

PREVENTION OF POSTPARTUM HEMORRHAGE AT HOME BIRTHS IN FIVE COMMUNITIES AROUND ZARIA, KADUNA STATE, NIGERIA

Technical Report

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The Population &
Reproductive Health
Partnership (PRHP)



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Executive Summary

The Population and Reproductive Health Partnership (PRHP) of Ahmadu Bello University, Zaria, Nigeria, collaborated with the Bixby Center for Population, Health and Sustainability at the University of California, Berkeley (UC Berkeley) and Venture Strategies Innovations (VSI) on a study to provide empirical evidence to inform policy decision-makers on the safety of misoprostol administered by traditional birth attendants (TBAs) at home births to prevent postpartum hemorrhage (PPH)—a preventable condition currently accounting for 23% of all maternal deaths in Nigeria. The study was undertaken in response to the Federal Ministry of Health's (FMOH) desire to achieve a significant reduction in the country's maternal mortality ratio in accordance with Millennium Development Goal (MDG) 5 as well as its specific request for local evidence on the use of misoprostol by non-skilled providers in Nigeria. The specific objectives were to determine the acceptability and uptake of misoprostol for the prevention of PPH; to identify and test the feasibility and effectiveness of distribution outlets and persons administering the drug to women at the community level; to document any symptoms that may be associated with the use of the drug; and to explore issues relating to sustainability of community distribution of misoprostol.

Across five communities around Zaria, Kaduna State (Hayin Ojo, Dakace, Tsibiri, Yakawada and Unguwan Godo) 41 traditional birth attendants (TBAs) and 29 community oriented resource persons (CORPs) recruited and counseled pregnant women on the importance of antenatal care and PPH prevention using misoprostol while 27 drug keepers were responsible for storing misoprostol, and dispensing it to TBAs, pregnant women or members of their households seeking the tablets for any woman in her last month of pregnancy. Midwives and nurses provided supportive supervision and technical backstop.

TBAs and CORPS enrolled 1875 women from January through December 2009 and results are based on 1800 completed postpartum interviews. Almost all women delivered at home (95%) and with a TBA (70%). Unguwan Godo had the fewest home births (80%) and Yakawada and Hayin Ojo had the highest percentage of home births (98%). Skilled attendance at delivery by a doctor, midwife, nurse or medical officer was low in this study population (7%).

The community awareness campaign included community dialogues, drama, print materials and interpersonal communication by TBAs and CORPs. Key messages included information on bleeding after delivery, the importance of delivery at a health facility, and the role of misoprostol. The most important source of information varied significantly across sites, underscoring the importance of each campaign component. TBAs were the most important source of misoprostol information in all communities but Dakace where CORPs played a larger role (31%). There was near universal comprehension of community messages; most women knew that PPH can cause death (84%), and understood how much is too much blood loss after delivery (83%). Fewer than half mentioned the importance of going to a health facility or to get help from a midwife if PPH occurs (49%). This could be a reflection of the lack of available services in the area and that most women deliver at home with TBAs.

In total, 84% of enrolled women received misoprostol tablets to use in the event they delivered at home. Births protected against PPH are those in which the delivering woman received any uterotonic drug, in injectable or tablet form, immediately after delivery to help reduce bleeding. The percentage of women who received injectable uterotonics is very low in these communities (4%).

Misoprostol protected 79% of the women enrolled in the project against PPH that would not have been protected otherwise. With the addition of misoprostol at home births a total of 83% of deliveries were protected. All of the communities involved in the study had on average a PPH incidence of around 3%--lower than expected.

Despite low literacy rates, method compliance was high. Among women who used misoprostol for PPH prevention, 98% reported taking three tablets correctly, and 88% reported correct route (oral) and timing. Among those who took misoprostol, a significant number experienced shivering (42% v. 9%). Shivering is an expected symptom of misoprostol use and 96% of the women knew to expect it as a symptom.

Bleeding-related problems developed during home births were successfully treated at home. Of the 1425 women who received misoprostol, only 16 of those who developed bleeding had blood loss of 500ml or more, and of those only one received additional interventions (intravenous fluids and blood transfusion). Among the much smaller number of 371 women who did not take misoprostol, 21 developed bleeding-related problems and were given misoprostol at home for treatment of PPH.

Acceptability of the intervention was extremely high in all communities with 95% of women expressing willingness to use misoprostol in a subsequent pregnancy; 96% willing to recommend misoprostol to a friend or relative; and 95% of women willing to pay an average price of N 522 (or \$3.50 USD) for a prevention dose of misoprostol.

Based upon the available data, we conclude that misoprostol at the community level is a feasible, safe, effective, and acceptable intervention by the community. This intervention has the potential to save many mothers' lives throughout Nigeria. We strongly recommend:

- Misoprostol be allowed to be used at the community level by appropriately trained community agents to protect women who cannot reach a facility to deliver.
- Policy development to include community health extension workers or TBAs as the vehicle for birth preparedness and misoprostol information and education.
- Prioritization of funding and resources to scale up the intervention to other communities and Local Government Areas (LGAs) in Kaduna State and countrywide.
- Policy development to enable inclusion of misoprostol in the delivery kit given to midwives involved in the Midwifery Corp Scheme and 'Mama Kits' for Safe Motherhood.
- Encouragement of pharmaceutical marketing of the drug to incite price competition and an affordable price to the end users.

Acronyms used in this report

ANC	Antenatal Care
CORPs	Community Oriented Resource Persons
FIGO	International Federation of Obstetricians and Gynecologists
FMOH	Federal Ministry of Health
ICM	International Confederation of Midwives
IEC	Information, Education & Communication
IV	Intravenously
LGA	Local Government Area
MCH	Maternal and Child Health
PHC	Primary Health Care
PPH	Postpartum Hemorrhage
PRHP	Population and Reproductive Health Partnership
SOGON	Society of Gynaecology and Obstetrics of Nigeria
TBA	Traditional Birth Attendant
VSHD	Venture Strategies for Health and Development
VSI	Venture Strategies Innovations
WHO	World Health Organization

1. Introduction

1.1 Background

1.1.1 Postpartum Hemorrhage in Nigeria

More than 20 years after the global launching of the Safe Motherhood Initiative in Nairobi, the outcome has remained disappointing. In spite of a renewed 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. Available evidence tends to suggest that globally the burden of maternal mortality is stagnant with Nigeria contributing disproportionately to the problem. The World Health Organization (WHO) identifies Nigeria as having the world's second highest number of maternal deaths. Of the 536,000 maternal deaths occurring every year, 59,000, or approximately 10%, take place in Nigeria (UNFPA, 2005), with 77% of these maternal deaths occurring during or after childbirth (FMOH, 2008), and postpartum hemorrhage (PPH) making a significant contribution to these deaths.

Worldwide, postpartum hemorrhage is the leading cause of maternal mortality. Similarly, PPH is the leading cause of maternal deaths in Nigeria; official estimates attribute 23% of the maternal mortality burden in the country to PPH (FMOH, 2007). Recent evidence from the World Health Organization (WHO) tends to suggest that PPH is underreported and could be responsible for as much as 40% of maternal deaths in some African countries (B-Lynch *et al*, 2006). This tends to be confirmed with the higher proportions of maternal mortality perceived to be due to PPH from Nigeria's national population-based surveys – 44% of maternal deaths in 2005 and 38% in 2007 were attributed to PPH (FMOH, 2005; FMOH, 2007a). While PPH is the leading cause of maternal mortality nationally, a hospital-based study conducted by the Society of Gynaecology and Obstetrics of Nigeria (SOGON) found regional variations in the relative contributions of PPH to maternal mortality: in the North Central Zone, it was the leading cause of maternal death, while it was the second leading cause in the North West and South East Zones and the third leading cause in the South South and South West Zones (SOGON, 2004). Generally, PPH is reported as being more common among poor, rural women of low economic status who deliver at home (Ujah *et al*, 2008).

While local studies on the causes of PPH in Nigeria are limited, the general assumption is that in line with global estimates, uterine atony, or failure of the uterus to contract after childbirth, accounts for 70% of the cases. Other causes include retained placenta or placental fragments and trauma to the genital tract, while associated risk factors are prolonged second stage labor, past history of PPH, uterine fibroids, mismanaged third stage of labor and Cesarean section (Ujah *et al*, 2006).

Postpartum hemorrhage is mostly unpredictable; up to 90% of women who develop PPH have no identifiable risk factors (USAID, 2009) and it can be rapidly fatal if treatment is not applied immediately, or prior interventions made to forestall it. The majority of PPH deaths occur within four hours of delivery as a result of problems with the third stage of labor (Shane, 2001). Unfortunately, most of the maternal deaths due to PPH in Nigeria, as in other developing countries, occur in places where there are no skilled birth attendants or because skilled birth attendants lack the required skills or resources to manage the PPH and shock (International Confederation of Midwives & International Federation of Gynecology and Obstetrics, 2006). This is compounded by a failure to recognize PPH and acknowledge its dangers as well as poor transportation systems which delay and limit access to prompt and effective treatment.

1.1.2 Misoprostol for Prevention of PPH

Developing countries have 50 to 100 times as many maternal deaths per 100,000 live births as developed countries (Fortney *et al*, 1986). PPH is the largest single cause of maternal mortality globally,

accounting for a quarter of all deaths (Mousa & Walkins, 2001). PPH accounts for an even higher proportion of maternal deaths in sub-Saharan African countries, associated with a third of maternal deaths (Khan *et al*, 2006). Developing countries lack the necessary drugs and skilled attendance during home births to prevent PPH and subsequent maternal deaths. In addition, the high prevalence of anemia among women in developing countries predisposes them to death from PPH as even modest blood loss can be life threatening.

Proven methods of controlling PPH exist; they include uterotonic drugs (e.g. oxytocin and ergometrine) and surgical procedures. The use of uterotonic agents in the management of the third stage of labor reduces the amount of bleeding and the need for additional treatments or interventions. However, current recommended uterotonic preparations (oxytocin) require both administration by injection and refrigeration, rendering them 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, including for controlling PPH (Calistan *et al*, 2003; Oboro & Tabowei, 2003). In 2007, the International Journal of Gynecology and Obstetrics published a special section entitled “Misoprostol in Obstetrics and Gynecology” which included a recommendation of 600µg oral misoprostol for prevention of PPH (Weeks & Faúndes, 2007). Misoprostol can be administered orally, rectally, vaginally or sublingually; it is inexpensive, easy to store, stable in field conditions, and it has an excellent safety profile (el- Rafeay *et al*, 1997). 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 (ICM/FIGO, 2006) and the WHO has recommended that in the absence of the active management of third stage labor, misoprostol should be offered by a health worker trained in its use for PPH prevention (WHO, 2007).

Additionally, there is evidence to support community-based distribution of misoprostol. In a study of misoprostol use in Tanzania, traditional birth attendants (TBAs) were trained to administer misoprostol in home births for the treatment of PPH (Prata *et al*, 2005). In rural areas of Tigray, Ethiopia, TBAs successfully administered misoprostol for PPH prevention (Prata *et al*, 2009). The Jhpiego group, an international health organization affiliated with Johns Hopkins University, conducted a study demonstrating that misoprostol could be successfully distributed and used to prevent PPH among women who gave birth at home in West Java, Indonesia and in Afghanistan (Sanghvi *et al*, 2004; Sanghvi *et al*, 2010). It is therefore imperative to explore further the options of using misoprostol in home births to protect women who deliver either by themselves or with family members and TBAs in order to strengthen the evidence needed to recommend its widespread availability at the community level.

1.2 Rationale for Misoprostol Distribution using TBAs and Community Drug Keepers for Prevention of Postpartum Hemorrhage at Home Births

With the support of Venture Strategies for Health and Development (VSHD), in 2006, Nigeria became the first country in the world to register misoprostol for the prevention and treatment of postpartum hemorrhage. In May 2007, the Federal Ministry of Health approved the clinical guidelines for the use of misoprostol in the country, which was subsequently ratified by the National Council on Health. Nigeria’s current guidelines limit the dispensing of this cost-effective and easy-to-administer drug to skilled providers, pharmacists, and health care workers trained in life-saving skills, thus frustrating its potential of making significant contributions to maternal mortality reduction from PPH in the country. This is because nationally, of the estimated six million deliveries that take place annually, 65% or 3,900,000 take place at home, without the supervision of trained health professionals. However, wide regional variations exist in the proportion of home deliveries; the percentage of home deliveries is highest in the North-West Zone (92%) where only 10% of all deliveries supervised by a skilled attendant (National Population Commission, 2009). Without a review of the guidelines, the women who need misoprostol

most, women who deliver at home without trained health professionals and are at higher risk of death from PPH, will be denied access to this life-saving intervention.

Though a number of studies have demonstrated that misoprostol can be used effectively by TBAs, (Walraven *et al*, 2005; Prata *et al*, 2005, Prata N *et al*, 2009a; Prata N *et al*, 2009b) the major concern expressed by the FMOH was that there was insufficient evidence for promoting the use of the drug by non-health professionals. The stakeholder/policy makers' meeting on misoprostol for the prevention and management of postpartum hemorrhage in December 2007 suggested that local evidence on the use of misoprostol by non-skilled providers is needed in Nigeria so that the level of access to the drug could be expanded to reach women who deliver at home without the supervision of skilled health care providers (Federal Ministry of Health, 2007). This operations research was thus undertaken as a response to this policy need of evidence.

The location of the study in Zaria, Kaduna State was informed by the fact that the majority of deliveries in these communities take place at home and are supervised either by TBAs, family members or by no one at all; in addition, past experiences training TBAs in safer birthing practices and keeping records have demonstrated the feasibility of this approach in enhancing their performance and data capture potentials which the study hoped to exploit (Ejembi, 1996; Ejembi, 1998). Also, in these communities, because of the lack of availability or the very poor state of primary health care facilities, patent medicine vendors are increasingly the major source of illness consultation and drugs. The research hoped to harness these resources already present and providing services at the community level for expansion of access to misoprostol for use in home births.

1.3 Proposal Development and Advocacy

1.3.1 Creation and Function of Partnerships

The study was undertaken as a partnership between the PRHP, the Bixby Center for Population, Health and Sustainability at UC Berkeley and VSI, with initial preparations conducted by VSHD. The Bixby Center has an impeccable record of collaborative research in the area of misoprostol for postpartum hemorrhage in Africa and Asia. In addition, the Bixby Center has a long term joint project with Ahmadu Bello University (ABU), a National Institutes of Health-Fogarty research training grant in population and reproductive health. It was under this project that the PRHP was founded.

The research was carried out under the auspices of the PRHP. This is a five-year collaboration between UC Berkeley and ABU. It is a fellowship program that is aimed at enhancing the capacity of staff of key departments at ABU to carry out community-based research for the promotion of reproductive health. The departments include Community Medicine, Obstetrics and Gynecology and Sociology as well as Mass Communication and Geography. The program seeks to stimulate innovative solutions to existing reproductive health problems, especially maternal morbidity and mortality. The long-term goal of the PRHP program is to train a critical mass of northern Nigeria's reproductive health researchers in community-based operations research on priority reproductive health issues. One of its activities in furtherance of this goal is the implementation of a five-year community-based research program in which the training of five cohorts of researchers would take place. The community-based research program aims to address urgent questions about how to effectively increase access to safe and affordable reproductive health services in resource poor settings. The conduct of this study was a logical response to the findings from the demographic and reproductive health survey conducted by the first year cohort that demonstrated high maternal mortality in the study communities with seven out of the 15 reported maternal deaths due to PPH.

VSI has provided technical and financial assistance to the project implementation since November 2008. VSHD, VSI's sister organization, funded the formative research that informed the development of the proposal. Both are California-based not-for-profit organizations at the forefront of increasing access and availability of misoprostol for PPH worldwide. Venture Strategies has had a strong presence in Nigeria since 2005, collaborating with local and international NGOs working in Nigeria, local universities and the FMOH.

1.3.2 Advocacy and Community Mobilization

Preceding the development of the proposal, advocacy visits were undertaken to traditional and religious leaders in the proposed study communities. During the visits, they were acquainted with the proposed study, its objectives and proposed methods. Following consent, these leaders and selected women and men were engaged in the preliminary interviews and focus group discussions that elicited wider interest in the project and also provided the information used for proposal development.

Before the commencement of the study, the research team conducted a series of segmented community dialogues, targeting male and female groups, in each of the study communities. A total of 18 community dialogues were held, with between 60 and 140 attendees during each session. More than 1800 people in the study communities were reached through these dialogues. The community dialogues provided a wider platform for sensitizing more members of the communities about the proposed research and obtaining community inputs on the operational modalities for the keeping, distribution and monitoring of use of the drug, including roles and responsibilities. During these extensive community dialogues, the research team worked with the women to create awareness of what amount is too much blood loss after delivery. A local rubber cup used for fetching water from the water pot, called *moda*, was found to hold exactly 500 ml of water. Similarly a wrapper, two yards of cotton material, when completely soaked, also holds 500 ml of water. 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. The community dialogues also provided a forum to counsel the members of the community and engage in community discussions to dispel any misconceptions about the use of misoprostol for the prevention of PPH.

1.4 Goals and Objectives

The purpose of this study is to provide empirical evidence to inform policy decision-makers on the safety of the administration of misoprostol by TBAs to prevent PPH, the leading cause of maternal deaths, at home births in Nigeria.

The specific objectives are:

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

2. Methods

2.1 Study Design

The study was essentially cross-sectional and descriptive in design and sought to describe community-level distribution, knowledge, acceptance and uptake of misoprostol in home births in the study communities. A community-based participatory approach was used in the conduct of the survey.

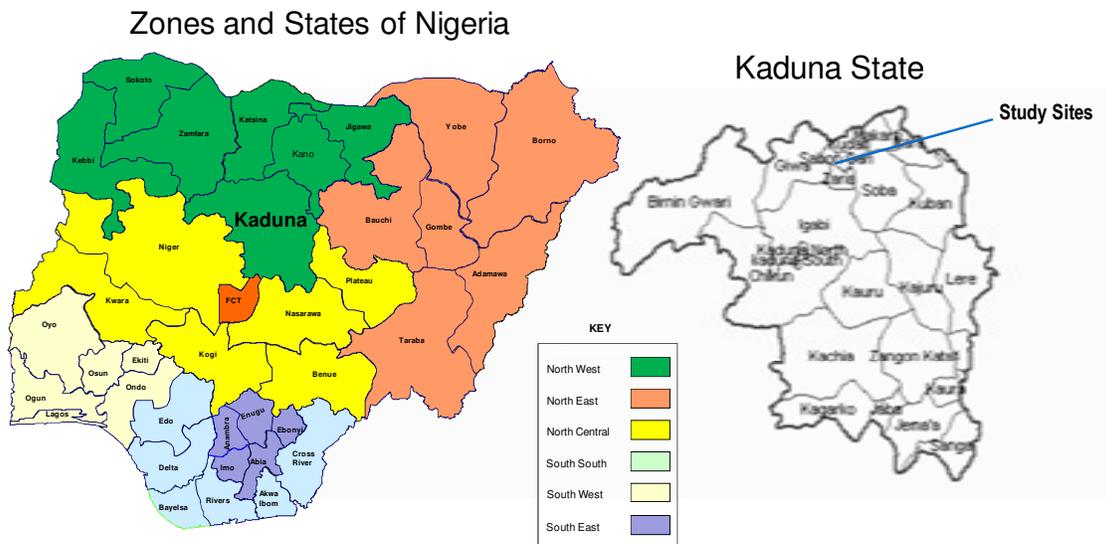
Preceding data collection, focus group discussions (FGDs), community dialogues and key informant interviews were conducted during which criteria for selection of community members that would be included as part of the research team as the community implementers and distributors of misoprostol were discussed and agreed upon. These criteria were used by the leaders of the different communities to select three groups of people in the community that would be included in the study: the drug keepers, who would distribute misoprostol in their shops; community oriented resource persons (CORPs), who would educate communities and identify pregnant women; and TBAs, who would also identify pregnant women, assist mothers in using their previously acquired misoprostol, and assist the research team in following-up women who had delivered in the project areas. Following training and community sensitization, distribution systems for misoprostol in the study communities were established.

Data was collected from the drug keepers to monitor misoprostol. Information was obtained from the TBAs and CORPs on all deliveries in the study communities and questionnaires administered to all consenting postpartum women identified in the study communities on their knowledge and use of misoprostol. In the event of complications and referrals, follow up visits to the referral health facilities were undertaken and data collected on the reason for referral, the management of the complication and outcome. Case reports were compiled for all cases of PPH reported to the research team and verbal autopsies conducted for all reported maternal deaths. Monthly community meetings were hosted by each of the village heads to monitor and review progress.

2.2 Location and Participants

The study was undertaken in five communities in Zaria and environs located in the northern part of Kaduna State in the North West geo-political zone of Nigeria (Figure 1). The communities, spread across three LGAs, are Hayin Ojo and Unguwan Godo in Sabon Gari LGA, Dakace in Zaria LGA, and Tsibiri and Yakawada in Giwa LGA. The North West geo-political zone has the second highest zonal maternal mortality ratio in Nigeria at 1,026 maternal deaths per 100,000 live births (Federal Office of Statistics and UNICEF, 2000), with higher rates observed among rural and less educated populations.

Figure 1: Study sites



The five study sites have a combined estimated population of around 21,000 with the majority residing in Hayin Ojo (8940), an urban slum, while Yakawada has an estimated population of 4100; Dakace, 3470; Unguwan Godo, 3000; and Tsibiri, 1490. Hausa Fulani Muslims are the dominant group among these populations with Hayin Ojo having a more heterogeneous population and Dakace having a sub-population of Christians of diverse ethnic groups. A 2007 reproductive health survey conducted as part of the Forgary-funded activities of the collaborative PRHP project of UC Berkeley and ABU showed that in three of these five communities the population is young, with 48% aged less than 15 years. Early marriage is the norm, with the mean age at marriage for females at 15 years; fertility levels are very high with the total fertility rate of 8.2 children per woman and use of contraception low. The vast majority of women - more than 80% - deliver at home. Lack of education, high poverty levels and limited access to quality health care are some of the major reasons for the high rates of home deliveries.

Home deliveries in these communities are supervised mainly by TBAs, family members or sometimes no one (Ejembi, 1998). Traditionally, TBAs play very little role during the antenatal period. For women who seek their assistance during pregnancy, traditional antenatal care (ANC) starts during the seventh month when the TBA provides some herbs for the pregnant woman to take monthly. During childbirth, the TBA is usually called after the head of the baby has been delivered. Her job, in normal deliveries, is limited to the delivery of the placenta, cutting of the umbilical cord and ritual burial of the placenta (Ejembi, 1993).

Maternal mortality is a common experience in the study communities with more than half of those deaths reported due to hemorrhage. The qualitative data collected as part of the planning for the study documented the high level of community concern over maternal deaths and hemorrhage as one of the leading causes of such deaths in the area.

There is currently no drug given for the prevention of PPH in the project communities, except, perhaps, the herbs given by TBAs to reportedly ease delivery and reduce complications.

Study Participants

Participants in the study were women in the third trimester of pregnancy, delivering at home with local TBAs or with the support of family members, and anticipating a vaginal delivery. Enrollment in the study was voluntary, but subject to the following eligibility criteria:

1. Ability to give informed consent (written or oral depending on the woman's literacy level) and complete the survey questionnaire;
2. Anticipation of an uncomplicated vaginal delivery;
3. Gestation greater than 36 weeks since the last menstrual period at the time of delivery;
4. Age 18 years or older.

The exclusion criteria were:

1. Patients with known bronchial asthma, or other chronic disease (e.g. cardiac diseases, diabetes, high blood pressure);
2. Patients expected to undergo cesarean section;
3. Patients who are enrolled but then needed to be referred before delivery for a cesarean section or an instrument-assisted delivery; and
4. Patients having other severe complications during labor and delivery that may put them at high risk for poor outcomes if they participate in the study.

In the first phase of the study, TBAs learned how to recruit and screen study subjects, take informed consent, administer misoprostol, and refer the patients to the local hospital if necessary.

Given the estimated population of the project communities, the crude birth rate and an estimated misoprostol acceptability rate of around 80%, the study anticipated that 774 pregnant women would enroll in the study within 12 months. However, from the beginning the researchers acknowledged that the population figures were likely underestimated and therefore there was a high likelihood of much higher enrollment than anticipated.

2.3 Development of Information, Education, and Communication Materials

Production of fact sheets and posters on PPH and its prevention and management

Fact sheets and posters, containing basic information on maternal mortality, causes of PPH, prevention and treatment of PPH, including use of misoprostol, and active management of third stage of labor, were produced in English and Hausa and distributed to trained health care providers in primary health care facilities and referral outlets used by the study population. These fact sheets were also made available to the drug keepers to be distributed along with the misoprostol tablets.

Hijabs and butas

Hijabs, the covering that Muslim women wear over their clothing, head ties for Christian women and *butas*, plastic kettles used for ablutions, for the Muslim men were produced. Each of these items had an inscription in Hausa that read, "Take three tablets of misoprostol immediately after birth to prevent PPH." These were distributed widely in the study communities, especially to all participants during the community dialogues and all the members of the research team before the commencement of drug distribution. These popular items helped to sustain interest and anticipation of the drug.

Production and dissemination of audiotaped drama and illustrated booklet on PPH

Community dramas have been found to be a very effective method of health education in these communities. A script was developed that addressed the issue of PPH and how it can be prevented with misoprostol. The storyline was developed in a very participatory manner with women in the communities and based on issues raised during the community dialogues. The English and Hausa versions of the script and drama were produced in collaboration with the staff of Kaduna State Media Corporation. The drama was mass produced on audio tapes and CDs and distributed in the study communities.

To accompany the audio-taped drama, an illustrated booklet titled 'Give Me a Chance' in English and "A *Bani Dama*" in Hausa that graphically depicted the drama. This booklet was intended for non-literate audiences to be used along with the audio drama or on its own. The booklet also includes questions and answers relating to maternal mortality and PPH for a literate person to read aloud and explain to others who cannot read.

The Kaduna State Media Corporation staff that produced the audio drama and the fine artist that did the illustrations attended some of the community dialogues to understand the issues and the setting. The first draft of the materials was pre-tested at the community level as well as among the TBAs during their training for aesthetics, comprehension and cultural acceptability before finalization, production and dissemination.

2.4 Project Personnel and Training

2.4.1 Organizational Structure

Members of the research team comprised doctors drawn from the departments of Community Medicine and Obstetrics and Gynaecology of Ahmadu Bello University Teaching Hospital, Zaria and nurse/midwives or primary health care workers from primary health care (PHC) facilities located in the

vicinity of the study communities, CORPs, drug keepers and TBAs. The community-based members of the research team were all respected members of the community who reside in the community, and speak the local language. They were selected by community members based on agreed upon criteria that included, among others, an interest in participating in the research and geographical representation to cover all the wards in the different study communities. The allocation of the team members to the different communities was proportionate to the population of the communities. The organizational structure of the research team is shown in Figure 2.

Figure 2: Organizational structure of the research team

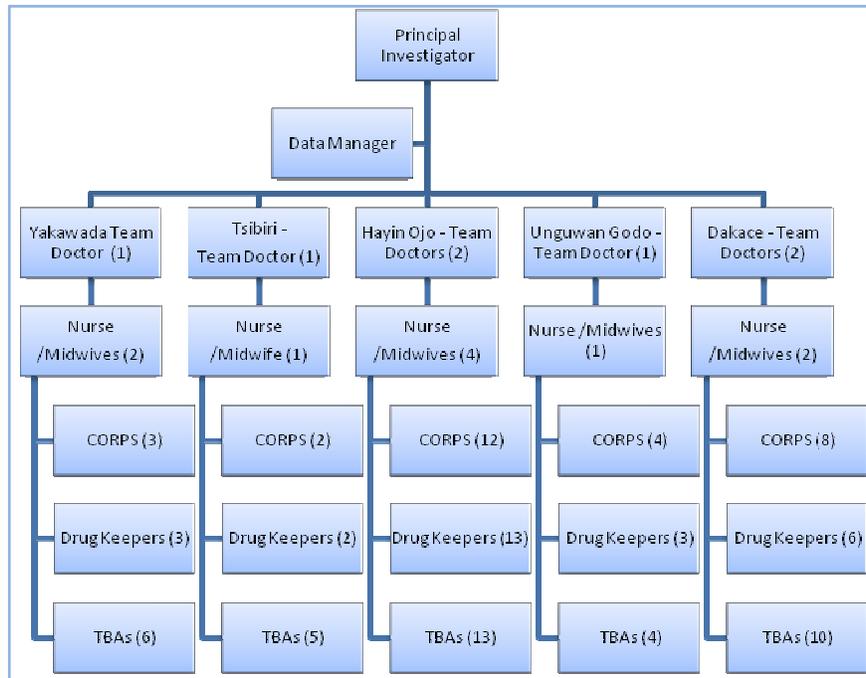


Table 1 provides a detailed description of the roles of the different members of the research team in each community. The TBAs were all females, aged less than 60 years, and actively practicing. Each TBA attended at least three deliveries per month, attended deliveries beyond those of immediate family members, and had someone in her respective compound that could help with keeping records of the deliveries she supervised. The TBAs were part of the research staff; they participated in recruiting study subjects, collected information and carried out the intervention. They were primarily responsible for the administration of misoprostol to the women after delivery. They sought the assistance of the nurse/midwives on the research team in the event of complications during delivery and referred parturient women to local hospitals as appropriate. They also kept information on all deliveries they supervised and others that occurred in their neighborhoods and reported these to the nurse/midwives.

The CORPs were a new cadre of community-based health workers introduced for this research. They served essentially as research assistants and were literate and willing members of their communities. Village health workers, previously trained under the PHC scheme would have been an ideal cadre to engage, but they have all disappeared with time because of a lack of sustainability strategies. The female CORPs provided support in the identification of pregnant women while the male CORPs counseled male members of the community and significant others on the importance of supporting the women and granting them permission to use misoprostol following childbirth. The major role of these CORPs was to reinforce messages covered in the community dialogues and fact sheets in one-to-one

interactions. The responsibilities of the female CORPs were to identify pregnant women in the wards assigned to them and counsel on pregnancy, ANC attendance, and use of misoprostol. They also kept information on deliveries in their areas of jurisdiction and reported these to the nurse/midwife.

Table 1: Roles and responsibilities of members of the research team

Research Team Member	Roles and Responsibilities
Doctors	<ul style="list-style-type: none"> • In collaboration with the nurse/midwives, organize and conduct training of CORPs. • Monitor and replenish drug stocks. • Monitor drug use at community level to ensure rational dispensing and use. • Provide immediate response and support in the event of reported complications or symptoms associated with misoprostol use. • Follow up health facility referrals of parturient women and complete the facility questionnaire after securing signed consent. • Provide continuing education to teams assigned to their village. • Convene monthly review meetings in the community. • Provide oversight for all data collection in assigned community.
Nurse/Midwives	<ul style="list-style-type: none"> • Reinforce education of TBAs, CORPs and drug keepers on PPH prevention and treatment using misoprostol. • Visit all women within two days of delivery and administer postpartum questionnaire. • In the event of reported symptoms associated with misoprostol use, inform doctors immediately, visit client and advise on management. If referral is necessary, assist with the referral and inform doctors of referral centre patient taken to. • Facilitate referral of women with reported delivery complications and inform the doctors immediately. • Provide childbirth support as feasible.
Drug Keepers	<ul style="list-style-type: none"> • Keep supply of misoprostol stock, ensuring security and safety of supply. • Ensure appropriate documentation of all drugs supplied and dispensed. • Monitor supply, if finishing before next visit of research team, call immediate supervisor to resupply. • Avail researchers of book and drug box for monitoring.
CORPs	<ul style="list-style-type: none"> • Identify all pregnant women in their area. • Provide midwife with the list of pregnant women. • Counsel the pregnant women on the importance of ANC, Tetanus Toxoid, rest, diet in pregnancy and birth preparedness. • Counsel pregnant women on prevention of PPH and use of misoprostol. • Inform midwives of any delivery in their area. • Male CORPs discuss with male members of the community and other influential community members to foster support for use of misoprostol.
TBAs	<ul style="list-style-type: none"> • Visit each pregnant woman and educate her on need for ANC, diet, rest and prevention of PPH, including use of misoprostol. • On invitation to conduct delivery, collect misoprostol supplies from person keeping the drug and give to the pregnant woman immediately after delivery, if she consents. • Monitor woman for at least six hours after delivery and notify midwives. • Inform nurses of any deliveries in her area within a day of the delivery.

The drug keepers included a broad range of literate and trusted community members that included either male or female patent medicine vendors (PMVs), TBAs, teachers, village head in one community or members of the village head's household in others. They were responsible for keeping the misoprostol, dispensing it to TBAs, pregnant women or members of their households seeking them for

any woman during her last month of pregnancy. They kept records of all of their transactions, which they made available to the nurse/midwives and doctors.

The nurse/midwives or primary health care workers were assigned sections of the town where they provided supervision to the community-based research team members, administered the questionnaires to all women that delivered in their areas of jurisdiction, and provided technical support to the TBAs.

Each of the communities had a doctor heading the research team, who had oversight for the research work in that community, including the day to day supervision of data collection, ensuring the integrity of data collected, dealing with complications and referrals, and organizing the monthly community-level review meetings.

2.4.2 Training Structure

A series of trainings were undertaken by all the members of the research team before the commencement of data collection.

Health Care Providers from PHC and Referral Outlets Used by Community Members: A one day sensitization workshop was organized for 45 health care providers comprised of doctors, nurse/midwives and other PHC workers drawn from the PHC facilities and referral outlets used by women in the project communities. The objectives of the workshop were to update participants on maternal mortality and its determinants, causes, prevention and control of PPH and active management of third stage of labor, and to acquaint them with the operations research and their potential roles. Additionally, the nurse/midwives serving on the research team had training on administration of the postpartum questionnaire to women that deliver in these communities.

Traditional Birth Attendants: Forty one TBAs were trained on home-based life saving skills for 10 days, where they were taught delivery practices and management of the third stage of labor, with specific focus on postpartum hemorrhage (identification of danger signs, measuring and monitoring postpartum blood loss with the use of *moda* or wrapper); inclusion criteria; obtaining informed consent; asking questions required for the study data collection instrument; identification of the possible symptoms; and following the study protocol, including the referral system. TBAs were trained to assist mothers in taking three (3) misoprostol tablets (600 micrograms) for the prevention of PPH. They were also taught emergency actions to take in the event of PPH, that included the insertion of five (5) tablets (1000 micrograms) of misoprostol rectally and referral to the health facility. The training was conducted by some of the doctors and nurses on the research team and the Maternal and Child Health (MCH) Coordinators from the Health Departments of the three LGAs where the research communities are located. The opening and closing ceremonies of the training, which took place in Sabon Gari Comprehensive Health Centre, were widely publicized and had in attendance representatives of the emirate, traditional leaders of the project communities, and representatives of primary and secondary referral health facilities used by the study communities. Thus, they served as further avenues to sensitize the community and mobilize support for the research.

Drug Keepers: A three day training was organized for the drug keepers with the training led by the doctors and nurses on the research team. The training focused on raising awareness on issues around maternal mortality and PPH, safe keeping of the misoprostol stocks, documentation of dispensing of the drug and how to secure informed consent at drug intake. The training for 27 drug keepers was held at the same time and venue as that for the TBAs and the two groups participated in some of the sessions together; the main purpose was for them to know each other, build rapport and begin to forge modalities of working together.

CORPs: This category of research assistants was trained at the community level by the doctors and nurses on the research team, in addition to the MCH coordinators from the respective LGA PHC departments. The training lasted two days. Twenty-nine people designated to serve on the research team attended the training. In two of the communities the village heads were in attendance throughout the duration of the training. This was done so as to further sensitize more community members. They were trained in counseling skills, identification and counseling of pregnant women on ANC and misoprostol use, and documentation of their activities.

2.5 Data Collection

Data was collected at three points in the study using logbooks, forms, and structured interviewer-administered questionnaires: 1) intake data at the point of misoprostol distribution, 2) postpartum data from a postpartum interview, and 3) referral documentation. Verbal autopsies provided qualitative data in the event of maternal death.

Intake Data: 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 to take it to her with instruction to have a literate person to read it to her and have her provide her thumb print. The drug keeper collected the following information from the person collecting the drug: name and address of the beneficiary, the gestational age and the purpose for collecting the drug. If some other person collected the drug on behalf of the client, the relationship of the person to the patient was documented. This information, kept in exercise books, was later transcribed into intake questionnaires (e.g. Misoprostol Forms) by the nurses and doctors on the research team.

Postpartum Data: Information about deliveries in the community was communicated to the nurse/midwives by the CORPs or TBAs and within two weeks of delivery the nurse/midwives visited the woman to administer the postpartum questionnaire. Prior to administration of the questionnaire, written informed consent was sought and where the respondent was non-literate, oral consent was obtained in the presence of an independent witness and the nurse/midwife confirmed the oral consent in writing. Following consent, the questionnaire was interviewer-administered. Information obtained included awareness and knowledge of PPH and misoprostol, antenatal care, place of delivery, attendant at delivery and use of misoprostol, and experience of symptoms and delivery complications and referrals.

Referral Data: All delivery referrals were reported to the doctors on the research team who then visited the referral hospital and administered the referral questionnaire to the attending physician that sought information on the cause of the referral, management and outcome.

Maternal Mortality Audit: All cases of maternal mortality that occurred in the study communities during the period of the study were investigated by the doctors on the team. They conducted verbal autopsies to try to establish the cause and circumstances surrounding the death, possible contributing factors and use or otherwise of misoprostol.

Information on all pregnancies and deliveries in the project sites was also collected. Information on all pregnant women in the communities, their ANC status, intention and otherwise to use misoprostol and delivery intentions was provided verbally by the CORPs to the TBAs, nurse/midwives and project team during the regular meetings. Information on deliveries, misoprostol use, incidence of bleeding and other complications, referrals or otherwise was collected verbally by the TBA and made available to the

nurse/midwife assigned to the area within 48 hours, and immediately in the event of complications, to the research team member assigned to the area.

2.6 Data Management and Analysis

Data collected from this operations research for this component of the study came from three sources:

- i. Program data from the Misoprostol Form documenting misoprostol distribution.
- ii. A postpartum interview conducted by supervisors and researchers of the project at the participants' home within two weeks of delivery. The postpartum interview included: socio-demographic characteristics and pregnancy information, place of delivery and assistance; estimated blood loss; monitoring of complications of labor; condition of the neonate and mother; knowledge, attitudes and practices related to misoprostol; symptoms experienced; source of knowledge and the drug; and willingness to pay for the drug.
- iii. Stock balance sheet forms kept by the community drug distributor. In addition, s/he had a register for keeping the following: date of requisition; name of person making request; designation of person making the request; purpose of request; and number of tablets dispensed.

Monthly review meetings were organized in each of the communities. These meetings were hosted by the respective village heads and attended by all of the members of the research team assigned to the village and any other interested community members. These review meetings provided a forum to monitor data collection, misoprostol stocks and uptake in each of the communities; audit all delivery referrals and mortalities; and address any community concerns related to the research. These reports were reviewed at the monthly meeting of the central research team made up of the local principal investigator, the doctors and the nurse/midwives on the research team. Additionally, this meeting provided a forum for monitoring performance against set targets.

All completed questionnaires were submitted to the doctors supervising each community research team, who reviewed them for completeness and consistency before submission to the local principal investigator during the monthly review meetings of the research team. All questionnaires were submitted to the data manager for data processing, which consisted of office editing, data entry and editing computer-identified errors. The data were processed by a team of four: one data manager and three data entry clerks. Data entry and editing were accomplished using Epidata. The data were subsequently imported to SPSS Version 17 and Stata version 11 for analysis.

2.7 Ethical Review

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. Women participating in this study gave verbal informed consent at enrollment and before the postpartum interview.

3. Results

The number of women expected to enroll in the study proved to be underestimated, as was anticipated. The available population based figures were probably underestimated. From January through December 2009, 1875 women delivered in the project areas and were registered by the project staff (Table 2). Enrollment surpassed expectations in Hayin Ojo, Yakawada, and Dakace. However, in

Unguwan Godo, the study intervention began only in July, so data in this report from this community refers only to six months of study implementation.

Table 2: Participants by village

	Tsibiri	Hayin Ojo	Yakawada	Dakace	Unguwan Godo	Total
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of women expected to enroll in project *	69	411	189	160	138	967
Number of women who delivered in project areas**	113	1068	299	262	133	1875
Number of completed postpartum interviews	105 (92.9)	1015 (93.0)	314 (95.2)	253 (96.6)	97 (72.9)	1800 (96)

* assumes a crude birth rate of 46/1000 population reported from Northern Nigeria.

** according to monthly case reports.

From the deliveries registered in the study the research team was able to follow up and administer a postpartum interview to over 96% of women. The results discussed in this section are based on the 1800 women who responded to the postpartum interview. The total number of women that responded to each specific indicator analyzed in this report might differ slightly from the overall total due to missing values. However, missing values are never more than 3%.

3.1 Antenatal and Delivery Characteristics

Table 3 presents participants' characteristics related to antenatal attendance and delivery place and assistance. Overall, almost 89% of women attended at least one antenatal care (ANC) visit during the pregnancy, varying from 61% in Tsibiri to 98% in Unguwan Godo. Of those attending ANC, the average number of visits was five.

Table 3: Antenatal care and delivery characteristics

	Tsibiri	Hayin Ojo	Yakawada	Dakace	Unguwan Godo	Total
	n=105	n=1013	n=314	n=252	n=113	n=1797
ANC attendance	64 (60.9)	948 (93.6)	239 (76.1)	229 (90.9)	111 (98.2)	1591 (88.5)
Average number of ANC visits (+SD)	3.9 (1.45)	5.7 (1.47)	4.0 (1.40)	5.5 (2.18)	5.6 (1.16)	5.2 (1.72)
Location of delivery	n=103	n=1007	n=314	n=251	n=113	n=1788
Home	96 (93.2)	988 (98.1)	307 (97.8)	224 (89.2)	90 (79.7)	1705 (95.4)
Health facility	7 (6.8)	19 (1.9)	27 (2.2)	27 (10.8)	23 (20.3)	83 (4.6)
Attendant at delivery	n=84	n=991	n=310	n=249	n=112	n=1746
Doctor	1 (1.2)	3 (0.3)	1 (0.3)	8 (3.2)	0 (0.0)	13 (0.7)
Midwife/ nurse/ medical officer	6 (7.1)	26 (2.6)	19 (6.1)	30 (12.1)	33 (29.5)	114 (6.5)
TBA	73 (86.9)	795 (80.2)	130 (41.9)	156 (62.7)	61 (54.5)	1215 (69.6)
Friend/ relative/ alone	4 (4.8)	167 (16.9)	160 (51.6)	55 (22.0)	18 (16.0)	404 (23.1)

Almost all women participating in this study delivered at home (95%). Slight variations in place of delivery can be observed between communities, with Unguwan Godo having the lowest percentage of home births (80%) of the five communities and Yakawada and Hayin Ojo with the highest percentage of home births (98%). Attendance at delivery is highly correlated with the person who assisted the birth. It is not surprising given that the vast majority of deliveries took place at home that TBAs assisted most of the deliveries (overall 70%). The only exception was Yakawada, where approximately 52% of the deliveries were assisted by friends, relatives or the woman delivered alone, while TBAs assisted in 42% of deliveries. Skilled attendance at delivery (of a doctor, midwife, nurse or medical officer) was very low overall (7%). Only in Dakace and Unguwan Godo did women report more than 10% of deliveries being assisted by a skilled person (15% and 30% respectively).

3.2 Feasibility: Coverage of Target Population with Misoprostol and IEC Messages

3.2.1 Coverage of Target Population with IEC Messages

The community awareness campaign was an important part of this project. The campaign included community dialogues, drama, printed materials and interpersonal communication through the work of TBAs and CORPs. The key messages included information about bleeding after delivery, the importance of delivery in a health facility, and all information related to misoprostol (use, dose, route, symptoms). Table 4 presents the responses to some of the key messages, asked after delivery during the postpartum interview.

Table 4: Exposure to IEC community outreach

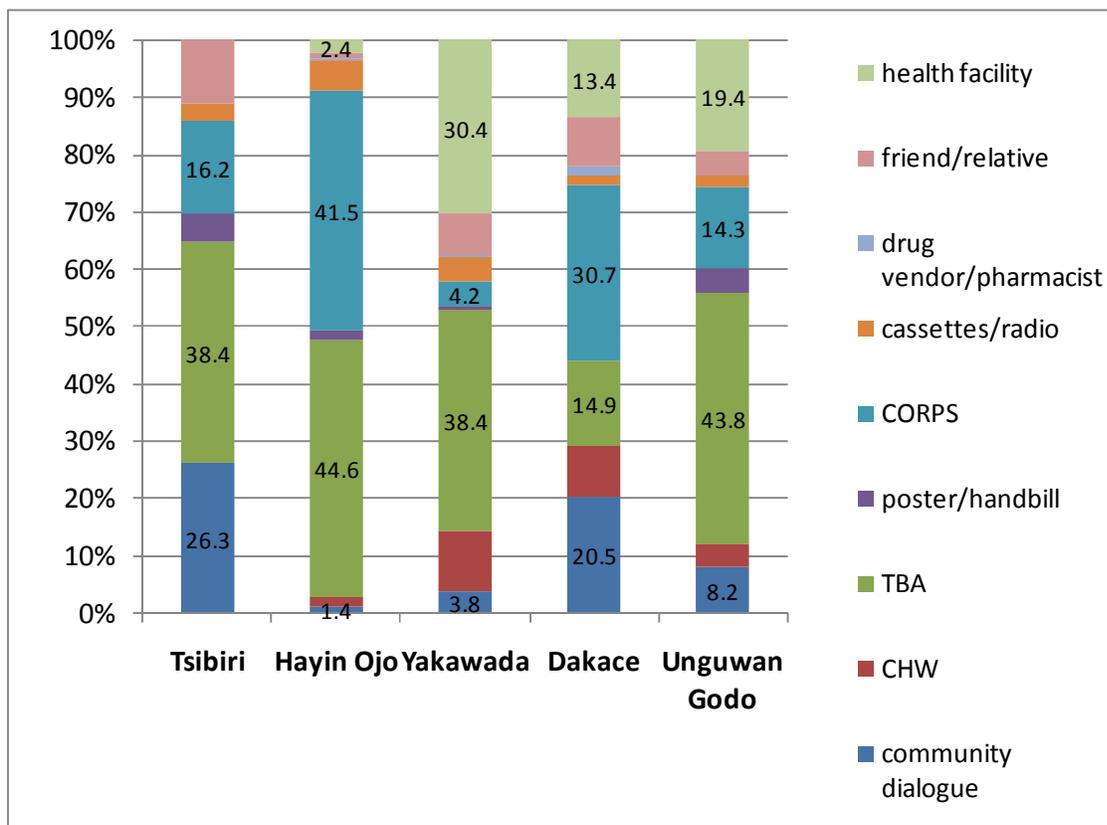
	Tsibiri	Hayin Ojo	Yakawada	Dakace	Unguwan Godo	Total
	n=104	n=1012	n=314	n=252	n=113	n=1795
Received information about bleeding after childbirth	97 (93.3)	990 (97.8)	9284 (90.5)	126 (50.0)	88 (77.9)	1585 (88.3)
Main sources of information on bleeding after childbirth						
Midwife	55 (55.6)	665 (67.2)	75 (26.9)	17 (13.7)	13 (14.8)	825 (52.3)
Community dialogue	50 (50.5)	107 (10.8)	74 (26.7)	16 (12.9)	7 (7.9)	254 (16.1)
CHW	49 (49.5)	246 (24.8)	16 (5.8)	2 (1.6)	4 (4.6)	317 (20.1)
TBA	87 (87.9)	918 (92.6)	162 (58.7)	16 (12.6)	38 (43.2)	1221 (77.4)
Poster/ handbill	38 (38.4)	153 (15.4)	11 (4.0)	0 (0.0)	21 (23.9)	223 (14.2)
CORPS	4 (4.04)	27 (2.7)	4 (1.5)	7 (5.7)	8 (9.1)	50 (3.2)
Friend/Relative	61 (61.6)	276 (27.9)	131 (46.9)	40 (32.6)	12 (13.6)	520 (32.9)
Health facility	16 (16.2)	533 (53.8)	135 (48.9)	33 (26.6)	58 (65.9)	775 (49.1)
Received information about misoprostol	100 (96.2)	989 (97.7)	265 (84.4)	128 (51.2)	98 (86.7)	1580 (88.1)
Main sources of information about misoprostol						
Midwife	45 (45.0)	583 (58.9)	71 (27.2)	16 (12.4)	3 (3.1)	718 (45.5)
Community dialogue	51 (51.0)	100 (10.1)	38 (14.7)	32 (34.8)	8 (8.2)	229 (14.5)
CHW	41 (41.0)	212 (21.4)	20 (7.8)	1 (0.8)	5 (5.1)	279 (17.7)
TBA	94 (94.0)	953 (96.3)	187 (71.7)	27 (20.9)	82 (83.7)	1343 (85.2)
CORPS	81 (81.0)	578 (58.4)	51 (19.7)	41 (31.8)	84 (55.1)	805 (51.1)
Cassettes/ radio	22 (22.0)	245 (21.8)	52 (20.0)	2 (1.6)	10 (10.3)	331 (21.0)
Drug vendor/Pharmacist	4 (4.0)	66 (6.7)	11 (4.3)	0 (0.0)	0 (0.0)	81 (5.2)
Friend/Relative	64 (64.0)	285 (28.8)	115 (44.2)	18 (14.0)	12 (13.4)	494 (31.4)
Health facility	11 (11.0)	212 (21.4)	116 (44.4)	9 (7.0)	38 (38.8)	386 (21.5)

Most women reported having received information about bleeding after delivery (88%). Overall, TBAs were the most reported source of information about PPH (77%), followed by midwives (52%), and health facilities (49%). The information, education and communication (IEC) campaign was equally successful in reaching targeted women with the message about misoprostol for PPH. Around 88% of women reported knowing about misoprostol for PPH, and this information reached as high as 98% in Hayin Ojo and 96% in Tsibiri. The main source of information about misoprostol was again the TBA (85%). Of the five communities, only in Dakace were community dialogues and CORPS reported to have been the main source of information about misoprostol for PPH (35% and 32 % respectively). With the exception of drug vendor/ pharmacist, across all communities, the role of each of the IEC campaign components differed slightly, but all seem to have played an important role. Women were reached with messages from a variety of sources and in many cases more than one source was reported.¹

The most important source of information about misoprostol is presented in Figure 3.

¹ It is important to note that women might be reporting based on the last person to give them information, the one that is fresh in their memory. Community dialogues happened at the inception of the program, and were directed to a sample of the respondents only. The distribution of the cassettes and illustration booklets was limited as just 300 of each were produced for all the communities. CORPS visited once or twice during the pregnancy.

Figure 3: Most important source of information about misoprostol



The most important source of information reported by women varied significantly across communities, underscoring the importance of each IEC campaign component. According to Figure 3 TBAs were consistently reported as the most important source of misoprostol information in all communities but Dakace, where CORPS played a bigger role (31%). CORPS also played a significant role in Hayin Ojo with almost 42% of the women reporting them as the main source of information about misoprostol.

3.2.2 Coverage of Misoprostol Distribution in Target Population

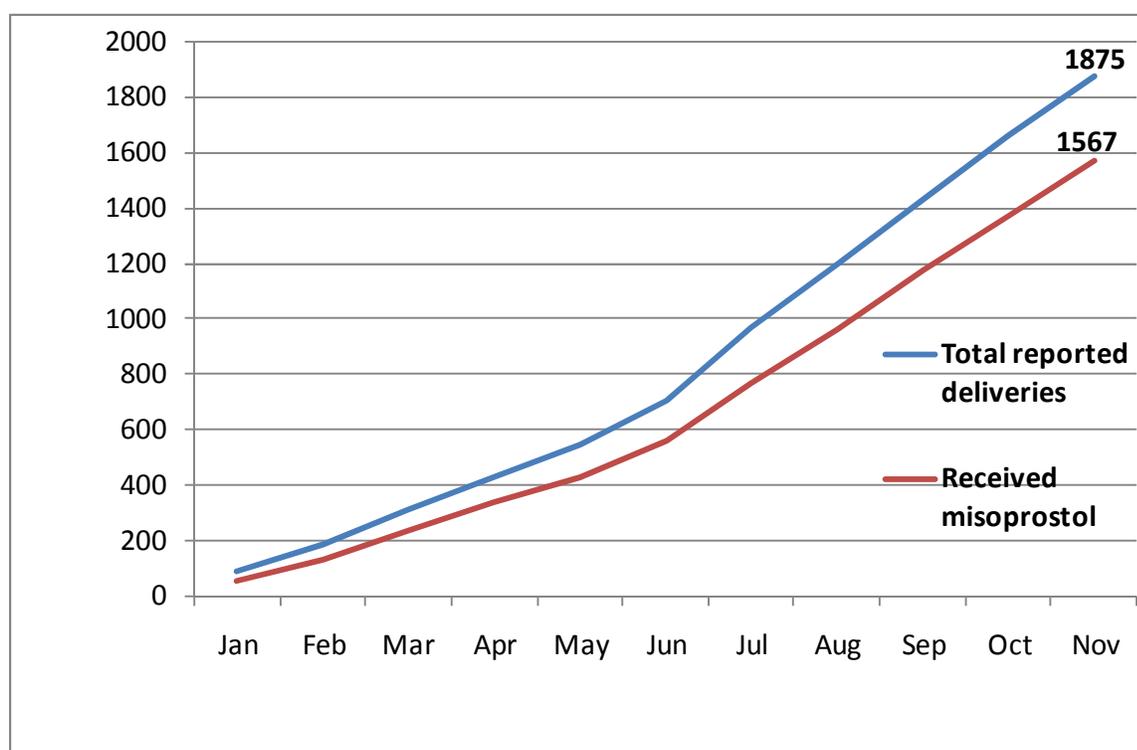
Across all communities TBAs and CORPS were very effective in reaching pregnant women with the message about PPH and misoprostol, and TBAs were very effective in accessing the drug using the community drug keepers. Around 84% of enrolled women received misoprostol to use in case they delivered at home (Table 5). This represents a significant uptake of the intervention in less than 12 months of the project. Yakawada and Dakace have the lowest percentages of women reached with the drug. Factors contributing to this are the much higher facility delivery rate in Dakace, and a large, more dispersed population to cover in Yakawada relative to the number of TBAs and drug keepers in the area.

Table 5: Number of women who received misoprostol among those who delivered in the project sites

	Tsibiri	Hayin Ojo	Yakawada	Dakace	Unguan Godo	Total
	n (%)	n (%)				
Enrolled in the project	113	1068	299	262	133	1875
Received misoprostol	100 (88.5)	984 (92.1)	190 (63.5)	172 (65.6)	121 (91.0)	1567 (83.6)

The monthly progress in reaching women throughout the duration of the project is presented in Figure 4. The figure demonstrates that women were reached with the messages and that misoprostol was being widely distributed to women enrolled in the study. The gap between the two lines in the graph represents those women who did not take misoprostol, which includes women who had an injection after delivery (4% over the course of the project).

Figure 4: Reported deliveries in the project sites and misoprostol intake



3.3 Program Effectiveness: Comprehension of IEC Messages and Coverage of Misoprostol at Home Births

3.3.1 Comprehension of IEC Messages in Target Population

Table 6 shows that women in the study had a very high level of comprehension of the IEC messages. The comprehension was assessed during the postpartum interview by asking specific questions and waiting for a spontaneous response. Most women knew that PPH could cause death (84%), and understood how much was too much blood loss after delivery (83%). However, fewer than half of women surveyed mentioned the importance of going to a health facility or the need to get help from a midwife if PPH occurred (49%). This could be a reflection of the lack of services available in the project areas and the fact that most women have been delivering at home with the assistance of TBAs.

Table 6: Comprehension of IEC messages

	Tsibiri	Hayin Ojo	Yakawada	Dakace	Unguwan Godo	Total
	n (%)	n (%)				
Information about PPH						
PPH can cause death	94 (95.0)	838 (84.7)	253 (89.7)	64 (50.8)	79 (89.8)	1328 (83.8)
Go to a health facility or get help from a midwife	19 (19.2)	578 (58.4)	101 (36.3)	39 (31.2)		772 (48.9)
Bleeding soaks one wrapper or more or fills one <i>moda</i> rubber cup or more	87 (93.6)	838 (90.3)	55 (47.4)	23 (28.8)	44 (88.0)	1047 (82.6)
Information about misoprostol						
Misoprostol prevents, stops, or reduces the chances of bleeding after childbirth	99 (99.0)	972 (98.9)	258 (99.2)	124 (96.1)	96 (99.0)	1549 (98.7)
Correct use (orally, immediately after baby is born)	100 (99.0)	979 (98.8)	254 (95.5)	120 (93.0)	95 (96.9)	1545 (97.7)
Correct dose (3 tablets)	91 (98.9)	867 (98.3)	211 (96.4)	143 (97.3)	82 (91.1)	1394 (97.5)
Knows potential symptoms associated with misoprostol use						
<i>Shivering</i>	96 (100.0)	947 (98.0)	103 (95.4)	34 (89.5)	57 (76.0)	1237 (96.4)
<i>Nausea</i>	87 (90.6)	488 (50.5)	27 (25.2)	8 (21.1)	27 (36.0)	637 (49.7)
<i>Vomiting</i>	65 (67.7)	579 (59.9)	45 (42.1)	3 (7.9)	18 (24.0)	710 (55.3)
<i>Diarrhea</i>	27 (28.1)	406 (42.0)	19 (17.8)	2 (5.3)	1 (1.3)	455 (35.5)
<i>Raise of temperature</i>	5 (5.2)	259 (26.8)	16 (15.0)	1 (2.6)	43 (57.3)	324 (25.3)
<i>Does not know any symptoms</i>	2 (2.1)	30 (3.1)	0 (0.0)	3 (7.9)	0 (0.0)	35 (2.7)

Regarding information about misoprostol and its effect on PPH prevention, in all communities over 90% of women correctly knew the function of misoprostol (overall 99%), and the correct dose of three tablets for PPH prevention was known by 98% of women. In addition, 96% of women knew at least one symptom of the drug, and only 2.7% of women reported not knowing any symptoms of misoprostol.

3.3.2 Use of Misoprostol at Home Births for Prevention of PPH in Target Population

Births protected against PPH are those in which the delivering woman received any uterotonic, in injectable or tablet form, immediately after delivery to help reduce bleeding. Table 7 presents data collected from the postpartum interviews on the uterotonic used immediately after delivery (i.e. protected births), either misoprostol use after a home delivery or injection after a health facility delivery for PPH prevention.

The use of misoprostol for PPH prevention at home births is by and large the most important contributor to births protected against PPH (Table 7). The percentage of women who received injectable uterotonics is very low in these communities (4%). With misoprostol available at the community level, 79% of the women enrolled in the project were protected against PPH that otherwise

would not have been. This demonstrates the importance of having an intervention for home births in communities where most of the deliveries take place at home.

With the addition of misoprostol at home births a total of 83% of deliveries were protected. It is expected that in developing countries, anywhere from 5% to 20%² of deliveries will develop PPH and most of them will require referral, transportation and additional interventions in facilities equipped to provide them. Results from this study further demonstrate the program effectiveness and the potential impact of misoprostol at home births. All of the communities involved in the study had on average a PPH incidence rate³ of around 3%, lower than expected.

Table 7: Coverage of misoprostol and protected births

	Tsibiri n=106	Hayin Ojo n=1029	Yakawada n=315	Dakace n=253	Unguwan Godo n=97	Total n=1800
Took misoprostol (PPH prevention)	89 (84.0)	892 (86.7)	215 (68.5)	147 (58.1)	78 (80.4)	1421 (79.0)
Received Injection	9 (8.5)	25 (2.4)	10 (3.2)	26 (10.3)	5 (2.0)	78 (4.3)
Did not receive / take any drug	8 (7.5)	112 (10.7)	89 (28.3)	80 (31.6)	14 (11.3)	303 (16.8)
Births protected from PPH*	98 (92.5)	917 (89.1)	225 (71.7)	173 (56.5)	83 (85.6)	1499 (83.3)

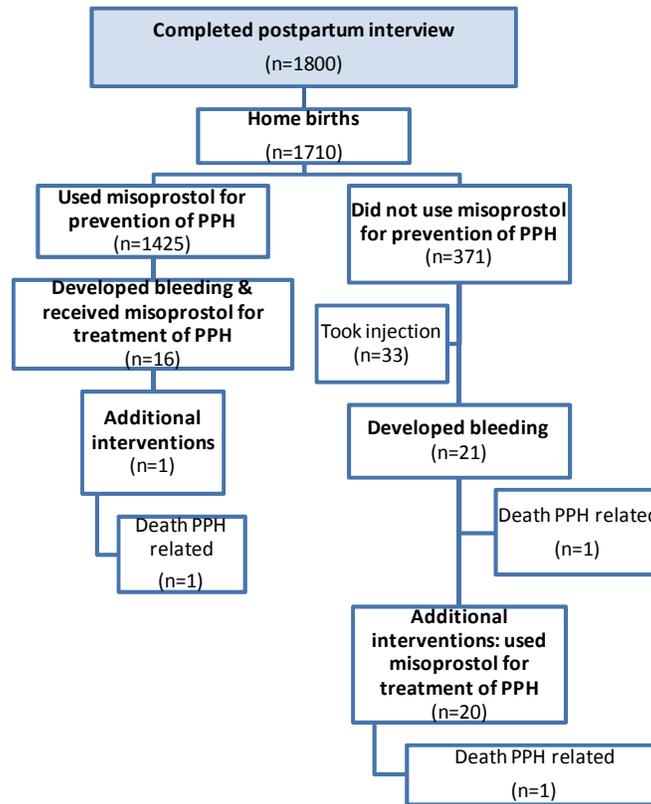
* percentage estimated from all births

Bleeding-related problems that developed during home births were successfully treated at home. Among those who took misoprostol at home, only one woman required additional interventions, was taken to the facility and died of bleeding-related complications. This bleeding-related problems category includes all women who had blood loss equivalent to 500ml or more, were referred to a health facility and/or received additional interventions. These interventions could vary from intravenous (IV) solutions, blood transfusion, additional uterotonics, manual removal of placenta, and surgery. Of the 1425 women who received misoprostol, only 16 had blood loss of 500ml or greater (1%), and all but one were successfully treated with misoprostol. From a much smaller number of 371 women who did not take misoprostol, 21 developed bleeding-related problems (5%), 20 of them were treated with misoprostol for PPH and of those treated only one needed additional interventions and subsequently died. One woman died of PPH without having received misoprostol (Figure 5).

² PPH incidence rates (blood loss of 500ml or more without the use of uterotonics) considered are from Egypt (5%) in a hospital study and blood loss measured with a calibrated drape; 12% from India in home births, blood loss measure with calibrated drape; and 20% in rural Tanzania, blood loss measured with a local “kanga” cloth.

³ Because measurement of blood loss at home births can be inaccurate, PPH incidence is measured as intention to treat among those who needed additional interventions.

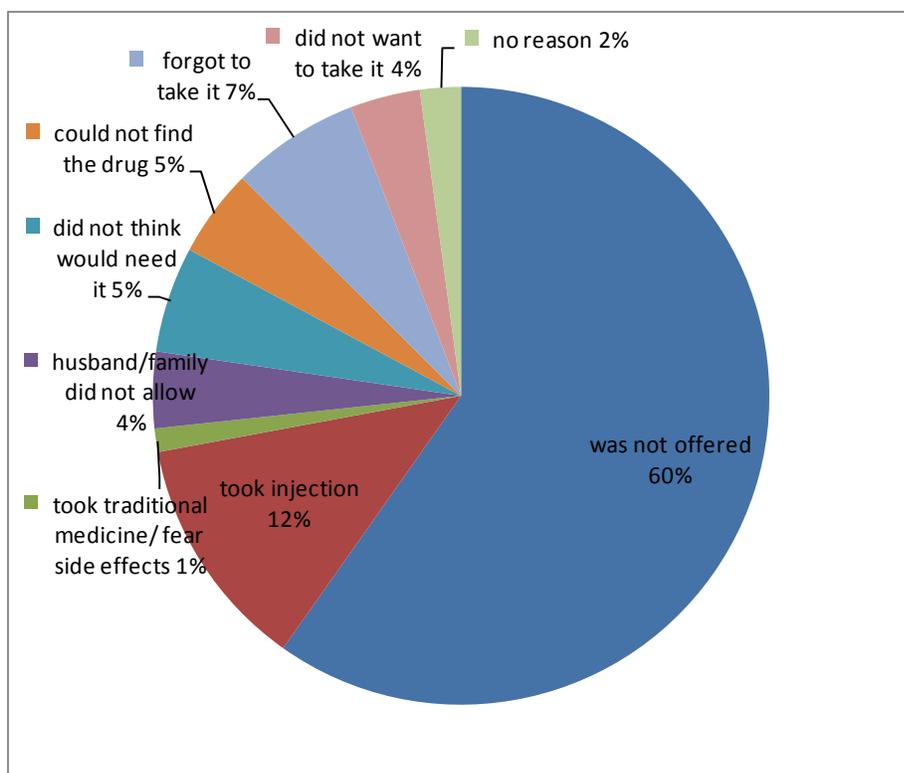
Figure 5: Bleeding-related referrals and need for additional interventions



Among the women who did not receive any uterotonic and delivered at home, the research team inquired during the postpartum interview the reasons for non-use of misoprostol. Half of the women reported not being offered the drug (60%), followed by 12% that received injection at home (Figure 6).

To better understand the reasons for non-use it is important to know that interviews of postpartum women were not limited to the women delivered under the supervision of the TBAs trained in the project. The research team interviewed other women who delivered in the communities. Only a fraction of the TBAs in each community were trained in the project. In addition, the strategy used for accessing the drug was that of family members or the pregnant women collecting the drug for the pregnant woman during ANC visits or at the time of labor. The TBA could also collect the drug for the woman when in labor, if the woman had not already collected the drug. In the event that the TBA that assisted the delivery was not a participating TBA in the project or the delivery was conducted by friends or the woman herself, the likelihood of their collecting and offering the drug to the woman was low. The researchers also assume that their level of awareness of, and interest in, the drug might also be lower. All these reasons may have contributed to the number of women who were not offered the drug. The intake forms from the drug keepers show that the majority of drugs were collected during the antenatal period.

Figure 6: Reasons for non-use of misoprostol among women who delivered at home (n=326)



3.4 Safety: Correct Use of Misoprostol and Postpartum Symptoms

Among women who used misoprostol for PPH prevention 98% reported using the correct dose, and 88% reported the correct route and timing (Table 8).

Table 8: Correct use of misoprostol

	Tsibiri n=92	Hayin Ojo n=874	Yakawada n=219	Dakace n=147	Unguwan Godo n=90	Total n=1422
Correct dose (3 tablets)	91 (98.9)	867 (98.3)	211 (96.4)	143 (97.3)	82 (91.1)	1394 (97.5)
Correct route and timing (oral)	70 (76.1)	852 (97.3)	186 (84.9)	56 (37.6)	84 (92.3)	1248 (87.5)

Self reported symptoms after delivery are presented in Table 9. Among those who took misoprostol a significant number experienced shivering compared to non-users (42% v. 9%). This value is not surprising, given that shivering is an expected symptom of misoprostol use. It is also important to note that overall 96% of the women knew to expect shivering as a symptom. Raised body temperature is also a symptom significantly more reported by women who have taken misoprostol than women who did not (11% vs. 5%). Other symptoms such as nausea, vomiting and diarrhea do not seem to differ significantly among those who took misoprostol and those who did not take it. Reported symptoms subsided within 30 minutes and none of the women required additional intervention or referral due to symptoms. It is important to note that the majority of the women (74%) did not experience any

symptoms, and the number was not statistically significantly different between those who took misoprostol and those who did not take the tablets.

Table 9: Reported experience of postpartum symptoms

	Took misoprostol n=1425	Did not take misoprostol n=371	Total n=1796	p-value
Shivering	603 (42.0)	34 (9.2)	637 (35.5)	<0.001
Nausea	83 (5.9)	15 (4.5)	98 (5.5)	0.109
Vomiting	29 (2.0)	10 (3.0)	39 (2.2)	0.425
Raise of body temperature	158 (11.1)	19 (5.2)	177 (9.9)	0.001
Watery stool	24 (1.7)	12 (3.3)	36 (2.0)	0.061
Did not experience any symptoms	1040 (74.6)	277 (68.3)	1316 (73.2)	0.035

3.5 Acceptability: User Perspectives on Misoprostol Use

Women were asked during the postpartum interview whether they would take misoprostol in the next pregnancy; recommend misoprostol to a friend or relative; and if they would purchase misoprostol. These are all considered measures of acceptability of the intervention, the willingness to pay being the ultimate sacrifice, a reflection of women being willing to give up something valued in exchange for misoprostol.

Acceptability was extremely high in all communities (Table 10). 95% of women said they would take misoprostol in a future pregnancy and 96% would recommend it to a friend. Women are willing to pay for misoprostol (95%). The average amount reported in the table reflects what they are willing to pay if the drug becomes available in their community for purchase. During the project the drug was made available for free. Based on these results, this community intervention can be considered acceptable to women and their communities.

Table 10: Acceptability of misoprostol and willingness to pay for the drug

	Tsibiri n (%)	Hayin Ojo n (%)	Yakawada n (%)	Dakace n (%)	Unguwan Godo n (%)	Total n (%)
Would use misoprostol in a subsequent pregnancy	97 (94.2)	967 (97.9)	270 (92.8)	186 (87.3)	108 (97.3)	1628 (95.4)
Would recommend misoprostol to a friend or relative	96 (93.2)	965 (97.6)	277 (95.2)	188 (87.4)	110 (98.2)	1636 (95.7)
Would purchase misoprostol	96 (93.2)	986 (97.8)	285 (91.6)	215 (89.2)	109 (97.3)	1691 (95.3)
Average amount willing to pay for misoprostol (Naira) of those willing to pay	745	497	510	320	867	522

Conclusions

The overall results of this operations research are positive and encouraging. From the data we conclude that:

- Community-based distribution of misoprostol is feasible. TBAs were highly effective in reaching women with the drug, and despite low literacy rates, method compliance was high. Drug keepers also played an important role in the community distribution.
- Misoprostol use was safe at the community-level. The majority of women used the drug correctly after a home birth for PPH prevention. The experience of symptoms associated with misoprostol use was within the normal range, self limiting and did not necessitate further intervention.
- Misoprostol was extremely acceptable to both women and men in these predominantly Hausa Muslim communities. Nearly all women stated they would recommend misoprostol, take it again in a subsequent pregnancy, and would be willing to pay for the drug.
- TBAs and CORPs were critical resources to the success of the intervention and effective community agents for interpersonal messages to women and men.
- The community awareness campaign was effective in reaching women and achieved near universal message comprehension. IEC messages could be stronger in underscoring the importance of a facility birth.
- This intervention is scalable on a national level and has the potential to save the lives of the numerous Nigerian women who still deliver at home.

Recommendations

While efforts to increase skilled delivery should continue and are encouraged, these are medium- to long-term solutions. The results of this study provide evidence to support the immediate expansion of community-based distribution of misoprostol to protect women who cannot reach a facility to deliver from PPH. As PPH remains the leading cause of maternal death in Nigeria and the vast majority of women currently deliver at home, home births deserve our attention.

Given the results of this study we strongly recommend:

- Misoprostol be allowed be used at the community level by appropriately trained community agents.
- Policies or strategies be developed that include community health extension workers or TBAs as the vehicle for birth preparedness and misoprostol information and education.
- Prioritization of funding and resources to scale up the intervention to other communities and LGAs in Kaduna State and countrywide.
- Evaluation of emerging strategies for community-based distribution of misoprostol. Nigeria recently established a Midwifery Corp Scheme whereby retired or recently qualified midwives are being recruited to work specifically in rural communities. A policy should be developed to include misoprostol in the delivery kit given to midwives involved in this program, encouraging them to use it routinely for the prevention of PPH.
- Development of policies to include misoprostol in the 'Mama Kits' for Safe Motherhood. The delivery kits are distributed at ANC and contain clean delivery supplies and other immediate needs of the mother and baby for safe delivery.

- Given willingness to pay, there is a need to encourage pharmaceutical marketing of the drug to maintain it at an affordable cost for end users.
- Given the results of this study we strongly recommend that misoprostol be allowed to be used at community level.

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