprint. Women beneficiaries were required to give oral informed consent prior to enrolling in the study. Further eligibility criteria included anticipation of an uncomplicated vaginal delivery, gestation greater than 38 weeks since the last menstrual period at the time of delivery, and age 18 years or older. Informed consent was obtained at enrollment prior to distribution of misoprostol, or at delivery with a TBA (before the TBA administered misoprostol for PPH prevention).

Training of Traditional Birth Attendants: Forty-one TBAs were trained for 6 days on home-based life-saving skills and on the use of misoprostol for the prevention and treatment of PPH. It is important to note that this is only a fraction of the TBAs practicing in the communities. TBAs were trained to assist women in taking the misoprostol and to identify PPH using the methods described above. They were also trained to insert five misoprostol tablets (1000 micrograms) rectally for PPH treatment and to refer PPH cases to a health facility. They were told never to give misoprostol to the women when the baby is still "inside the women" (undelivered), to use it only after the baby has been delivered, and to promptly refer the women to the hospital if severe bleeding continues despite using the drug. TBAs visited pregnant women in their communities and educated them on healthy pregnancy and delivery practices and how to prevent PPH with misoprostol.

When TBAs were called to conduct a delivery, they either collected the misoprostol tablets from the person keeping the drug (either the pregnant woman or her family member) or used their own stock, which they then gave to the woman immediately after delivery. Post-delivery, the TBAs monitored women for at least six hours. TBAs assessed blood loss after delivery and treated with misoprostol as necessary, using their own stock. They also assisted the research team in following up with women who had delivered in the project area within two weeks of delivery for a postpartum interview.

In the event of complications and referrals, follow up visits to the referral health facilities were undertaken by study personnel and data were collected on the reason for referral, the management of the complication and outcome. Forty-five providers from primary health care facilities and higher-level referral facilities were sensitized to the project during a one-day

workshop. Verbal autopsies provided qualitative data in the event of maternal death.

Data Collection

Data were collected both at the point of misoprostol distribution and after delivery using structured interviewer-administered questionnaires. When drug keepers distributed misoprostol, they collected information on the person receiving the drug, including their name, address, gestational age of the beneficiary and the purpose (the drug could only be given for PPH prevention and treatment). TBAs and CORPs reported all deliveries in the study areas to research staff (nurses and midwives). Research staff, often with the assistance of TBAs, then conducted a postpartum interview with consenting women within two weeks of delivery. The structured questionnaire included socio-demographic characteristics and pregnancy information; place of delivery and assistance; estimated blood loss; monitoring of complications of labor; conditions of the neonate and mother; knowledge, attitude and practices related to misoprostol; symptoms experienced following delivery and misoprostol ingestion; source of knowledge about the drug; and willingness to pay for the drug.

Outcome Variables and Analysis

The primary outcome of interest in this study was uterotonic coverage at birth, which meant either taking misoprostol or receiving an injection immediately after delivery for the prevention of PPH. This was assessed through two questions in the postpartum interview: "Did a midwife or doctor give you an injection in the thigh or buttocks right after the baby was born?" and "Did you take misoprostol tablet(s) offered to you by a TBA or the ones you collected?" While it can be assumed most of the injections are oxytocin, since women could not differentiate between injections of oxytocin and other uterotonic drugs (e.g. ergometrine), this distinction is left intentionally vague. A secondary outcome, which measured the feasibility of the intervention, was determining where women got the drug. The effectiveness of the intervention was measured by assessing the number of women who had perceived PPH after a home delivery, as well as the additional interventions that they required.

To determine the safety of community-level distribution of misoprostol, the correct use of misoprostol was assessed by asking women about the dose, route, and timing of misoprostol administration at home births, either by self-administration or administration by a TBA. Finally, to assess acceptability women were asked women if they would use misoprostol in a subsequent pregnancy, recommend it to a friend, and if they would purchase the drug.

Data were entered using Epidata[34] and imported to SPSS Version 17[35] and Stata version 11[36] for analysis. Results were summarized using frequency distributions and cross-tabulations. Differences between groups were assessed by X^2 test for association. Statistical significance was assessed using a criterion of $p<0.01$. Ethical approval for this study was given by the University of California, Berkeley Committee for Protection of Human Subjects (#2008-9-57) and the Ahmadu Bello University, Nigeria.

Results

Table 1: Antenatal and Delivery Characteristics

	Total (n=1,577)
ANC attendance	
Average number of ANC visits (+SD)	5.3 (1.78)
Location of delivery	
Home	95.1%
Health facility	4.9%
Attendant at delivery*	
TBA	66.1%
Friend/relative	13.9%
Alone	10.2%
Doctor	0.8%
Midwife/medical officer	5.7%

*Missing responses on attendant at delivery for 53 women

Of the 1,875 women who were enrolled in the study, postpartum interviews were completed for 1,577 women. Table 1 shows the antenatal and delivery characteristics of the women who completed postpartum interviews. The majority of study participants delivered at home (95%) and two-thirds were attended by a TBA. The average number of antenatal care visits was 5.3.

Table 2: Misoprostol distribution coverage

	Total (n=1,577)
Took misoprostol for PPH prevention	80.2%
Received misoprostol from:	
TBA	74.0%
Drug keeper	9.7%
Community-oriented resource person (CORPS) and other community health workers	6.6%
Health provider/chemist	3.2%
Family member/friend	3.6%
Community health extension worker	0.2%

Table 3: Uterotonic coverage at delivery

	Home birth (n=1,500)	**Facility birth (n=77)**	**Total (n=1,577)**
Took misoprostol for PPH prevention^*	82.6%	32.5%	80.2%
Received injection*	2.0%	48.1%	4.2%
Did not receive/take any drug to prevent PPH	15.4%	19.5%	15.6%
Protected Births	84.6%	80.5%	84.4%

*p<0.01
^Missing responses from 166 women as to whether they took misoprostol for PPH prevention.

The majority (80%) of women in the postpartum follow-up group took misoprostol at delivery, and of these women almost three-quarters received the misoprostol from a TBA (Table 2). Approximately one in ten women received misoprostol directly from a drug keeper prior to their delivery and 7% of women received their misoprostol from a CORPS or other community health worker.

Significantly more women took misoprostol at home births (83%) than facility births (33%) (Table 3). Overall, with the addition of misoprostol, 84% of women in the postpartum sample received a uterotonic for PPH prevention. A total of 231 women who delivered at home did not take misoprostol at delivery. Of these women, 59 said that they did not have the misoprostol, 56 said that they did not have any information about misoprostol, 19 said they forgot to take the misoprostol,13 said that their husband/family did not want them to take the misoprostol,12 said that they did not think they would need misoprostol, 10 said that they did not want to take the misoprostol, eight said that they could not find the misoprostol, three had a fear of side effects, two said that they did not know how to take the misoprostol, and one said that a TBA gave her traditional medicine.

Of all the women who took misoprostol, 93% took the correct dose (3 tablets) and 87% took misoprostol at the correct time (before the delivery of the placenta) Table 4. There were no reports of women taking misoprostol before the delivery of the baby. The proportion of women who took the *correct dose* of misoprostol did not have much variation across attendant at delivery (ranging from 94% with doctors/midwives/medical officers to 96% with TBAs, friends/relatives and women who delivered alone). However, higher proportions of women who delivered with a TBA or a friend/relative reported taking misoprostol at the *correct time* (89% and 85%, respectively) than women who delivered alone or with a doctor/midwife/medical officer (77% and 79%, respectively).

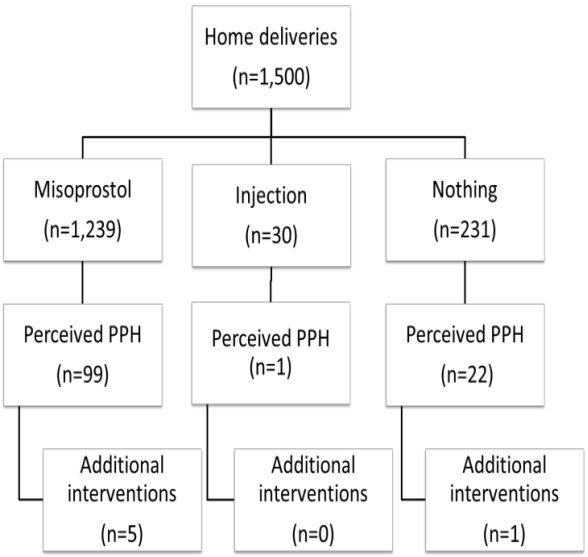

Figure 2: Perceived PPH and additional interventions at home deliveries

Perceived PPH was determined by asking the woman "Did you bleed a lot more than normal following childbirth?" Of the 1,239 women who delivered at home and took misoprostol, 99 (8%) perceived that they had excessive bleeding. Five of these women reported needing additional interventions. Of these five women, one underwent manual removal of the placenta, one

underwent manual removal of the placenta and was given IV fluids, and the remaining three women were only given IV fluids. Twenty-two women who received no uterotonic reported that they perceived PPH (10%), and of these, one woman needed an additional intervention, which was manual removal of the placenta. There was not a statistically significant difference between the proportion of women who took misoprostol and perceived that they developed PPH and the proportion of women who did not take misoprostol and perceived that they developed PPH.

Acceptability of misoprostol was highest in women who had taken misoprostol at delivery, compared with women who had been given an injection or had no uterotonic (Table 5). Almost all women who had taken misoprostol at delivery would recommend misoprostol to a friend or relative (100%) would use misoprostol at their next delivery (99%) and would purchase misoprostol (99%). Further, women who had taken misoprostol were willing to pay almost twice as much for misoprostol [410.53 naira ($2.61 USD)] as what women who had been given an injection were willing to pay for misoprostol [262.71 naira ($1.67 USD)].

Table 4: Correct use of misoprostol, by attendant at delivery

	TBA (n=1,043)	**Friend/relative (n=219)**	**Alone (n=160)**	**Doctor/midwife/medical officer) (n=102)**	**Total (n=1,577)**
Took miso for PPH prevention*	88.1%	67.1%	66.3%	46.1%	80.2%
Correct dose (3 tablets)**	96.2%	95.9%	96.2%	93.6%	93.2%
Correct timing (before the delivery of placenta)***	88.9%	85.0%	77.4%	78.7%	87.3%

*Missing responses for 45 women who took misoprostol for PPH prevention on their attendant at delivery
**Missing responses for attendant at delivery for 44 women who took the correct dose of misoprostol
***Missing responses for attendant at delivery for 32 women who took misoprostol at the correct time

Table 5: Acceptability of misoprostol, by uterotonic received at delivery

	Misoprostol (n=1,264)	**Injection (n=67)**	**Nothing (n=246)**	**Total (n=1,577)**
Would recommend misoprostol to a friend or relative	99.7%	77.6%	75.0%	94.9%
Would use misoprostol at next delivery	99.4%	77.6%	73.6%	94.5%
Would purchase misoprostol ^	99.1%	86.6%	72.3%	95.2%
Mean amount willing to pay for misoprostol (NGN) (min; max)*	410.52	262.71	361.71	374.90 (0;5000)

^Missing responses from 20 women as to whether they would purchase misoprostol. 49 women who said that they would purchase misoprostol did not specify who their attendant was at delivery.
*Currency is presented in Nigerian naira (NGN). 1 NGN is equal to approximately 0.0063 US Dollars

Misoprostol use is associated with a number of side effects, the most prominent of which is shivering. When the drug keepers distributed the drug, they ensured that TBAs, women and their families understood the potential side effects. Of the women in the postpartum sample who took misoprostol for PPH prevention, 539 (43%) reported shivering, 158 (13%) reported feeling dizzy, 150 (12%) reported developing a fever and 143 (11%) reported abdominal cramping. area of Nigeria where women live in *purdah*, which constrains their access to already sparsely available health facilities. In this low-resource setting, this study illustrated that it is possible to reach women who deliver outside of health facilities with a uterotonic at delivery. Use of

Discussion and Conclusions

This study demonstrated that distribution of misoprostol through community drug keepers is a feasible, safe and acceptable intervention in a rural

misoprostol at home births was extremely high (83%), and one-third of women who delivered in a health facility also took the drug. As such, not only did misoprostol provide essential uterotonic protection for women delivering at home, it also helped to fill a gap at facilities, where oxytocin may have been unavailable. As indicated by the high rates of uterotonic coverage at home deliveries, community drug keepers are able to effectively distribute misoprostol and put it into the hands of women in these isolated communities. In the absence of community-level distribution of misoprostol the vast majority of women who delivered at home would not have received any protection against PPH.

Evidence from this study can be used to inform policymakers in Nigeria that it is feasible and safe to provide community-level distribution of misoprostol for home deliveries. Thus, efforts to expand the services already proven in Zaria should be part of a national scale-up plan to reduce maternal mortality at home births. Additionally, this study can serve as an example to other countries where cultural and structural barriers limit access to health facilities. By undertaking the formative groundwork to create a cadre of trusted and trained community drug-keepers, many of the barriers that prevent women in Zaria, Nigeria, from receiving a uterotonic at delivery were overcome.

Although a smaller proportion of women who took misoprostol at home self-reported perceived PPH than those who received no uterotonic at a home delivery (8% vs. 10%), the difference was not statistically significant. One explanation for this is that it is extremely difficult to visually measure blood loss and women may not have been self-reporting their perceived blood loss accurately. Although women had been educated to understand excessive bleeding by the visual representation of a *moda* or soaked cotton material, it is difficult to report accurately on blood loss, and it is particularly difficult to self-report this after one's own delivery. While misoprostol has been proven to reduce the risk of excessive bleeding after delivery, a normal delivery will still include a small amount of bleeding. As such, women taking misoprostol may have experienced a small amount of bleeding after delivery and reported it as PPH because they assumed they would not experience any bleeding.

Of all the women who took misoprostol for PPH prevention, 93% reported taking the correct dose (3 tablets) and 87% reported taking it at the correct time. An important finding from this study is that those women attended at delivery by a TBA had the highest self-report of correct use. This illustrates that TBAs can be trained to effectively aid women in taking misoprostol for PPH prevention at home deliveries, which appropriately aligns with the World Health Organization's current support of misoprostol administration by lay health workers for PPH prevention where skilled birth attendants are not present and oxytocin is unavailable[37]. Trained TBAs can be a critical part of effective maternal health task-shifting strategies in countries where women have little access to skilled birth attendants. With proper training and consistent supervision, TBAs can contribute to positive maternal health outcomes in low-resource settings. Particularly in settings where women live in *purdah*, trained TBAs can act as gate-keepers who bring critical maternal health services to women where they live.

It is noteworthy that almost 100% of women who took misoprostol found the drug to be very acceptable, stating that they would recommend misoprostol to a friend or relative, would use misoprostol at their next delivery, and would purchase misoprostol. Women who had taken misoprostol were willing to pay the highest amount (410.52 naira) and women who had taken no uterotonic were willing to pay 361.71 naira.

The use of community drug keepers in this study is, to the authors' knowledge, the first time that this cadre has been utilized for community-level distribution of misoprostol. This study adds not only to the rapidly growing evidence base for community-level distribution of misoprostol, but also to evidence illustrating the successful practice of using trained cadres of community health workers to distribute essential health commodities. For example, trained community health workers have successfully distributed contraceptives in Ethiopia, Uganda, Madagascar, Peru and Malawi[38-42] and mosquito nets in Tanzania[43]. Additionally, the WHO has called for community health workers to be involved in screening for and

treating malaria[44]. The findings from this study support the distribution of misoprostol by community drug keepers as an intervention that can provide life-saving uterotonic protection to women who deliver at home.

As a result of this study, policy change and further implementation of community-level misoprostol distribution have taken place in other areas of Nigeria. The *Guidelines for Community Use of Misoprostol for Prevention and Treatment of Postpartum Hemorrhage* in Nigeria were approved in 2010 and have been published. Additionally, Sokoto State in Nigeria has partnered with USAID/TSHIP, managed by JSI Research and Training Institute, Inc., in order to implement community-level distribution of misoprostol. It is our hope that the key results of this study can continue to inform health policy in Nigeria and be a part of the evidence base on how to scale up this critical maternal health intervention throughout the country.

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Contribution of Authors

CE and OS were local co-principal investigators in the study and contributed to study implementation and manuscript preparation; MM conducted data analysis and contributed to manuscript preparation; FA, OO, BS, IH, LA, MAA and VA were co-investigators and contributed to study implementation and data collection; NW was the project manager and contributed to manuscript preparation; as principal investigator NP designed the study, oversaw data analysis and contributed to manuscript preparation. All authors read and approved the manuscript.

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