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PREVENTION OF POSTPARTUM HEMORRHAGE AT HOME BIRTH IN AFGHANISTAN



**A Joint Program between the Afghanistan Ministry of Public Health and the
ACCESS Program, with the Support of USAID**

AUTHORS

Harshad Sanghvi
Nasratullah Ansari
Ndola Prata
Hannah Gibson
Aftab Tariq Ihsan
Jeffrey M. Smith

TABLE OF CONTENTS

ACKNOWLEDGMENTS	vi
EXECUTIVE SUMMARY	viii
INTRODUCTION	11
Background	11
Misoprostol for Prevention of PPH	11
Postpartum Hemorrhage in Afghanistan	14
Demonstration Project	15
MATERIALS AND METHODS	16
Proposal Development and Advocacy	16
Preparation	18
RESULTS	29
General Characteristics of Study Participants	29
Characteristics of the Study Population	29
Program Effectiveness/Effort: Coverage, Workload	30
CONCLUSIONS	44
Key Findings	44
Guidance for Introduction in Other Countries	45
RECOMMENDATIONS	46
REFERENCES	47

LIST OF TABLES AND FIGURES

List of Tables

- Table 1** Summary of evidence for using misoprostol to prevent PPH, selected studies
- Table 2** Health profile of selected project study areas
- Table 3** Qualitative data collection
- Table 4** Characteristics of the study population
- Table 5** Delivery information
- Table 6** Use of misoprostol (intervention areas only)
- Table 7** Use of uterotonic drugs
- Table 8** Women's perception of excessive bleeding according to uterotonic used
- Table 9** Reported postpartum blood loss
- Table 10** Place of birth and misoprostol use among women in intervention area
- Table 11** Recollection of messages about PPH (unprompted responses)
- Table 12** Sources of information about PPH
- Table 13** Sources of information about misoprostol (intervention area)
- Table 14** Recall of information about side effects of misoprostol (intervention area)
- Table 15** Support persons who received information about PPH and misoprostol (intervention area)
- Table 16** Recall of key misoprostol messages by women according to type of birth assistant (intervention area)
- Table 17** Recall of information about signs of excessive bleeding
- Table 18** Recall of information about causes of excessive bleeding
- Table 19** Acceptability and willingness to pay for misoprostol (intervention area)
- Table 20** Relationship between knowledge and experience of misoprostol-related side effects and willingness to pay for misoprostol
- Table 21** Reported symptoms
- Table 22** Referrals

LIST OF FIGURES

- Figure 1** Key stakeholders
- Figure 2** Examples of educational materials on birth preparedness and use of misoprostol
- Figure 3** Research and service delivery components of the project
- Figure 4** Coverage of expected population of newly pregnant women with identification and education visit by CHWs (June 2006 to February 2007)
- Figure 5** Coverage in intervention area with educational message and misoprostol distribution, and misoprostol use over time (June 2006 to August 2007)

ABBREVIATIONS AND ACRONYMS

ACCESS	Access to Clinical and Community Maternal, Neonatal and Women’s Health Services Program
AMTSL	Active Management of the Third Stage of Labor
BHC	Basic Health Center
CHC	Comprehensive Health Center
CHS	Community Health Supervisor
CHW	Community Health Worker
MCH	Maternal and Child Health
MOPH	Ministry of Public Health
NGO	Nongovernmental Organization
PPH	Postpartum Hemorrhage
SAFE	Safety, Acceptability, Feasibility, and program Effectiveness
TAG	Technical Advisory Group
TBA	Traditional Birth Attendant
USAID	United States Agency for International Development
WHO	World Health Organization

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EDITORS:

Melissa McCormick, Jaime Mungia and
Susi Wyss

REVIEWERS:

Patricia Gomez, Nancy Caiola, Sheena Currie,
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¹ The ACCESS Program is the U.S. Agency for International Development's global program to improve maternal and newborn health. The ACCESS Program works to expand coverage, access, and use of key maternal and newborn health services across a continuum of care from the household to the hospital—with the aim of making quality health services accessible as close to the home as possible. Jhpiego implements the program in partnership with Save the Children, Constella Futures, the Academy for Educational Development, the American College of Nurse-Midwives, and IMA World Health.

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EXECUTIVE SUMMARY

Afghanistan has one of the highest maternal mortality ratios in the world, estimated to be about 1,600 per 100,000 live births, and only 19% of all births are attended by a skilled provider (Ministry of Public Health [MOPH], Afghanistan Health Survey, 2006). A large number of women are dying from preventable causes simply because they do not have access to skilled care or simple interventions that could save their lives. Postpartum hemorrhage (PPH), currently the leading cause of maternal death in Afghanistan, presents such an example, as it can often be prevented by giving the woman a uterotonic drug after the birth of the baby and before the delivery of the placenta (World Health Organization [WHO], 2007a).

The purpose of this study was to demonstrate the Safety, Acceptability, Feasibility, and program Effectiveness (SAFE) of community-based distribution of misoprostol—an effective uterotonic drug—by Community Health Workers (CHWs) to reduce the incidence of PPH at home births in Afghanistan. This study was funded by the United States Agency for International Development (USAID) and was a collaborative partnership between the Afghanistan MOPH; the Jhpiego-led Access to Clinical and Community Maternal, Neonatal, and Women’s Health Services (ACCESS) Program; Venture Strategies for Health and Development; and implementing partners Save the Children/U.S. and International Medical Corps.

The study included 3,187 women: 2,039 women in the intervention group (Qorghan and Qaramqul districts in Faryab province, and Qarabagh district in Kabul province), and 1,148 women in the comparison group (Qarqin and Khamab districts in Jawzjan province, and Guldara district in Kabul province). During home visits by CHWs in both comparison and intervention groups, pregnant women and family members designated as the women’s support persons received counseling on: 1) birth preparedness and complication readiness; 2) recognition of danger signs—especially PPH—during pregnancy, childbirth, and the postpartum period; 3) the importance of having a skilled provider² present at the birth; and 4) what to do in case of a complication, including where and from whom to seek care.

Women in the intervention area also received counseling on the purpose and correct timing and use of misoprostol to prevent PPH, the risks of taking misoprostol before the birth of the baby, and common side effects of misoprostol. Counseling messages emphasized that women should: 1) deliver with a skilled provider, where active management of the third stage of labor can be offered to prevent PPH; and 2) use misoprostol only if a skilled provider is not present at the birth. At the end of the counseling session, the women and their support persons were asked to describe in their own terms the purpose and correct use of misoprostol and the risks associated with use and misuse of the drug. To ensure the safety of the women, counseling was repeated until the participants could correctly restate the information. Three 200-mcg tablets of misoprostol in foil packets, called “*Guli Zedi Khunrizi Bad Az Weladat*” (“tablet against bleeding after childbirth”), were packaged together in

² According to WHO, a skilled attendant is an accredited health professional—such as a midwife, doctor or nurse—who has been educated and trained to proficiency in the skills needed to manage normal (uncomplicated) pregnancies, childbirth, and the immediate postnatal period; and in the identification, management, and referral of complications in women and newborns. Both trained and untrained traditional birth attendants are excluded.

sealed plastic bags, labeled with pictorial messages about correct use, and distributed by CHWs to women in the intervention areas during their eighth month of pregnancy. The misoprostol was given directly to the pregnant woman herself, as opposed to her support persons, since the woman might deliver alone and she is the only person certain to be present at birth. Of the 2,039 women who were eligible to receive misoprostol, 2,021 (99%) were offered the drug, and 1,421 (70%) used the drug. Of those women who took the misoprostol, 96% took misoprostol correctly. No women took the drug at the wrong time or took the drug prior to the birth of the baby (or second baby in the case of twins). Trained and supervised CHWs successfully counseled women on the risks of PPH and educated them on the safe and correct use of misoprostol.

The study achieved near universal coverage of a PPH prevention initiative in the intervention areas, with identification of pregnant women and the first educational message completed for 94% of the expected population by the end of the recruitment period. Distribution of misoprostol paralleled the recruitment of women, in that almost every woman identified as pregnant accepted misoprostol by the CHW (96%).

SAFETY

Of the 1,421 women in the intervention group who used misoprostol, all women took it after the birth of the (last) baby. The misoprostol was taken immediately after delivery of the baby and before the placenta was delivered by 96% of the women.

The side effects of misoprostol (e.g., shivering, nausea, cramping, and transient fever) are known and predictable. Contrary to expectations, however, the rates of all reported symptoms were higher in the comparison areas than in intervention areas. In fact, 60% of women in the intervention areas who received misoprostol reported experiencing no unpleasant symptoms, compared with only 19% of women in the comparison areas who reported no unpleasant symptoms. The higher rates of unpleasant symptoms reported among women in the comparison area was surprising. In-depth interviews with recently delivered women revealed that in the comparison area, women were more likely to use herbal products (such as yellow fat mixed with herb [*sar bogha*] and eggs, herbal root [*shirin booya*], or molasses mixed with opium extract) during labor and delivery and postpartum. These herbal products may have produced similar symptoms to those commonly associated with uterotonic drugs, such as shivering and nausea. One possible explanation for this occurrence is that women were more likely to use herbal products if they did not have a method to protect themselves against PPH.

ACCEPTABILITY

Misoprostol was highly acceptable to women and their families: 92% of women said they would recommend misoprostol to their friends and use it in their next pregnancy, and 88% said they would be willing to pay for misoprostol in the future. CHWs are also an acceptable cadre of health workers to provide women with basic information on pregnancy, childbirth, the danger signs of pregnancy (including PPH), and the use of misoprostol for prevention of PPH. Of particular note, the distribution of misoprostol by CHWs did not deter women from seeking care by a skilled provider. In fact, 30% of women in the intervention area gave birth with a skilled provider present compared with 28% of women in the comparison area.

FEASIBILITY

The feasibility of a community-based education and PPH prevention scheme was demonstrated by reaching up to 94% of pregnant women with home visits, overcoming various challenges such as logistics, terrain, and low literacy levels of both CHWs and study participants. The training courses for the CHWs used educational materials that were developed in a pictorial format, and role plays were used to practice counseling skills. Special pictorial flipcharts were created for use by the CHWs during counseling sessions with the women and their support persons. All CHWs were volunteers and were not provided with monetary rewards for their work in this study; instead, the project worked with key stakeholders in the CHWs' communities to devise non-monetary rewards and incentives, such as free transportation or electricity and the use of respectful titles by the communities.

Program Effectiveness

The study achieved near-universal coverage: 96% of women in the intervention group received a uterotonic drug. Although the study was not designed to assess the effectiveness of misoprostol in preventing PPH, it is interesting to note that reported PPH (estimated as two or more cloths soaked with blood within one hour following the birth) was reported by 49% of women in the comparison area compared with only 11% of women in the intervention area.

CONCLUSION

In summary, this study demonstrates that trained and supervised CHWs can successfully provide counseling and information on PPH prevention and can safely distribute misoprostol to women for use at a home birth. The study also demonstrates that the women and their support persons were able to understand and act on the messages given to them by the CHWs: there was not a single case of misuse of misoprostol. Importantly, the study shows that pregnant women are likely to continue to seek skilled care when possible even if they have access to a drug that can prevent PPH at home births, again demonstrating that women understand the educational messages given to them about the importance of delivering with a skilled provider.

The results of this intervention demonstrate that until skilled assistance during birth is available and accessible to all women, a strategy of prevention of PPH at home births using a community-based program of health education messages and distribution of misoprostol will have an impact in Afghanistan. Gradual expansion of the project is therefore recommended as an appropriate strategy. This expansion should be integrated within the existing framework for delivery of health care in Afghanistan, the Basic Package of Health Services, and through the contracting out of health services lead by the Grants and Contracts Management Unit of the MOPH. A robust monitoring system is required, and with training and adequate follow-up, CHWs and their supervisors could include this within their existing reporting schedules. Technical oversight and guidance could be provided by the ACCESS Program under its Health Services Support Project. Misoprostol should be added to the Essential Drug List and made available to implementing nongovernmental organizations.

INTRODUCTION

BACKGROUND

Postpartum hemorrhage (PPH) due to atonic uterus (failure of the uterus to contract after delivery of the placenta) is the major cause of maternal mortality in Africa and Asia (Khan et al., 2006). Once hemorrhage occurs, the woman's condition can rapidly deteriorate and she may require rapid resuscitation, blood transfusion, and other costly and invasive measures to prevent hemodynamic collapse and manage the cause of the hemorrhage. In low-resource settings, however, rapid referral and transport are often unavailable, and emergency preparedness at the referral site may be inadequate, placing the woman at even greater risk of death.

The importance of skilled attendance at birth is highlighted by the fact that between 60% and 80% of PPH can be prevented if appropriate care is available during labor and childbirth (Rogers et al., 1998; UNFPA, 2006). The most effective intervention for preventing PPH is Active Management of the Third Stage of Labor (AMTSL), a procedure that includes prophylactic use of a uterotonic drug after the birth of the baby, clamping and cutting of the umbilical cord, and controlled traction on the cord to deliver the placenta. Assessment or massage of the uterus after the placenta is delivered is also commonly included to ensure the uterus remains well contracted. Use of AMTSL has been shown to decrease the incidence of blood loss of one liter or more, decrease the need for blood transfusion, and decrease the need for additional uterotonic drugs (Prendiville et al., 2000). The World Health Organization (WHO) currently recommends that AMTSL should be performed only by skilled attendants and offered to all women who are giving birth (WHO, 2007a).

A meta-analysis of randomized controlled trials (Prendiville et al., 2007) confirms that compared to expectant management, AMTSL (in maternity hospital settings) is associated with the following reduced risks:

- maternal blood loss (weighted mean difference -79.33 mL, 95% confidence interval [CI] -94.29 to -64.37);
- blood loss of more than 500 mL (relative risk 0.38, 95% CI 0.32 to 0.46); and
- prolonged third stage of labor (weighted mean difference -9.77 minutes, 95% CI -10.00 to -9.53).

Although AMTSL was associated with an increased risk of maternal nausea (relative risk 1.83, 95% CI 1.51 to 2.23), vomiting and raised blood pressure (probably due to the use of ergometrine), no advantages or disadvantages were apparent for the baby.

MISOPROSTOL FOR PREVENTION OF PPH

Despite attempts to increase skilled attendance at all births, only 63% of births worldwide are attended by a skilled provider (WHO, 2007b), and in Afghanistan in 2006, only 19% of women gave birth in the presence of a skilled provider (Ministry of Public Health [MOPH], Afghanistan Health Survey, 2006), demonstrating that increasing the proportion of women who deliver with a skilled birth attendant remains a challenge. Preventing PPH at home births therefore remains an

important target area for programs which aim to improve maternal survival. Research has shown that misoprostol may be very useful in these circumstances. Misoprostol (e.g., Cytotec®, Pfizer) is a synthetic prostaglandin E₁ analogue that is available in tablet form. Originally developed to prevent gastric ulcers due to non-steroidal anti-inflammatory drugs, misoprostol also causes uterine contractions and has found numerous potential applications in obstetric and gynecologic practice (Broekhuizen, 2000). Misoprostol has particular advantages for use in low-resource settings: misoprostol is inexpensive, acts within three to five minutes of oral administration (Prevention of Postpartum Hemorrhage Initiative, 2008), has a shelf-life of more than seven years, and is not inactivated by light or tropical temperatures.

Several studies have examined the role of misoprostol in preventing PPH (see summary in Table 1). The efficacy of misoprostol in preventing PPH was demonstrated most convincingly by a carefully designed trial from India (Derman et al., 2006), in which either misoprostol or a placebo was given by auxiliary nurse midwives (lower-level providers with some midwifery skills, but who do not meet the full definition of skilled birth attendant) at home and sub-center births. The study accurately measured blood loss after delivery using a calibrated device and demonstrated a reduction in PPH with the use of misoprostol, with a decreased incidence of blood loss ≥ 500 mL (12% vs. 6.4%; RR 0.53, 95% CI 0.39–0.74, $p < 0.0001$).

Table 1. Summary of evidence for using misoprostol to prevent PPH, selected studies

AUTHOR, YEAR, AND LOCATION OF STUDY	STUDY TYPE	KEY FINDINGS
Bamigboye et al., 1998 Johannesburg, South Africa	<ul style="list-style-type: none"> Randomized trial Misoprostol 400 mcg rectally (n = 241) vs. Syntometrine 1 ampoule IM (n = 250) 	<ul style="list-style-type: none"> No significant differences in length of third stage of labor, postpartum blood loss, or postpartum hemoglobin levels Postpartum hypertension more common in women receiving Syntometrine (systolic blood pressure, $p = 0.00004$; diastolic blood pressure, $p = 0.00007$)
Hofmeyr et al., 1998 Johannesburg, South Africa	<ul style="list-style-type: none"> Randomized, double-blind, placebo-controlled trial Misoprostol 400 mcg orally (n = 250) vs. placebo (n = 250) 	<ul style="list-style-type: none"> Misoprostol decreased incidence of blood loss $\geq 1,000$ mL (6% vs. 9%; RR 0.65, 95% CI 0.35–1.22) Misoprostol decreased the need for therapeutic oxytocin (2.8% vs. 8.4%; RR 0.33, 95% CI 0.14–0.77)
Gülmezoglu et al., 2001 Argentina, China, Egypt, Ireland, Nigeria, South Africa, Switzerland, Thailand, and Vietnam	<ul style="list-style-type: none"> Randomized, double-blind, placebo-controlled, multi-center trial Misoprostol 600 mcg orally (n = 9,264) vs. oxytocin 10 IU given IV or IM (n = 9,266) 	<ul style="list-style-type: none"> Decreased incidence of severe PPH ($\geq 1,000$ mL), oxytocin vs. misoprostol (3% vs. 4%; RR 1.39, 95% CI 1.19–1.63, $p < 0.0001$) Decreased need for therapeutic uterotonic, oxytocin vs. misoprostol (11% vs. 15%; RR 1.40, 95% CI 1.29–1.51, $p < 0.0001$) Authors concluded that when both drugs are available, oxytocin is preferred over misoprostol

AUTHOR, YEAR, AND LOCATION OF STUDY	STUDY TYPE	KEY FINDINGS
Hoj et al., 2005 Guinea Bissau	<ul style="list-style-type: none"> • Randomized, double-blind, placebo-controlled trial • Misoprostol 600 mcg sublingual (n = 330) vs. placebo (n = 331) 	<ul style="list-style-type: none"> • Misoprostol decreased mean blood loss by 10.5% • Misoprostol decreased incidence of blood loss >1,000 mL (RR 0.66, 95% CI 0.45–0.98) • Misoprostol decreased incidence of blood loss >1,500 mL (RR 0.28, 95% CI 0.12–0.64)
Derman et al., 2006 Four primary health centers in rural India	<ul style="list-style-type: none"> • Randomized, placebo-controlled trial • Misoprostol 600 mcg orally (n = 812) vs. placebo (n = 808) 	<ul style="list-style-type: none"> • Misoprostol decreased incidence of blood loss \geq500 mL (12% vs. 6.4%; RR 0.53, 95% CI 0.39–0.74, $p < 0.0001$) • Misoprostol decreased incidence of severe blood loss \geq1,000 mL (1.2% vs. 0.2%; RR 0.20, 95% CI 0.04–0.91, $p < 0.0001$) • Misoprostol decreased mean blood loss (262.3 mL vs. 214.3 mL, $p < 0.0001$) • One case of PPH was prevented for every 18 women treated

RR = relative risk; CI = confidence interval

Three effective uterotonic drugs are potentially available for use in low resource settings. Oxytocin has minor side effects, including nausea, vomiting and diarrhea, and requires storage in cool temperatures (5–25 degrees), although it can be kept outside these temperatures for short durations. Side effects with ergometrine are more common, and ergometrine cannot be used in the 10 to 15% of women who have hypertension in pregnancy (Hogerzeil et al., 1993). Ergometrine is less stable in warm temperatures and requires storage in the dark. Both require a skilled provider trained in safe injections, and the availability of sterile syringes and needles.

The third uterotonic drug, misoprostol, is also effective, available in tablet form, and has relatively common but minor side effects such as shivering and transient elevation in temperature. Because of these attributes, misoprostol has the potential for use in preventing PPH at homebirths where there is no skilled provider. Lumbiganon et al. (1999) documented that the side effects of misoprostol are dose-dependent and determined that the optimal dose of misoprostol for postpartum use is 600 mcg.

Based on the available data, Goldberg et al. (2001) concluded that when oxytocin is not available, use of misoprostol to prevent PPH should be considered a Category A recommendation (i.e., strong and consistent evidence to support the recommendation). The U.S. Pharmacopoeia Expert Advisory Panel has also recommended that prevention of PPH be considered an “accepted” indication for use of misoprostol (Carpenter, 2001). Most recently, WHO recommended that, “in the absence of AMTSL, a uterotonic drug (oxytocin or misoprostol) should be offered by a health worker trained in its use for prevention of PPH” (WHO 2007a).

To date, only one study has examined using a scheme for community-based distribution of misoprostol for preventing PPH at home births (Sanghvi et al., 2004). In this study, conducted in Indonesia, trained community volunteers identified pregnant women in the community, educated

them about birth preparedness and PPH, distributed misoprostol to pregnant women at eight months' gestation, and followed up the women after childbirth. In an area where skilled care is available to only half of the women, this community-based distribution strategy achieved 94% coverage with a method to prevent PPH. The study showed that this intervention was SAFE, i.e. *Safe* (among the 999 women who took misoprostol, there were no cases of misuse of the drug); *Acceptable* to women and their families, even though the women experienced common side effects such as shivering; *Feasible* in a community setting; and programmatically *Effective*. Such results prompted this demonstration study for Afghanistan, to determine if such a strategy would also be SAFE.

POSTPARTUM HEMORRHAGE IN AFGHANISTAN

In 2005, Bartlett et al. published the results of their study of maternal deaths in four districts in Afghanistan, adding additional insight into the challenges of safe motherhood in Afghanistan. Among their findings:

- Afghanistan has one of the highest maternal mortality ratios in the world, estimated to be about 1,600 per 100,000 live births.
- The lifetime risk of maternal death is between 1 in 6 and 1 in 9, which translates into an estimated 26,000 women dying from pregnancy-related causes every year, or one woman dying every 27 minutes.
- Between 48% and 55% of deaths among women of reproductive age (15–49 years) are from pregnancy-related causes.
- Hemorrhage is the most common cause of maternal mortality in Afghanistan, responsible for about 38% of the maternal deaths; approximately 30% of the deaths are related specifically to PPH, which translates into an estimated 7,600 women every year.

Afghanistan has set a goal to reduce their maternal mortality ratio by 50% by 2015, which presents an enormous challenge in a country where only an estimated 19% of women deliver with the assistance of a skilled provider (MOPH, Afghanistan Health Survey, 2006). A substantial effort is currently underway to increase the number of professionally trained midwives as well as the number of births attended by skilled providers, but providing skilled professional care to all women in the country is still many years away. Furthermore, there is limited availability of emergency obstetric care and women face substantial geographic and other challenges when attempting to access such care. Therefore, any maternal survival strategy must consider what can be achieved at the community level, where skilled professional providers are not routinely available.

Two scenarios for distribution of misoprostol within the community were considered, including distribution during informal home visits by Traditional Birth Attendants (TBAs) or through the existing network of Community Health Workers (CHWs) who provide elements of antenatal care during structured home visits. Afghanistan has a growing community education and health outreach program and in the last three years most districts have achieved the target of having at least one CHW per 100–150 households. It was therefore reasonable to expect that a strategy for prevention of PPH at home births in Afghanistan could be implemented using a community-based program that relied on these CHWs. Furthermore, these community-based workers are widespread and

accepted in the community, and infrastructure and supervision systems already exist to manage them and provide supplies. Accordingly, this project sought to leverage the CHW model to test a strategy of community-based distribution of misoprostol through a demonstration project to assess whether it was SAFE: *Safe* and not likely to be misused, *Acceptable* to women and their families, *Feasible* to implement, and programmatically *Effective*.

DEMONSTRATION PROJECT

With the objective to demonstrate the safety, acceptability, feasibility, and program effectiveness of community-based distribution of misoprostol to reduce PPH at home births in Afghanistan, the following issues were specifically measured:

- Safety:
 - Severity of expected side effects (e.g., shivering, nausea, abdominal cramps, vomiting, diarrhea) due to misoprostol
 - Ability of women to take misoprostol at the correct time
 - Type and severity of complications and adverse events associated with misoprostol
- Acceptability:
 - Acceptability by women who actually took misoprostol after delivery
 - Approval of misoprostol use by the husband and family members, and reasons for non-use or disapproval of misoprostol by the woman and/or her family
 - Willingness of women to recommend misoprostol to family and friends or to purchase misoprostol for use during a future delivery
 - Knowledge and use of misoprostol among local providers, including CHWs and skilled providers, and their level and type of support for misoprostol
- Feasibility:
 - Ability to distribute misoprostol to all pregnant women, including those not likely to have a skilled provider present at their birth
 - Ability to promote misoprostol for home-based, unattended births without directly contradicting safe motherhood messages that strongly encourage use of a skilled attendant
 - Determination of best method to ensure correct misoprostol information and use, including women not in the skilled providers' network
 - Assessment of training needs regarding misoprostol, in both the public and private sectors
 - Assessment of the level of provider supervision required to ensure safety and appropriate distribution and dissemination of misoprostol and information about misoprostol
- Program effectiveness:
 - Ability to achieve universal or near-universal coverage of all women with a method of PPH prevention at home birth

MATERIALS AND METHODS

The study protocol, which used a non-random experimental control design, was approved by the Afghanistan MOPH's PPH Technical Advisory Group (TAG), Essential Drug Board, and Ethical Review Board under approval 23.02.2006, no. 358322 MOPH Afghanistan.

The study was conducted between June 2005 and August 2007. The project was divided into three phases: 1) proposal development and advocacy, 2) preparation, and 3) implementation.

PROPOSAL DEVELOPMENT AND ADVOCACY

Technical Advisory Group

A national PPH TAG was established to provide a high-level forum where stakeholders from the MOPH and implementing partners could be integrally involved in oversight of the study. Members of the PPH TAG included the following individuals:

- Deputy Minister, Reproductive and Maternal and Child Health
- Director, Provincial Public Health, MOPH
- Director, Primary Health Care, MOPH
- Director, International Relations Department, MOPH
- Strengthening Mechanism Coordinator, MOPH
- Jhpiego Medical Director, Baltimore
- Jhpiego Afghanistan Country Director
- Director, Safe Motherhood Initiative, MOPH
- Essential Medicine Manager, WHO
- PPH Program Officer, Access to Clinical and Community Maternal, Neonatal, and Women's Health Services (ACCESS) Program
- Health Program Manager, Save the Children/U.S.
- Head, Essential Drug Department, MOPH

The responsibilities of the TAG included the following:

- Review the study proposal and provide guidance;
- Approve educational materials, the CHW training outline, and the monitoring framework;
- Clarify policy on community-based drug distribution;
- Monitor progress of implementation;
- Lead dissemination of results;
- Commit to stepwise national implementation on the basis of positive mid-point results;
- Provide strategic guidance for national scale-up if the project was successful (safe, acceptable, feasible, and programmatically effective);
- Initiate measures to register misoprostol for use in programs authorized by MOPH;
- Develop and disseminate program implementation guidelines; and

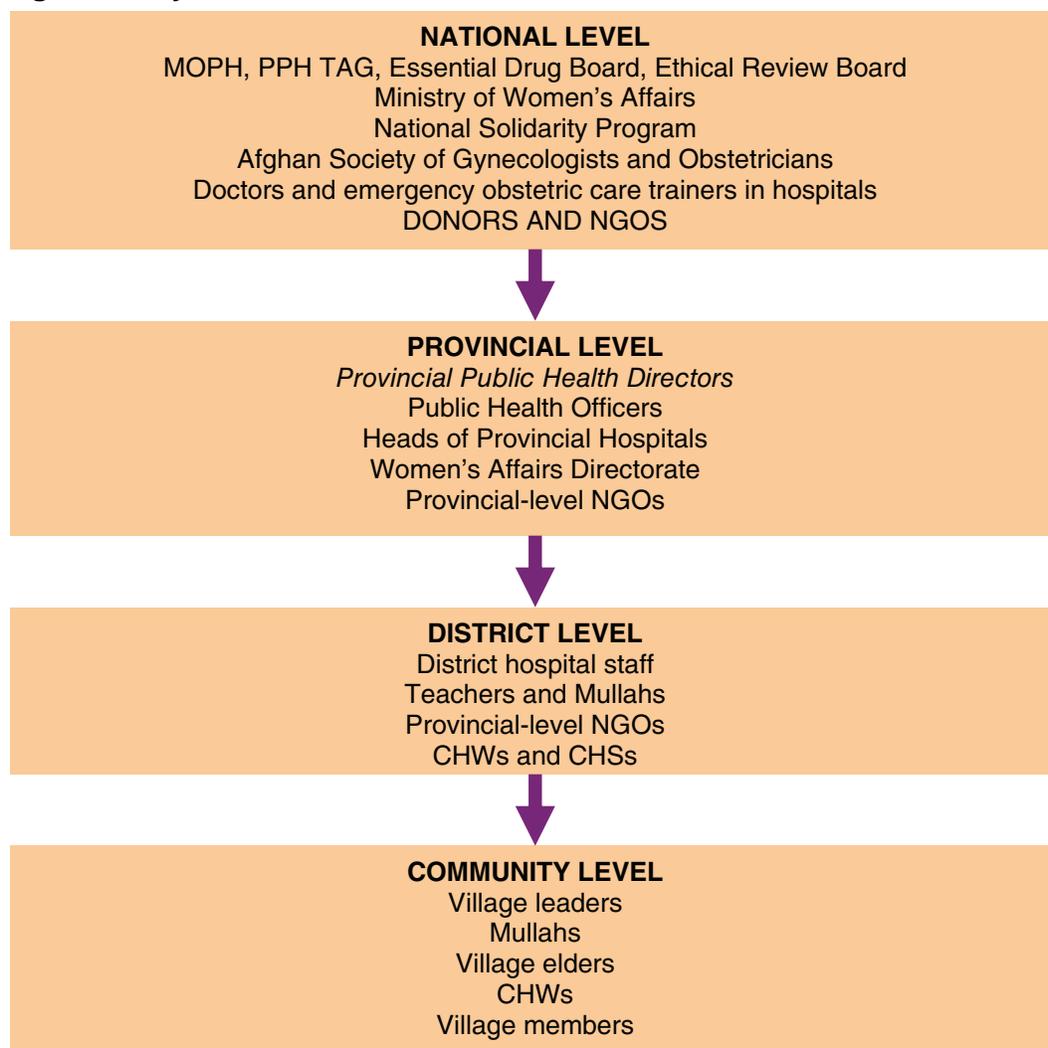
- Incorporate the PPH prevention program into the national health planning agenda and budget.

Advocacy and Socialization

The advocacy component of the study involved a series of sensitization and socialization meetings with stakeholders at various levels to promote understanding of the study and garner support for the intervention. (Figure 1 shows the stakeholders by various levels.) National-level meetings provided an opportunity to introduce stakeholders and participants to the study and begin a discussion regarding the importance of birth preparedness and complication readiness to prevent PPH. The socialization strategy at the community level targeted expectant families and built on successful strategies used by the White Ribbon Alliance. Through these community contacts, Community Health Supervisors (CHSs) and CHWs were encouraged to share information with their communities about the PPH prevention program.

Advocacy messages were developed according to the roles of the various participants. At the national level, messages were developed to facilitate decision-making processes and obtain technical guidance to feed into the study design and implementation. At the community level, the exchange of information focused on the purpose of the study, who was involved, and individual roles and responsibilities.

Figure 1. Key Stakeholders



PREPARATION

Site Selection

The PPH TAG, with approval by the Ethical Review Board, identified the provinces and districts that served as implementation sites based on specific criteria. Provinces were selected if they already received support from the United States Agency for International Development (USAID; the project was financed by USAID and was intended to build on existing programming) and had no constraints that could jeopardize the ability of the project to provide a high level of monitoring and data collection. Districts within these provinces were then selected for the study based on: 1) the availability of baseline data on maternal health status; 2) existence of a CHW network and nongovernmental organizations (NGOs) supporting CHW work; 3) availability of a functioning health center or hospital within a reasonable distance (can be reached within two hours travel time); 4) presence of other community activities, such as birth preparedness, on which to build; and 5) a high volume of births not attended by skilled providers. Women in these areas were generally non-literate. The areas chosen for the study and a summary of their health statistics are shown in Table 2.

Table 2. Health profile of selected project study areas

PROVINCE	DISTRICT	STUDY GROUP	POPULATION	WOMEN OF REPRODUCTIVE AGE	BIRTHS PER YEAR	NUMBER OF CHWS
Faryab	Qarghan	Intervention	40,900	8,589	2,258	22
	Qaramqul	Intervention	17,100	3,591	944	12
Jawzjan	Qarqin	Comparison	21,100	4,431	1,165	12
	Khamab	Comparison	12,100	2,541	668	6
Kabul	Qarabagh	Intervention	66,200	13,902	3,655	28
	Guldara	Comparison	19,900	4,179	1,099	8

Identification and Recruitment of Pregnant Women

CHWs used a community mapping exercise to identify pregnant women, and then an oral consent process, which does not require a signature, to explain to the women the purpose of the project, the type of health information to be provided, and the confidentiality of all information. Women who agreed to participate in the project received registration cards. The CHWs used pictorial forms to gather information on participants, including the name of the pregnant woman and her husband; age; identification number; and name of village, district, and province.

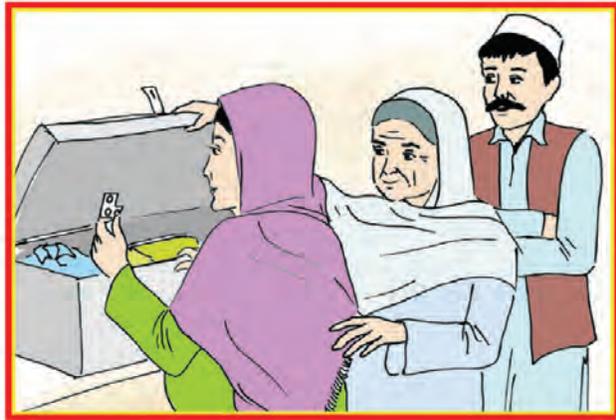
Development of Education Materials

Focus group discussions and in-depth interviews with recently delivered mothers, husbands, TBAs, CHWs, and pregnant women were conducted by trained NGO Maternal and Child Health (MCH) promoters to provide an in-depth understanding of the knowledge, attitudes, and practices surrounding pregnancy and childbirth in rural Afghanistan.

A national-level workshop used this information to develop educational pictorial messages, as well as packaging for misoprostol and tools for monitoring and supervision that were based on messages and drawings previously used in Nepal and Indonesia and using the information gathered during the interviews and focus group discussions. Workshop participants were invited from the field and included CHSs; field coordinators and managers; the MOPH Departments of Information, Education and Communication and Reproductive Health; and obstetrician/gynecologists. Once developed, the materials were submitted to the MOPH for review, field tested, and then reviewed by the PPH TAG. Figure 2 shows a few examples of the educational materials for birth preparedness and use of misoprostol.

Figure 2. Examples of educational materials on birth preparedness and use of misoprostol

2a. Store misoprostol with other things needed at birth



2b. Misoprostol should be taken directly after the birth of the baby and before placenta is delivered



2c. Never take misoprostol when pregnant

2d. CHW provides education messages to all support persons, including mother, husband, and mother-in-law

Project Personnel and Training

Project personnel—CHWs, CHSs, and field coordinators—were recruited by the implementing NGOs (Save the Children/U.S. and IMC) in their respective areas, and ACCESS hired the data entry clerk and the project officer. These project personnel functioned as part of the research component of the study and worked with the pre-existing service delivery components (See Figure 3).

A three-day training-of-trainers workshop was conducted in Kabul for project trainers to develop the knowledge and skills required to train CHWs for counseling pregnant women and their families. The workshop also focused on project strategies, supervision, and on review of the skills required of CHWs to complete monitoring and evaluation activities using the developed tools. The trainers replicated the

training in the field to train more CHW trainers and CHSs on counseling and educating women and their families, as well as supervision and monitoring methods. All CHW trainers and CHSs in the study areas were trained. In both intervention and comparison study areas, activities focused on birth preparedness and complication readiness, childbirth, home delivery, danger signs in pregnancy and childbirth (such as PPH and its prevention), community mapping, and monitoring and supervision. However, education on misoprostol was only included in the intervention area.

Community Health Workers

All active CHWs in the participating provinces were identified and recruited for the project. Criteria for selecting CHWs included completion of basic CHW training and willingness to conduct home visits. To address cultural barriers, all selected CHWs were female, some of whom were accompanied by a male escort (*mahram*).

A three-day course was designed to train CHWs, most of whom were illiterate. The objectives of the course for CHWs working in the intervention areas included specific objectives related to misoprostol that were not included in the course given to CHWs working in the comparison areas. The topics covered in the course in intervention areas included the following:

- Importance of having a skilled provider attend each birth;
- Danger signs in pregnancy and childbirth;
- Main causes of PPH and how it can be prevented;
- How misoprostol is used to prevent PPH at home birth;
- How the CHW can help prevent PPH through the use of misoprostol;
- Use of a community mapping exercise to determine which women in their community are pregnant and register those women for the study (during the community mapping exercise, heads of household were interviewed to obtain information about the status of the families' childhood immunization coverage, reproductive health knowledge, and current pregnancy and antenatal care practices; each residence was drawn on a neighborhood map, and color coding and symbols were used to indicate what services each client was eligible for and/or was using);
- How to effectively counsel pregnant women and their support persons;
- How to provide misoprostol to women in their eighth month of pregnancy;
- How to conduct follow-up visits to women's homes after birth; and
- How to report information about registered women and their use of misoprostol to the CHS on a regular basis.

Since many of the CHWs were illiterate, the following unique approaches were used in the training:

- All education materials were developed in a pictorial format;
- Practical sessions used anatomic models to explain the reproductive tract and causes of PPH;
- Role plays were used to practice counseling skills;
- The course schedule allowed for the addition of a few new topics each day, building upon previous lessons; and

- The CHWs were continually provided with positive and constructive feedback and non-monetary rewards.

Upon completion of the workshop, each CHW was given pictorial flipcharts on birth preparedness/complication readiness and on PPH and prevention, as well as 25 pictorial CHW monthly reporting forms. CHWs met with their supervisors every week during the first month of the study, followed by meetings every two weeks at the nearby health center. The CHWs regularly reported information about registered women and their use of misoprostol to the supervisor and requested misoprostol from the health supervisor on a weekly or bi-weekly basis.

In accordance with MOPH policy, no monetary incentive was paid to the CHWs, with the exception of transportation costs to attend training courses and meetings. During the advocacy process, the project negotiated with village committees to provide non-monetary incentives to the CHWs, such as free electricity, free local transport, help preparing the CHW's house for winter, etc. In addition, the members of the village referred to the CHWs using respectful titles and offered them gifts in-kind when the CHWs visited their families.

Community Health Supervisors

The implementing NGOs worked with CHSs already in post in the study areas and recruited one new and additional CHS per district. In Kabul provinces, two new supervisors were recruited per district due to the larger population. CHSs were hired based on their educational background, work experience, and previous training. These supervisors were required to:

- Provide technical assistance to CHWs on the counseling process and recording of information on the participant registration forms;
- Conduct weekly joint visits with CHWs to the homes of pregnant women to reinforce project messages, assist in the postpartum interview, and collect unused misoprostol;
- Meet with key stakeholders in the community to reinforce the importance of skilled birth attendance and social marketing of misoprostol, and discuss any problems related to CHW motivation, mobility, and performance;
- Receive misoprostol from the pharmacist; and
- Assist in data collection and reporting.

Field Coordinators

One full-time field coordinator was hired by the implementing NGOs for each province. The field coordinators were expected to:

- Ensure that project activities occurred on schedule and according to plan;
- Monitor and supervise newly hired CHSs, and identify and resolve any problems;
- Conduct monthly visits to monitor and supervise trained CHWs;
- Assist CHSs in the preparation and submission of monthly reports to the health management information system officer; and

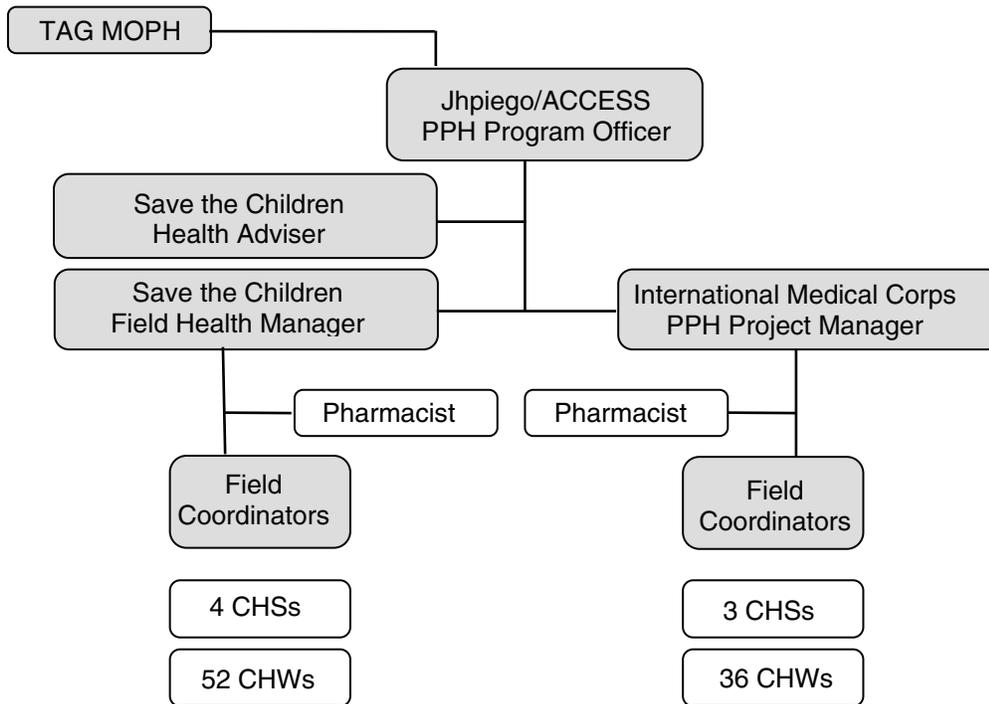
- Attend meetings with community elders and female council (*shura*) members to reinforce benefits of misoprostol for prevention of PPH and highlight the importance of skilled birth attendance.

Skilled Providers/Midwives

Skilled providers at the facilities and district health officials in the implementation districts participated in a one-day orientation session at the health centers facilitated by project managers. This orientation included an overview of the project, causes of PPH and how it can be prevented, promotion of AMTSL, the use of misoprostol to prevent PPH at home births, correct use of misoprostol, potential side effects and their management. ACCESS staff and implementing NGOs conducted regular monitoring visits with skilled providers throughout project implementation.

Figure 3 shows the relationship of the research (shaded boxes) and service delivery components of the project.

Figure 3. Research and service delivery components of the project



Implementation

CHW Home Visits and Counseling

In both the intervention and comparison areas, CHWs visited pregnant women and their families three times: when they were first registered, during their eighth month of pregnancy, and within one week after the birth. Counseling and education were provided to the women and their families at all three visits.

Women in the intervention and comparison areas who agreed to participate in the project and provided informed consent were interviewed by the CHW using a pictorial data form. The CHWs provided one-on-one counseling of the women and any available household members designated by them as their support persons. The CHWs used pictorial flip charts to provide counseling to all participating women on:

- Birth preparedness and complication readiness;
- Recognition of danger signs during pregnancy, childbirth, and the postpartum period, especially PPH;
- The importance of skilled birth attendants; and
- What to do in case of a complication, and where and from whom to seek care.

In addition to this information, women in the intervention areas also received counseling on:

- Purpose and correct timing and use of misoprostol to prevent PPH,
- Risks of taking misoprostol before the birth of the baby, and
- Common side effects of misoprostol.

At the end of each counseling session, women and household members were asked to describe, in their own terms, the purpose and correct use of misoprostol and the risks associated with use and misuse of misoprostol. To ensure the safety of study participants, counseling was repeated until the participants could correctly restate the information provided to them.

At the end of the second visit (during the eighth month of gestation), women in the intervention group who agreed to accept the misoprostol were given a package containing three tablets of 200 mcg misoprostol, labeled “*Guli Zedi Khunrizi Bad Az Weladat*” (“tablet against bleeding after childbirth”), as well as pictorial and written educational materials with instructions on correct and safe use of misoprostol. Women who chose to give birth with a professional midwife at home had the option to take misoprostol unless the midwife chose to override the protocol. CHWs conducted their third visit to the participants within one week of giving birth to collect information and then inform the CHSs of the results from those postpartum visits.

Data Collection: Quantitative and Qualitative

The project developed several quantitative data collection and supervision tools to ensure the safety of registration, counseling, and misoprostol distribution. These tools included:

- CHW pictorial visit form
- CHS drug request and receipt form
- CHS weekly meeting summary report form
- CHS monthly report form
- Field coordinator monthly summary report form
- Monitoring indicators
- Misoprostol distribution logbook
- Pharmacist monthly reporting form
- Postpartum questionnaire
- Supervision checklist for CHSs and field coordinators
- Adverse event form
- Hospital admission form

Information gathered from the qualitative component guided the development of the materials to ensure messages were culturally appropriate and acceptable to the community. The first phase of qualitative research was conducted from November to December 2005 with the objectives to:

- Identify and gain an in-depth understanding of the knowledge, attitudes, and behavior surrounding pregnancy and childbirth;
- Collect recommendations from women, husbands, and mothers-in-law regarding community-based distribution of misoprostol, including the distribution process and overall acceptability of the intervention; and
- Provide recommendations and identify implications for contextual programming of the intervention.

Focus group discussions and in-depth interviews were held in Faryab, Jawzjan, and Kabul provinces. The focus group discussions were conducted by six trained teams of individuals of NGO MCH promoters (Table 3).

Table 3. Qualitative data collection

FOCUS GROUP DISCUSSIONS AND IN-DEPTH INTERVIEWS	NUMBER OF PARTICIPANTS
Six focus group discussions with recently delivered women with a first child	42
Six focus group discussions with recently delivered women with more than one child	36
Six focus group discussions with fathers of first child	36
Six focus group discussions with fathers with more than one child	34
Six focus group discussions with mothers-in-law	36
Twelve in-depth interviews with recently delivered women with a first child	12
Twelve in-depth interviews with recently delivered women with more than one child	12

Questions posed in the focus group discussions and in-depth interviews were structured into three themes and corresponding topics:

- Theme 1. Pregnancy: perceptions of pregnancy, awareness and knowledge of signs of pregnancy, practices regarding care during pregnancy, and knowledge of danger signs during pregnancy.
- Theme 2. Childbirth: knowledge regarding expected date of delivery, preparation for delivery, knowledge of placenta, knowledge of PPH, and perception about delivery of twins.
- Theme 3. Misoprostol: suggestions regarding misoprostol.

Data were analyzed, following complete transcription into electronic format, using thematic approach/content analysis. Data were post-coded to identify themes, topics, and a sense of the prevalence of practices and beliefs. Overall, there were several key conclusions from the first phase of formative research that guided and informed the programming of the project:

- The husband and mother-in-law hold significant decision-making power regarding the woman's fertility, pregnancy, and childbirth, and in the decision to seek care at a health facility.
- Although many women, mothers-in-law, and husbands could name several danger signs in pregnancy, knowledge surrounding birth preparedness and complication readiness could be strengthened, particularly among first-time mothers.
- The decision to deliver at home with a TBA is multi-factorial, including inadequate access to health facilities, unaffordable fees for services, lack of midwives at the health clinic, and community trust in TBAs.
- Barriers to seeking emergency obstetric care in the northern areas include lack of money to pay for transport and obstetric care services, long distances to the referral hospital, and impassable roads due to heavy snowfall.
- Although mothers-in-law and women with more than one child knew danger signs of PPH, the practice of using home remedies for the treatment of PPH is prolific and *Mullahs* (religious leaders) are occasionally sought for care.
- Overall, there is awareness regarding signs of possible twin pregnancy and the importance of visiting a health facility for consultation if twins are suspected.
- Community-based distribution of misoprostol appears to be an acceptable method of preventing PPH:
 - Many participants showed a willingness to learn about misoprostol, given the number of women in their communities who die from PPH, and participants even recommended safe places to store misoprostol, such as inside a metal box or in a plastic bag hung high on the wall.
 - Most women said that their mother-in-laws and husbands would make the decision whether they would use the misoprostol.
 - Many women recommended that TBAs and/or CHWs should be the cadre of individuals to provide misoprostol and information to pregnant women.

Data Monitoring and Management

The project's monitoring and evaluation plan was divided into four components:

- Identifying all pregnant women in villages and their approximate gestational age by CHWs using the community mapping tools.
- Distributing misoprostol to women and their families.
- Collecting information during a postpartum interview in which a standardized structured questionnaire was used to ask the woman about exposure to and comprehension of messages about PPH and misoprostol and the woman's source of this information, antenatal care and delivery information, reported PPH, experience with side effects, use and timing of misoprostol, reasons for taking or not taking misoprostol, perceptions of abnormal bleeding, referrals, and acceptability and willingness to pay for misoprostol.
- Monitoring the use of misoprostol by scrutinizing stock cards and records to ensure that the misoprostol was not misused, and that all packs of the drug that were distributed were accounted for.

All data were collected from the field and manually reviewed for completion and accuracy. Data entry and preliminary (monthly) analyses were conducted at the ACCESS Program office in Kabul using Microsoft Access. Further analysis was conducted in Baltimore, Maryland, and Berkley, California, using Stata 10.0. Results were summarized using frequency distributions and cross tabulations. Bivariate analyses according to study area (intervention and comparison) were used to assess differences between indicators. Two-tailed Student's *t*-test for comparison of two proportions or two means was estimated, and statistical significance was established at $p < 0.05$.

To inform the stakeholders of the project's progress, the PPH officer and investigators produced a quarterly fact sheet and presented the midterm results of the project to MOPH stakeholders and the PPH TAG with the major indicators. Midpoint results included the following key findings:

- No adverse events were reported since project inception,
- All women took misoprostol correctly,
- Almost universal coverage of deliveries with a uterotonic drug was achieved in the intervention area, and
- CHWs were found to be an acceptable source of counseling women and distributing misoprostol.

Based on these findings, the MOPH and PPH TAG determined that key objectives of the intervention were being fulfilled, implementation of the project was adhering to the protocol, and the demonstration would proceed.

RESULTS

GENERAL CHARACTERISTICS OF STUDY PARTICIPANTS

There was some variation of ethnic background and language among the 3,187 women who participated in the project. The participants in the northern study districts were Turkmen and Uzbek, had similar socioeconomic backgrounds, and were mostly illiterate. Almost 45% of the study participants (1,418) were Turkmen, spoke Turkmani, and lived in Khamab, Qarqin, and Qaramqul districts. An additional 693 women (22%) were Uzbek and lived in Qorghan and spoke Uzbek. The women in Kabul had similar socioeconomic backgrounds and were often illiterate. There were two main ethnicities in Kabul: Tajik (Dari speakers) women who mainly lived in Guldara (291 women; 9%), and Pashtun (Pashtu speakers) women who mainly lived in Qarabagh (785 women; 25%). There was at least one health facility (Basic Health Center [BHC], Comprehensive Health Center [CHC], or district hospital) in each implementation district. The estimated time to access the health facility from the woman’s home ranged from 15 minutes to 1½ hours.

CHARACTERISTICS OF THE STUDY POPULATION

Information on characteristics of the study population was obtained during postpartum interviews and is shown in Tables 4 and 5. There were 20 multiple births (1%) in the intervention group, emphasizing the importance of the counseling messages on the correct timing of use of misoprostol (i.e., after the birth of the last baby). Primary care services in the study areas are provided by NGOs, but some of these BHCs and CHCs do not have qualified skilled providers and antenatal care is often provided by any female health worker. In the intervention group, 15.6% of women received antenatal care from a midwife and in the comparison group, 20.9% received antenatal care from a midwife. While this shows differences between the two groups (15.6% vs. 20.9%), any bias that is introduced with the intervention is likely to favor the comparison group, considering that the proportion of women that received antenatal care from a midwife was higher in this group.

Table 4. Characteristics of the study population

	PARTICIPANTS		
	COMPARISON (%)	INTERVENTION (%)	
	(N = 1,148)	(N = 2,039)	p-Value
Multiple births	1.2	1.0	0.60
Cesarean section	0.4	0.9	0.08
Gravida 1	14.3	15.2	0.49
Gravida > 1	85.7	84.8	0.49

The place of delivery is shown in Table 5. The majority of births in both areas occurred at home. There were fewer deliveries at the BHC than at the CHC/hospital in the intervention area. The proportion of births at a health facility was 18% in the comparison area and 21% in the intervention

area. More births occurred at the midwife's house in the intervention area. A skilled provider attended 28% of births in the comparison area and 30% of births in the intervention area, which was not a statistically significant difference. The introduction of misoprostol in the intervention areas did not deter women from seeking care with a skilled provider.

Table 5. Delivery information

	COMPARISON (%)	INTERVENTION (%)	
	(N = 1,148)	(N = 2,039)	P-VALUE
PLACE OF DELIVERY:			
Woman's home	80.1	70.6	<0.001
TBA's home	0.1	0.3	0.26
Midwife's home	1.8	7.8	<0.001
Health facility	18.1	21.4	<0.001
ASSISTANCE DURING DELIVERY:			
Doctor/midwife	27.6	29.9	0.17
TBA	41.9	46.9	0.01
Friend/relative	28.9	20.7	<0.001
CHW	0.9	2.1	0.01
No one	0.7	0.3	0.10

PROGRAM EFFECTIVENESS/EFFORT: COVERAGE, WORKLOAD

Coverage of Population in Study Areas

Figure 4 shows the steady recruitment of women throughout the study period. The population estimates used in the denominator are the expected number of new pregnant women per month based on population census data. The CHW target was to reach every such woman. On average, each CHW conducted nine home visits per month in the intervention area and 13 in the comparison area. This difference is partly due to the fact that the duration of the visit was longer in the intervention area. On average in these districts, each CHW looks after three pregnant women per month, and a skilled provider (midwife) usually attends eight births per month. The figure shows a steady increase in the proportion of pregnant women who were recruited and received educational visits, reaching almost 94% of the expected births in the intervention area and 80% in the comparison area. One possible explanation for the slightly higher rate of recruitment in the intervention area could be the value placed on misoprostol distribution and its impact on CHW motivation. In both comparison and intervention areas, because of the community component of the project, there were higher rates of recruitment and education visits by CHWs than would have been achieved through the existing facility-based health delivery system. Notably, home visits were occurring even during severe winter months when much of the study areas are normally completely snowed in and formal health care services tend to come to a standstill.

Figure 4. Coverage of expected population of newly pregnant women with identification and education visit by CHWs (June 2006 to February 2007)

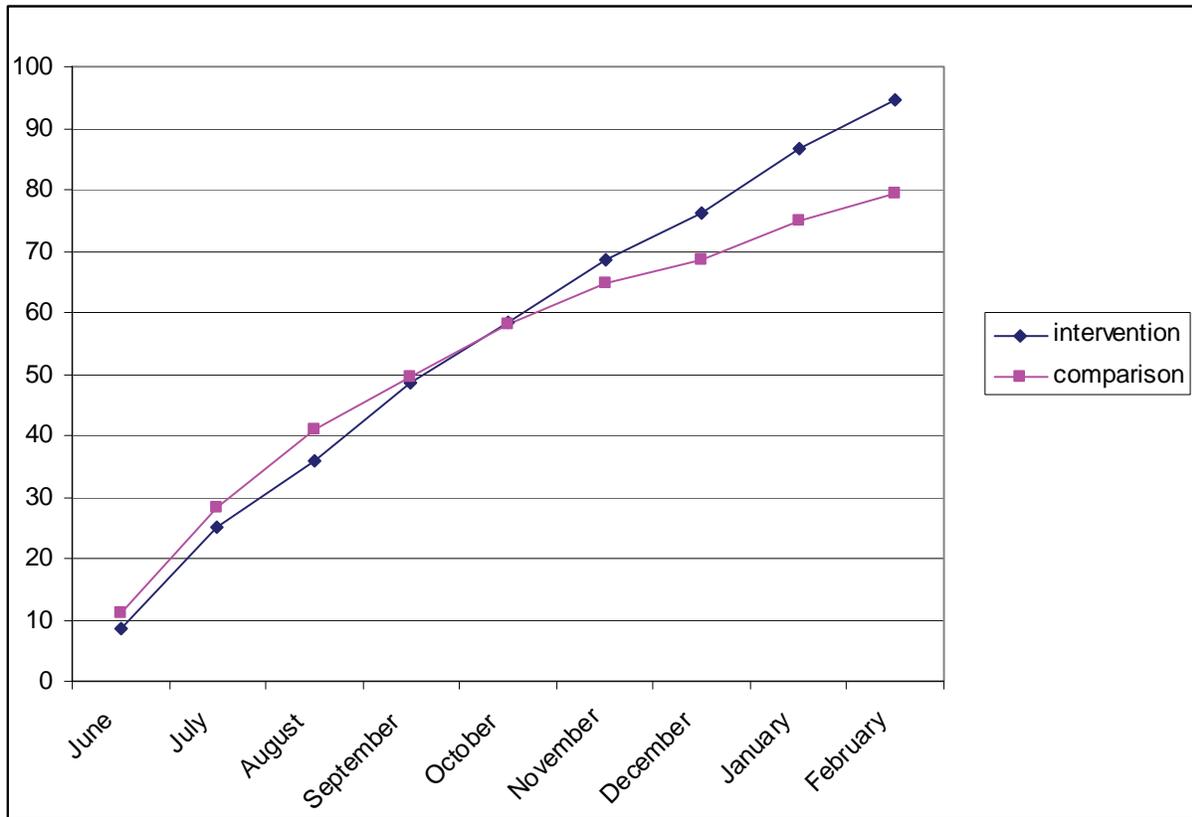
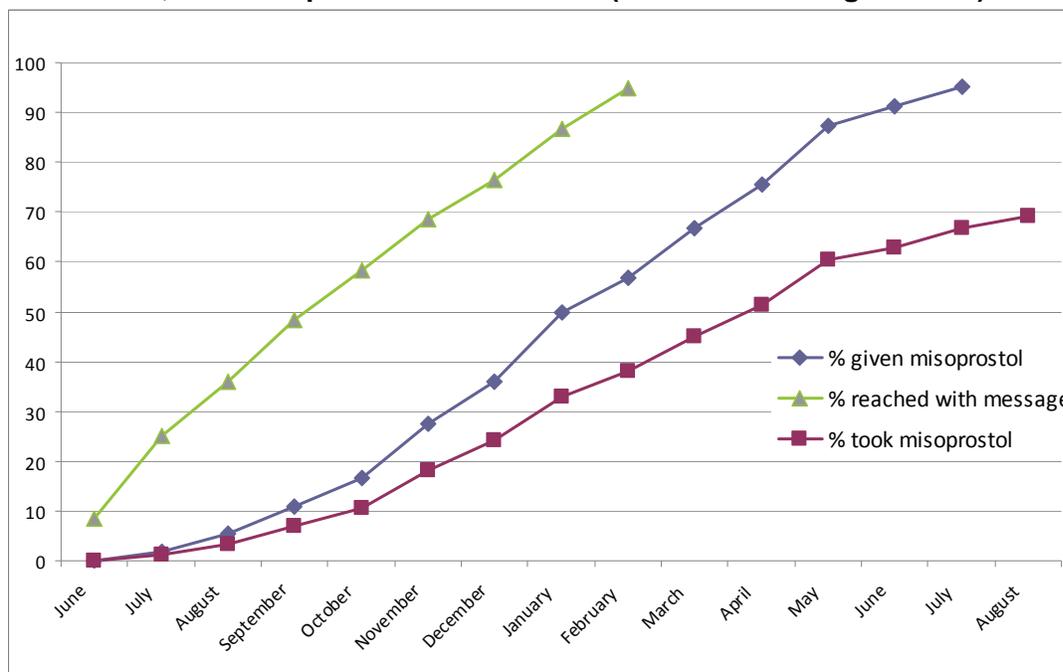


Figure 5 shows progress toward achieving universal coverage in the intervention area. Recruitment ended in February, with identification of pregnant woman and the first educational message completed for 94% of the expected population. Misoprostol distribution paralleled the recruitment of women, in that almost every woman identified as pregnant received misoprostol. The use of misoprostol also shows a steady increase, reaching a plateau at 70%.

Figure 5. Coverage in intervention area with educational message and misoprostol distribution, and misoprostol use over time (June 2006 to August 2007)



Use of Misoprostol

Of the 2,039 women in the intervention area who were identified as pregnant during community mapping, 2,021 (99%) were offered misoprostol (Table 6); the other 18 women were either not found at home during the visit at eight months gestation, were missed for other reasons, or had already given birth. Of the 2,021 (99%) women who were offered misoprostol, 1,970 (96%) accepted the drug. The 51 women who did not accept misoprostol had planned to deliver at a health facility, or had firm plans for delivering with a skilled provider. Of the women identified as pregnant, 1,421 (70%) women used the drug. No woman took the misoprostol before the birth of the (last) baby, even in the 14 cases of women with twin births who took the misoprostol.

Table 6 shows measures of timing to reflect correct use of misoprostol. These measurements are consistent with educational messages delivered by CHWs to the women and her support persons during home visits. Women were instructed to take misoprostol immediately after the baby was born, making sure there is no twin, and before the delivery of the placenta. Three women did not take the full dose of three tablets, because one pill was dropped/lost. The misoprostol, as per protocol, was taken immediately after delivery of the baby and before the placenta was delivered by 96% of the women who took the drug. Four percent of women took it after the placenta was delivered.

Table 6. Use of misoprostol (intervention areas only)

	NUMBER	RESPONDENTS (%)
Identified as pregnant:	2,039	100.0
Offered misoprostol:	2,021	99.1
• Accepted misoprostol by CHW	1,970	96.6
Used misoprostol:	1,421	69.7
• Took before the baby was born	0	0
• Took after the baby was born		
– Took after the baby was born and before placenta delivered ^a	1,361	95.8
– Took after the baby was born and after placenta delivered ^b	60	4.2

^a Correct use of misoprostol as recommended to women by the project

^b If in the event that placenta is delivered quickly, women were still encouraged to take misoprostol after birth of placenta

Of the 2,039 women in the intervention group, 1,366 (67%) women took only misoprostol, 540 (27%) received only an injection, 54(3%) took the misoprostol and received an injection, and 78 (4%) received neither misoprostol nor an injection (Table 7). The injection was presumed to be oxytocin because several recently-graduated midwives had been newly posted in these areas in the previous one to two years and all are skilled in AMTSL, including the injection of oxytocin. In fact, the study design encouraged midwives to use AMTSL if they had the skills for this procedure and if oxytocin was available and had been properly stored. While we presume that an injection given immediately after the birth of a baby was oxytocin, it is possible that the injection was anesthesia or some other medication. In some cases, a woman may have received misoprostol and another uterotonic, such as oxytocin. In looking at the severity and occurrence of symptoms, no difference was found between women who received misoprostol and an injection compared with women who received misoprostol. In the comparison area, 295 women (26%) received only an injection (presumed to be oxytocin) immediately after the birth of the baby and 853 (74%) did not get any drug. These results provide evidence that community-based distribution of misoprostol can achieve near universal coverage with an uterotonic drug (even in areas of low attendance by a skilled provider) while at the same time not discouraging use of skilled care.

Of the women in the intervention area, 78 (4%) did not take misoprostol, despite another uterotonic (e.g. oxytocin) being unavailable to them. Of those women, 42 chose not to take misoprostol because of fear of side effects or because they did not think it would work, did not think it was needed, or did not want to take it. In 27 cases, the woman or support person forgot the drug or could not find it right away. In four cases, the husband or family decided not to allow the woman to take it, and in five cases the health care provider (usually not a midwife) decided the woman did not need it. All unused misoprostol tablets were collected by project personnel, as per protocol.

Table 7. Use of uterotonic drugs

	COMPARISON (N = 1,148)	INTERVENTION (N = 2,039)	p-VALUE
Did not use any drug	853 (74.3%)	78 (3.8%)	<0.001
Used uterotonic	295 (25.7%)	1,960 (96.2%)	<0.001
• Used only misoprostol	NA	1,366 (67.0%)	NA
• Used only injection ^a	295 (25.7%)	540 (26.5%)	0.62
• Used misoprostol and injection ^a	NA	54 (2.7%)	NA

^a Presumed to be oxytocin

NA = Not applicable

Women were asked during postpartum interviews to report the number of soiled cloths (*teka*) during the birth. For the purposes of this study, it was estimated that two or more cloths soaked in blood was equivalent to PPH, and four or more cloths soaked in blood was equivalent to severe PPH. Table 8 below shows that reported PPH estimated in this manner was significantly lower in women who had received misoprostol alone than in women who had not received any uterotonic drug (*p*-Value 0.001).

Table 8. Women's perception of excessive bleeding according to uterotonic drug used^a

	NO PPH	PPH	SEVERE PPH	NUMBER
Used only misoprostol	93.0%	5.2%	1.8%	1,366
Received only injection ^b	80.2%	13.9%	5.9%	835
Used misoprostol and received injection ^b	70.4%	14.8%	14.8%	54
Did not take/receive any drug	44.8%	34.2%	21.1%	931
Total number of women	2,396	513	278	3,187

^a PPH is self-reported bleeding using number of soiled cloths as a measure. PPH is 2–4 cloths; Severe PPH is >4 cloths.

^b Presumed to be oxytocin

Although this study was not designed to determine the efficacy of misoprostol, it did investigate reported blood loss following delivery (Table 9). Women received educational messages warning them to take action if two cloths were soaked with blood. PPH was self-reported by 49% of women in the comparison area, compared with 11% of women in the intervention area. Using an intention-to-treat analysis, there was a highly significant reduction in reported PPH in the intervention areas. Using only those women who used misoprostol in the intervention area, the reported rate of PPH was even lower, at 8%. The rate of reported severe PPH (soaking of four or more cloths) may be a better indicator of PPH, and again a highly significant reduction occurred in the intervention area and among misoprostol users.

Table 9. Reported postpartum blood loss

	ALL WOMEN IN COMPARISON AREA (N = 1,148)	ALL WOMEN IN INTERVENTION AREA (N = 2,039)	p-VALUE: INTERVENTION VS. COMPARISON	WOMEN WHO TOOK MISOPROSTOL IN INTERVENTION AREA (N = 1,421)	p-VALUE: WOMEN IN COMPARISON AREA VS. WOMEN WHO TOOK MISOPROSTOL
PPH^a (soaking two or more cloths)	49.3%	11%	<0.001	7.9%	0.00
Severe PPH^a (soaking four or more cloths)	18.6%	3.1%	<0.001	2.3%	0.00
No excess bleeding	51.7%	89%	<0.001	92.1%	0.00

^aPPH is self-reported bleeding using number of soiled cloths as a measure. PPH is 2–4 cloths; Severe PPH is >4 cloths.

Table 10 shows the place of birth and proportion of women who took misoprostol among women in the intervention area. Ninety-four percent of women who gave birth at home used misoprostol. Of the 158 women who gave birth at a midwife’s house, 29 (18%) used misoprostol, and 8% of women who delivered in a health facility used the misoprostol that was given to them. Of the 129 women who gave birth at a midwife’s house and did not use misoprostol, 128 (99%) received an injection (presumed to be oxytocin), and one woman did not receive any uterotonic drug.

Table 10. Place of birth and misoprostol use among women in intervention area

PLACE OF DELIVERY	DID NOT USE MISOPROSTOL (N = 618)	USED MISOPROSTOL (N = 1,421)
Home (n = 1,439)	89 (6.2%)	1,350 (93.8%)
TBA's home (n = 7)	0	7 (100%)
Midwife's home (n = 158)	129 (81.7%)	29 (18.3%)
Health facility (BHC, CHC, hospital) (n = 435)	400 (92.0%)	35 (8.0%)

Feasibility: Exposure and Comprehension of Message

CHWs provided education on various aspects of birth preparedness and complication readiness to all women and their support persons during antenatal home visits. The women had to accurately recall this information before the CHW offered the misoprostol. This section describes comprehension of PPH-related knowledge among recently delivered women.

During postpartum interviews, women were asked to repeat messages about PPH that they received during the antenatal period. Table 11 shows the unprompted response to these questions. Overall, recalling at least one correct message about PPH was nearly universal and only a very small proportion of women could not recall any message. In the intervention area, 84% of women recalled that PPH can cause death, compared with 63% of women in the comparison area. More women in the comparison group recalled messages about going to a facility promptly, or getting help from a skilled provider/midwife, than in the comparison group (82.2% and 51.8%, respectively). These data can be interpreted in various ways. In the worst case scenario, it is possible that giving misoprostol to women for prevention of PPH decreased the perceived importance of going to a facility, or seeking help from a skilled provider. In the best case scenario, the differences found between the intervention and comparison groups could be the result of a flaw in the study design. Women may have remembered multiple educational messages, but only offered one response if she was unprompted by the interviewer for additional responses. In counseling, CHWs did not prioritize the importance of various educational messages to women and their support persons; all were given equal value. Therefore, the fact that almost all women recalled at least one message is important, not necessarily which message was reported. Lastly, women acting upon messages does not necessarily translate to unprompted recall of those messages: 9.8% of the women in the intervention group had an unprompted response about the need to take three misoprostol tablets, but 99.8% of the women in the intervention group took all three tablets correctly. Ultimately, this data warrants further investigation and consideration in future programming.

Table 11. Recollection of messages about PPH (unprompted responses)

	RESPONDENTS (%)	
	COMPARISON (N = 1,148)	INTERVENTION (N = 2,039)
Received any information about PPH	99.8	99.9
Information reported about PPH:		
• Can cause death	62.3	83.5
• Go to facility promptly/ or get help from skilled provider/midwife	82.2	51.8
Recalled correct information about PPH:^a		
• Did not recall info	3.1	0.1
• Recalled at least one message	96.8	99.9
• Recalled at least two messages	53	35.9
• Recalled all three messages	5.9	5.8
Received any information about misoprostol	NA	99.95
Information reported about misoprostol:^a	NA	

	RESPONDENTS (%)	
	COMPARISON (N = 1,148)	INTERVENTION (N = 2,039)
• Prevents bleeding	NA	99.9
• Swallow tablets after delivery of baby	NA	100.0
• Take three tablets	NA	9.8
• Correct information about misoprostol	NA	99.7

^a Correct information about PPH includes: can cause death, go to facility promptly, and get help from midwife. Correct information about misoprostol includes: prevents bleeding, should be taken after delivery of baby, correct dose is three tablets. NA = not applicable.

In both comparison and intervention areas, the main source of information regarding PPH was the CHW (Table 12), which is not surprising because the study areas are very poorly served by a formal health care system. Eighteen percent of women in the comparison area had seen posters about PPH, compared with only 5% in the intervention area. Overall, 97% and 99% of women in the comparison and intervention areas, respectively, reported receiving information from correct sources (CHW, skilled provider, BHC, CHC/hospital).

Table 12. Sources of information about PPH

SOURCE OF INFORMATION:	RESPONDENTS (%)		p-VALUE
	COMPARISON (N = 1,148)	INTERVENTION (N = 2,039)	
Skilled provider/Midwife	2.4	6.6	<0.001
CHW	96.0	97.5	0.02
TBA	0.5	0.2	0.14
BHC	0.6	0.7	0.74
Friend/relative	0.3	0.1	0.19
Poster	17.9	4.7	<0.001
CHC/Hospital	4.5	0.8	<0.001
Received information from CHW only	89.7	91	0.23
Received information from correct sources ^a	96.9	98.7	<0.001

^a Correct sources include: CHW, midwife, BHC, CHC/hospital

All but one woman in the intervention area had correct information about misoprostol. The main source of this information was the CHW (97%); few women reported receiving this information from a skilled provider (Table 13). Only one woman was not able to recall any side effects of misoprostol,

14% recalled all side effects, and 55% recalled both shivering and fever (Table 14). There were no unusual rumors regarding side effects, a finding that was revealed during the qualitative interviews. Focus group discussions with recently delivered women indicated that the education they received from CHWs about the benefits of misoprostol in the prevention of PPH was a motivator for their use and acceptance of the drug.

Table 13. Sources of information about misoprostol (intervention area)

SOURCE OF INFORMATION ^A	RESPONDENTS (%) (N = 2,039)
Skilled provider/midwife	2.4
CHW	97.2
TBA	0.3
BHC	0.4
Friend/relative	0.1
Poster	5.6
CHC/Hospital	0.6
Women who considered the CHW to be most important source of information	97.6

^a Women could name more than one source of information.

Table 14. Recall of information about side effects of misoprostol (intervention area)

SIDE EFFECTS	RESPONDENTS (%) (N = 2,039)
Recalled at least one side effect:	99.9
Recalled specific side effects:	
• Shivering	98.3
• Nausea	71.8
• Abdominal cramping	51.7
• Vomiting	75.4
• Diarrhea	77.4
• Fever	55.6
Recalled all side effects	13.5
Recalled shivering and fever	54.5
Recalled neither shivering nor fever	0.6

As part of the protocol, information about PPH was provided to the women's support persons. In the intervention area, this information was received by 75% of mothers-in-law, followed by smaller numbers of sisters-in-law (24%), husbands (17%), and mothers (13%). Only 6% of women did not have an informed support person. Overall, 94% of births were attended by support persons who had been exposed to PPH information (Table 15). Table 16 shows the relationship between the presence at delivery of a knowledgeable person and the percentage of women with spontaneous recall of messages about misoprostol.

Table 15. Support persons who received information about PPH and misoprostol (intervention area)

SUPPORT PERSON	RESPONDENTS (%) (N = 2,039)
Family member received information about PPH:	
• Husband	16.9
• Mother	12.8
• Mother-in-law	75.4
• Sister	4.7
• Sister-in-law	24.0
Family members received information about PPH and misoprostol:	
• No one besides the woman	6.1
• One other family member	73.3
• Two or more family members	20.6
Attendance of informed family member at birth	94.0

Table 16. Recall of key misoprostol messages by women according to type of birth assistant (intervention area)

TYPE OF BIRTH ASSISTANT	RECALL OF MISOPROSTOL MESSAGES BY WOMEN (UNPROMPTED RESPONSES)		
	TAKE MISOPROSTOL ONLY AFTER DELIVERY	TAKE THREE TABLETS	TAKE MISOPROSTOL BEFORE DELIVERY OF PLACENTA
Knowledgeable family person	100.0%	99.8%	96.4%
Skilled provider/midwife	100.0%	100.0%	78.9%
TBA	100.0%	99.8%	97.0%

Table 18 shows that the concept of excessive bleeding (two or more soaked cloths) was equally well understood in the comparison and intervention areas (86% and 90%, respectively). Spontaneous recollection of feeling weak and faint as a sign of excessive bleeding was recalled less frequently by

both groups (39% in comparison area and 43% in intervention area), as was blood clots (32% and 25%, respectively). Very few women recalled the concept of slow bleeding lasting longer than one hour as an indicator of excessive bleeding, particularly in the intervention area. There was a high level of recall for at least one cause of PPH (Table 19), with the concept of uterine atony best recalled by women in the intervention area (76%) and retained placenta or placental fragments best recalled by women in the comparison area (76%).

Table 17. Recall of information about signs of excessive bleeding

	RESPONDENTS (%)	
	COMPARISON (N = 1,148)	INTERVENTION (N = 2,039)
Recalled any information	98.8	99.9
Knowledge of signs reported:		
• Two or more cloths soaked by blood	86.3	89.6
• Feeling weak and faint	38.8	43.2
• Bleeding for more than 1 hour	11.1	1.4
• Passing blood clots	31.6	25.0
Does not recall any information	1.1	1.1
Recalls/knows all four signs	0.6	0.1

Table 18. Recall of information about causes of excessive bleeding

	RESPONDENTS (%)	
	COMPARISON (N = 1,148)	INTERVENTION (N = 2,039)
Recalled any information	98.9	99.9
Knowledge of causes reported:		
• Uterus does not get firm	65.4	75.6
• Placenta or part of placenta is left in the uterus	75.6	56.8
• Injury or cut in the uterus/birth canal	32.6	20.6
Does not recall any causes	2.1	1.8
Recalls/knows all three causes	13.4	5.5

Acceptability

Misoprostol was very well accepted by the women in the intervention area: 92% of all women, regardless of whether they actually took the misoprostol, said they would recommend misoprostol to

their friends and use it in their next pregnancy, and 88% said they would be willing to pay to receive misoprostol in the future (Table 19). Although some women did not use misoprostol, all women in the intervention area were exposed to the educational messages; thus, they could respond to acceptability questions. Findings from the qualitative research component of the project suggested that misoprostol was acceptable to women’s husbands and mothers-in-law. Of the women who said they would be willing to pay for misoprostol, 88% were willing to pay at least 50 AFN (equivalent to \$1 USD). Willingness to pay and acceptance measures were analyzed according to correct knowledge of PPH, knowledge of misoprostol, knowledge of side effects, actual occurrence of side effects, and what type of uterotonic drug was used. Statistically significant associations were found between acceptance measures and uterotonic used (Pearson Chi-square = 422.6930, $p = 0.000$) and acceptance measures and experience of side effects (Pearson Chi-square = 18.6946, $p = 0.005$). High acceptance of misoprostol persisted under all other circumstances.

Table 19. Acceptability and willingness to pay for misoprostol (intervention area)

	RESPONDENTS (%) (N = 2,039)
Would recommend to a friend	91.5
Would use if pregnant again	91.6
Would purchase misoprostol	88.4
Willingness to pay:	
• Would not pay/does not know	11.7
• Would pay 50 AFN	43.6
• Would pay 100 AFN	29.2
• Would pay 200 AFN	15.2

50 AFN = Afghani, equivalent to \$1 USD

Among women who took misoprostol, willingness to pay and acceptance measures were analyzed according to whether women would use misoprostol in their next pregnancy, their correct knowledge about misoprostol, and their experience of side effects (Table 20). Overall, correct knowledge of misoprostol and having experienced shivering and fever after childbirth were not determining factors in the woman’s willingness to pay at least 50 AFN for misoprostol.

Table 20. Relationship between knowledge and experience of misoprostol-related side effects and willingness to pay for misoprostol

	NUMBER	WILLINGNESS TO PAY AT LEAST 50 AFN FOR MISOPROSTOL
Willingness to use misoprostol if pregnant again	1,421	1,386 (97.0%)
Spontaneously recalled all information about use of misoprostol	1,415	1,381(97.6%)
Spontaneously recalled all side effects of misoprostol	179	175 (97.7%)
Experienced at least one symptom after childbirth	473	466 (98.5%)
Experienced shivering and fever in first 6 hours after childbirth	67	65 (97.0%)

50 AFN = Afghani, equivalent to \$1 USD

Safety and Side Effects

Misoprostol has known and predictable side effects, mainly shivering, nausea, cramping, and a transient rise in body temperature. Table 21 shows the symptoms reported after delivery by women. Contrary to expectation, the rates of all reported unpleasant symptoms were actually higher in the comparison areas than in intervention areas. Although all of these symptoms are commonly present after childbirth, the higher rate among women in the comparison area, who did not receive misoprostol, was surprising. One explanation may be that women in the intervention area were given information about the side effects of misoprostol and were better prepared to expect them. The women were also advised on the transient nature of the symptoms and of some home remedies to treat them. No such information was given to the women in the comparison area. The qualitative survey also revealed that the women in the comparison area were more likely to use herbs and local traditional remedies than in intervention areas. The explanation was that women in the intervention area had something to depend on, but in the comparison area, women were using what they have always used, which although they are often used, can potentially be ineffective or even harmful.

More specifically, recently delivered women in the intervention area of Faryab province reported that no medications were used to treat shivering and fever, crediting the education provided by CHWs that these symptoms are common side effects of misoprostol. In contrast, most women in the comparison area of Jawzjan province reported that oral medications from the bazaar or clinic were used to treat shivering and fever, which suggests that the education provided by CHWs in the intervention area influenced the women's perception of whether treatment is needed for unpleasant symptoms experienced after delivery. Future programming might consider expanding CHW education on common discomforts experienced after delivery, whereby further guidance would be provided to women and their families on how to address minor discomforts associated with childbirth.

Further analysis of the duration of side effects shows that short-lived shivering (less than 30 minutes) occurred in 22% of women in intervention areas compared with 11% in the comparison area, and long-lived shivering (more than 2 hours) occurred in 1% of women in the intervention area compared with 3% in the comparison area (data not shown). It is reassuring that widespread use of misoprostol in the intervention area did not increase the incidence of reported side effects and may have actually reduced the reliance on harmful and untested local remedies.

Table 21. Reported symptoms

	RESPONDENTS (%)		P-VALUE
	COMPARISON (N = 1,148)	INTERVENTION (N = 2,309)	
No side effects	18.6	60.3	<0.001
Shivering	33.2	28.2	<0.001
Fever	32.6	8.5	<0.001
Nausea	20.0	7.0	<0.001
Abdominal cramping	69.7	6.7	<0.001
Shivering and fever	14.3	4.5	<0.001
Vomiting	9.5	3.9	<0.001
Diarrhea	3.5	1.7	<0.001

More women in the comparison area than in the intervention area required referral for retained placenta or excessive bleeding (Table 22). During the postpartum visit, women were asked if the support person present at birth referred them to the next level of care (family member to TBA, then TBA to skilled provider). 5.1% and 11.4% for comparison versus intervention group were referred to the next level. 15.3% of women in the comparison group were referred because placenta did not come out as expected compared to 6% in the intervention group. As advised, 39% of women were asked to seek help at the next level of care in the comparison group because bleeding exceeded soaking of two cloths, as compared to 19.7% in the intervention group.

Table 22. Referrals

Reason for Referral	Respondents (%)	
	Comparison	Intervention
Retained placenta	15.3	6.0
Excessive bleeding	39.0	19.7

CONCLUSIONS

Afghanistan faces a huge burden of maternal mortality, and in the context of a health care system that is undergoing a period of massive reconstruction and reform following more than 20 years of civil war and isolation. Although maternal and neonatal health is regarded as a priority public health concern for the Government of Afghanistan, and interventions such as the national program for educating and deploying of skilled providers is receiving substantial attention, it will take many years before there are sufficient midwives, particularly in the rural areas, to provide adequate coverage for births. It is clear, therefore, that in conjunction with efforts to scale up coverage by skilled providers, simple solutions that are feasible and effective should be made available to women who either choose to or are compelled to deliver at home, thus advancing the fundamental human right of a woman to a safe pregnancy and childbirth.

PPH, the most common cause of maternal death in Afghanistan, cannot be predicted, and once it occurs, rapid and complex therapy must be provided to save the woman's life. The key to preventing maternal death is universal coverage with effective interventions. Misoprostol has been shown to be effective in preventing PPH, but the real question is how to achieve high coverage safely, acceptably, and equitably, even for the most rural and remote populations. This study has demonstrated that a community-based distribution system of misoprostol, supported with simple educational messages provided by CHWs, can indeed achieve near universal coverage of an effective method of preventing maternal deaths due to PPH.

KEY FINDINGS

- Key findings of this study include the following:
- High coverage of a method to prevent PPH is possible even in difficult areas where less than 25% of births are attended by a skilled provider; 96% of the women in the intervention area received an uterotonic agent compared with only 26% of women in comparison areas.
- The majority of CHWs believed that misoprostol was easily accepted by women, correctly used, and effective in preventing PPH. The CHWs also noted that the project underscored the important role of midwives in pregnancy and the benefits of delivering with a skilled provider in a health facility.
- Many CHWs stated that community recognition was a primary impetus that motivated them to fulfill their responsibilities related to the project, and their communities devised creative and innovative non-monetary methods of providing recognition for their work.
- Women do respond to educational messages. In spite of 45% coverage with antenatal care by skilled providers, CHWs trained for this project were considered to be the main source for information about birth preparedness, complication readiness, PPH, and misoprostol. CHWs have time to spend with the women and their families and are able to convey the simple educational messages. These educational messages were also effective; women were able to recall key information regarding PPH. Contrary to popular belief, the concept of prevention is understood by rural women in Afghanistan.

- Providing educational messages to the women's support persons works. Involving the mother-in-law, sister-in-law, husband, and mother in the educational process reinforced the messages and ensured that at nearly all births there was at least one support person who was knowledgeable about PPH and misoprostol.
- The intervention is safe. As a result of the educational messages, the strategy of asking women to repeat key information before supplying the misoprostol, and the pictorial warning information on the drug packaging, there was not a single case of use of misoprostol before the birth of the (last) baby, even in the cases of unanticipated twins. In addition, the education regarding side effects proved effective, in that women were well prepared when shivering and a transient increase in temperature occurred after use of misoprostol. The level of reported symptoms was higher in the comparison area, and the possibility of use of traditional remedies in comparison areas cannot be excluded. Providing women with effective and safe medicines is an effective deterrent for use of untested traditional remedies.
- The intervention was highly acceptable to women and their families, and many women said they would be willing to pay for misoprostol in the future or recommend it to a friend.
- The intervention is feasible. Trained CHWs are an acceptable source of educational messages and misoprostol distribution, and they were able to reach many women not previously covered by the health care system.

GUIDANCE FOR INTRODUCTION IN OTHER COUNTRIES

This intervention is suitable for countries or regions where a large proportion of births are not attended by skilled providers and where there is an existing network of CHWs or volunteers who are willing to visit all pregnant women in their homes. Countries interested in implementing this intervention should:

- Obtain commitment at the national level to scale up the intervention if the intervention is found to be successful in a small, pilot area;
- Invest sufficient resources in training and supervision;
- Monitor progress;
- Advocate for the intervention at the national and local level as part of an overall safe motherhood campaign; and
- Use all of the available training and counseling materials, program implementation guides, evaluation tools, and posters to facilitate implementation.

RECOMMENDATIONS

The results of this intervention demonstrate that PPH can be prevented at home births using a community-based program of health education messages and distribution of misoprostol. Using the counseling skills of trained CHWs to disseminate messages about birth preparedness and complication readiness also has the benefit of increasing the number of women seeking a skilled attendant for their birth, because women are more aware and educated of the benefits of using skilled care at birth. This fits within the Government of Afghanistan's strategy to increase the number of deliveries by skilled providers and encourage facility-based deliveries. Because a great number of women in Afghanistan will continue to deliver their babies at home, it is strongly recommended that the MOPH adopt a strategy that includes prevention of PPH for home birth settings as part of an interim strategy. Gradual expansion of the demonstration project is therefore recommended as an appropriate strategy.

Expansion of the project should take place in a phased manner in selected districts in selected provinces. As with the demonstration project, expansion needs to be integrated within the existing health care delivery system, the Basic Package of Health Services (BPHS). Implementation will be more cost-effective if NGO grantees of the BPHS have this PPH prevention intervention included in their grants or contracts, rather than as a separate intervention.

The selected districts and the CHW referral health facilities within those districts need to have a midwife or other skilled provider present. If no midwife is present in the district, linkages with programs of community midwifery education can work toward ensuring that the demand generated by the project in seeking care by a skilled provider will be met. To date, there are 25 community midwifery education programs in various provinces throughout Afghanistan.

A robust monitoring system is required, and with training and constant follow-up, CHWs and CHSs could include this within their existing reporting schedules. Technical oversight and guidance could be provided by the ACCESS Program under its Health Services Support Project.

Upon approval of the expansion of the community-based distribution of misoprostol, it is also recommended that the national MOPH PPH Reduction Strategy highlight the existing description of the use of a community-based scheme for prevention of PPH using misoprostol and that misoprostol be included in the national Essential Drug List.

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