PREVENTING POSTPARTUM HEMORRHAGE AT THE COMMUNITY LEVEL
a compendium of operations research
Preventing Postpartum Hemorrhage at the community level

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<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ANC</td>
<td>Antenatal care</td>
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<td>CDK</td>
<td>Clean delivery kit</td>
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<td>CHV</td>
<td>Community Health Volunteer</td>
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<td>CHW</td>
<td>Community Health Worker</td>
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<td>CORPS</td>
<td>Community-oriented Resource Persons</td>
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<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
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<td>ICCDR,B</td>
<td>International Centre for Diarrhoeal Disease Research, Bangladesh</td>
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<tr>
<td>KAP</td>
<td>Knowledge, attitudes and practices</td>
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<tr>
<td>KEEA</td>
<td>Komenda-Edina-Eguafo-Abirem district</td>
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<td>MDG</td>
<td>Millennium Development Goal</td>
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<td>M&amp;E</td>
<td>Monitoring and Evaluation</td>
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<td>MMR</td>
<td>Maternal Mortality Ratio</td>
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<td>NGO</td>
<td>Non-governmental organization</td>
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<td>OR</td>
<td>Operations research</td>
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<td>PPH</td>
<td>Postpartum hemorrhage</td>
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<td>PRHP</td>
<td>Population and Reproductive Health Partnership</td>
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<td>RDRS</td>
<td>Rangpur Dinajpur Rural Services</td>
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<td>SMAG</td>
<td>Safe Motherhood Action Group</td>
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<td>TBA</td>
<td>Traditional Birth Attendant</td>
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<td>VSI</td>
<td>Venture Strategies Innovations</td>
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<td>WHO</td>
<td>World Health Organization</td>
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Despite remarkable progress toward improved maternal health, most developing countries are not on track to meet the fifth Millennium Development Goal to significantly reduce maternal mortality by 2015 (World Health Organization, 2012a). Postpartum hemorrhage (PPH) remains the leading direct cause of maternal deaths despite being preventable with the use of a uterotonic drug immediately after birth. Misoprostol has emerged as an effective and safe uterotonic that is especially suited for home births, which is where the majority of women in developing countries deliver. These home deliveries place women at a high risk for PPH and subsequent death. However, limited evidence exists on the effectiveness of service delivery models to distribute misoprostol for PPH prevention at home births despite international recognition of its potential in community settings.

In response to this knowledge gap, the non-profit women’s health organization, Venture Strategies Innovations (VSI) worked on a series of independent operations research programs across seven countries in Africa and Asia. Between 2008 and 2012, VSI, in collaboration with local and international partner and research organizations, conducted operations research to determine the feasibility, acceptability, and program effectiveness of misoprostol use to prevent PPH at the community level.

VSI designed a unified approach for these programs, which was then adapted to each country and its unique sociocultural context and development needs. The operations research model consisted of a misoprostol distribution strategy, either through antenatal care visits or via traditional birth attendants, and a community awareness campaign to highlight the importance of delivering in a health facility, the danger of PPH and the correct use of misoprostol. Based on the analysis of program results, several important cross-country findings were observed:

- Community-level distribution of misoprostol reaches women;
- Protection from PPH can be significantly increased through community-level distribution of misoprostol;
- Women can use misoprostol correctly during home births and experience minimal, self-limiting side effects; and
- Women view misoprostol as beneficial and would use it in a subsequent pregnancy or recommend it to a friend.

Additionally, this compendium identifies several facilitating factors that contributed to program success that can increase the likelihood of effective scale-up on a national level: strong government support; high levels of antenatal care coverage; the identification of local methods to measure blood loss; and the adaptability of program methods to the local context.
HOME BIRTHS AND MATERNAL MORTALITY

In developing countries maternal mortality remains a significant problem that is concentrated predominately among the poor (Ronsmans and Graham, 2006). Countries where most women deliver outside of a health facility have the highest rates of maternal mortality. In sub-Saharan Africa and South Asia, where the majority of maternal deaths are concentrated, only 7 to 22% of women in the poorest wealth quintiles deliver in a facility (Ronsmans and Graham, 2006; Montagu et al., 2011). This means that most women, and the vast majority of poor women, give birth at home and more often than not, these home deliveries are unattended by a skilled provider (Montagu et al., 2011). If the fifth Millennium Development Goal (MDG 5) to significantly reduce the maternal mortality ratio (MMR) is to be achieved, then interventions must address the fact that many women are delivering at home and without a skilled attendant (Ronsmans and Graham, 2006).

POSTPARTUM HEMORRHAGE

Globally, the leading obstetric cause of maternal deaths is postpartum hemorrhage (Hogan et al., 2010), commonly defined as blood loss of 500 ml or more within 24 hours after delivery (World Health Organization (WHO), 2012b). However, postpartum hemorrhage (PPH) is both preventable and treatable. The use of a uterotonic drug immediately after birth is one of the most effective interventions to prevent PPH (WHO, 2012b). Currently, oxytocin is the recommended uterotonic drug of choice for preventing and treating PPH, and is administered by a skilled provider. The Uniject™ auto-disable injection system developed by the US-based non-governmental organization, PATH, might be a future solution to allow for oxytocin to be used during home births; however, it is still in the early stages of use and distribution (Althabe et al., 2011). Consequently, the vast majority of poor women in developing countries give birth at home without access to injectable uterotonics and as a result they remain at a high risk of complications from PPH and subsequent death (Montagu et al., 2011; Prata et al., 2011; Ronsmans and Graham, 2006).

MISOPROSTOL FOR PREVENTION OF PPH

Misoprostol is a globally recognized alternative uteroton for the prevention of PPH (Lalonde, 2012; WHO, 2012b; United Nations, 2012). As an effective uteroton with an excellent safety profile, misoprostol has been increasingly used in obstetrical and gynecological practice (Derman et al., 2006; Alfirevic et al., 2007) and in 2011 was added to WHO’s Model List of Essential Medicines for PPH prevention (WHO, 2012c). Unlike oxytocin, which in its current formulation must be refrigerated and delivered via injection by a skilled provider, misoprostol tablets are administered orally, are inexpensive and easy to store (Parsons et al., 2007; Derman et al., 2006; Prata et al., 2006). When used during home deliveries, where no other medicine is available, misoprostol is shown to decrease the risk of PPH from 24% (Mobeen et al., 2011) to 47% (Derman et al., 2006).
Misoprostol tablets are ideally suited for PPH prevention at home births and in resource-poor settings. In its 2012 “Recommendations Optimizing Health Worker Roles to Improve Access to Key Maternal and Newborn Health Interventions through Task Shifting,” WHO recommends administration of misoprostol by community and lay health workers for PPH prevention at home deliveries when oxytocin is unavailable (WHO, 2012d). However, a limited body of evidence exists on the effectiveness of service delivery models to distribute misoprostol for PPH prevention at home births despite international recognition of its potential in community settings (Mobeen et al., 2011; Prata et al., 2009; Diadhiou et al., 2011; Sanghvi et al., 2010; Rajbhandari et al., 2010, Smith et al., 2013).

MISOPROSTOL DISTRIBUTION AT THE COMMUNITY LEVEL

In response to a knowledge gap on misoprostol use at the community level for PPH prevention, VSI collaborated on a series of independent operations research programs across seven African and Asian countries. This research was further motivated by a strong desire from these countries’ governments to address high maternal mortality ratios and accelerate progress toward MDG 5, and with an understanding that most maternal deaths occur at home. Between 2008 and 2012, VSI, in collaboration with local and international partner organizations and research institutions, conducted operations research programs to evaluate the feasibility, acceptability, safety and program effectiveness of misoprostol use to prevent PPH at the community level. While early programs provided proof of concept, later programs served as pilots to demonstrate feasibility in the local context for implementation and subsequent policy development. Each program was adapted to the local setting while a standard approach was employed across all countries. This compendium summarizes VSI’s study findings.

IN RANDOMIZED CONTROL TRIALS, MISOPROSTOL WAS SHOWN TO DECREASE THE RISK OF PPH FROM 24% TO NEARLY 50% IN HOME DELIVERIES.

OPERATION RESEARCH COMPENDIUM OVERVIEW

This compendium provides a systematic review of VSI’s operations research on community-level use of misoprostol in resource-constrained settings. The compendium includes:

Section II: Operations research (OR) model overview that describes the basic components of VSI’s OR model for implementing distribution of misoprostol for community-level prevention of PPH in rural, low-resource settings.

Section III: Country program summaries that provide specifics of how the OR model was adapted to individual country settings.

Section IV: Cross cutting results that summarize important findings shared across countries and highlight best practices and key factors for program success.

Developed with policy makers, stakeholders and researchers in mind, the goal of this compendium is to contribute to the growing evidence base on the community-level use of misoprostol to prevent PPH, including advanced provision of misoprostol to pregnant women. The findings highlighted in this compendium demonstrate that misoprostol distribution at the community level is a safe, acceptable, feasible and effective way to reduce PPH in resource-poor settings.
II. VSI OPERATIONS RESEARCH MODEL

This section outlines the basic components of VSI’s operations research (OR) model for implementing distribution of misoprostol for community-level prevention of postpartum hemorrhage (PPH) (Figure 1). While this general model applies to all of VSI’s OR programs, each program was tailored to the specific needs and context of the country (see Section IV).

I. PLANNING
   a. Collaboration with Partners
   b. Formative Research
   c. Analysis of Health Care Access and Utilization Patterns
   d. Community Engagement

II. IMPLEMENTATION
   a. Community Awareness Campaign
   b. Misoprostol Distribution
   c. Data Collection
   d. Data Entry and Management

III. ASSESSING PROGRESS
   a. Supportive Supervision
   b. Final Technical Report
   c. Disseminate Results

FIGURE 1
VSI OPERATIONS RESEARCH MODEL FOR COMMUNITY-LEVEL MISOPROSTOL DISTRIBUTION

I. PLANNING
   a. Collaboration with partners: Within each country, VSI collaborated with government ministries of health, non-governmental organizations (NGOs) and other partners such as health institutes, professional obstetrician and gynecologist associations, social marketers and local universities with a share goal of improving maternal health outcomes. For several programs, VSI partnered with the Bixby Center for Population, Health and Sustainability at the University of California, Berkeley. By utilizing existing partnerships, infrastructure, markets and distribution networks, the organization built on the strength of established resources and capacities within each country.

VSI places great value on engaging stakeholders to gain buy-in for future policy decisions related to widespread adoption of safe motherhood programs. Securing governmental commitment and support is key to successfully launching and scaling-up projects and programs. As such, each operations research program was designed to answer specific policy and programmatic questions to facilitate subsequent policy developments related to PPH prevention in the country and enable its broader adoption outside of the pilot districts.

b. Formative research: Prior to the design of the operations research model, VSI assessed community Knowledge, Attitudes and Practices (KAP) related to labor, delivery and blood loss. Information obtained from KAP assessments was crucial to the research design, including identifying potential opportunities for awareness creation and the ability to introduce a medicine in the context of traditional birthing practices. Identification of blood loss measurement tools that are culturally appropriate and context-specific was also an important outcome. Through discussions with local experts and using qualitative research techniques such as focus groups with traditional birth attendants (TBAs), a locally used method for identifying excessive blood loss was established (see Text Box 1, page 4). This method was then used in all education activities to inform women and communities how to identify PPH and when to refer a woman for life-saving interventions.

c. Analysis of health care access and utilization patterns: In program districts, VSI analyzed health care access and utilization patterns to identify
appropriate distribution mechanisms for misoprostol tablets and ways to educate women that capitalized on existing health care infrastructure and established health-seeking behaviors. VSI worked to integrate the new PPH-prevention intervention into the existing health care system and to strengthen monitoring and evaluation activities of maternal health programs.

Researchers selected program sites in consultation with local governments based upon their stated objectives and programmatic needs, or to prioritize certain target populations. For example, program sites were selected based on their geographic remoteness, the presence of existing NGOs or complementary community-level safe motherhood programs, or because they were priority areas identified by the government.

**d. Community engagement:** Since the Alma Ata Declaration in 1978, community engagement and empowerment have gained wide acceptance as critical tools for strengthening health systems, addressing inequities and increasing demand for essential health services (WHO, 1978). Informed and mobilized communities have played an important role, for example, in fostering acceptance of and demand for maternal health services across the continuum of care from home to health facility. Given the particular emphasis on women who deliver at home, these operations research programs included the voices of local village leaders, informal and formal community groups, and religious organizations during the planning phase; this helped ensure community acceptance of the program and bolstered local awareness of the health issue under study. Partnerships with local leaders, health workers and NGOs active in the area meant women could be reached by people whom they knew and trusted.

### 2. IMPLEMENTATION

**a. Community awareness campaign:** A community awareness campaign on birth preparedness and PPH prevention was an essential component of VSI’s OR programs. The campaigns utilized a mix of
Information, education and communication (IEC) strategies to bolster safe delivery practices, reinforce the importance of delivering in a facility and increase women’s knowledge of PPH and misoprostol use for PPH prevention. The community awareness campaigns in all the OR programs focused on four key messages:

- **Message 1:** The importance of delivering at a health facility;
- **Message 2:** Birth preparedness and early planning for a safe delivery;
- **Message 3:** PPH identification, consequences and recognition using the identified postpartum blood loss measurement method (e.g., kanga in Tanzania); and
- **Message 4:** The importance of misoprostol in the prevention of PPH in home births.

Programs used one or more of the following approaches to educate women and communities: pictorial instructions, informational posters, facility-based educational sessions, community-level awareness meetings, home visits and radio spots (**Figure 2**).

**b. Misoprostol Distribution:** While a standard dose of misoprostol was used in all countries (three tablets equaling 600 mcg), each program had a misoprostol distribution strategy tailored to the local context. In any of the following distribution strategies, misoprostol was distributed either as tablets alone or

**FIGURE 2**

**INFORMATION, EDUCATION, AND COMMUNICATION STRATEGIES**

Projects used one or more of the following strategies to educate women and communities

| PICTORIAL INSTRUCTIONS | • Local artists created pictorial images to illustrate the correct use of misoprostol and warning messages indicating when to refer for excessive bleeding.
| | • Used for educational materials, such as pamphlets and posters.
| | • Women always received a pamphlet with pictorial instructions when they were given misoprostol. |
| INFORMATIONAL POSTERS | • Described misoprostol and where it could be obtained—designed for each program.
| | • Presented one or more of the community awareness campaign’s key messages.
| | • Displayed in prominent locations at clinics (e.g., waiting areas) and in central community locations (e.g., market or village well). |
| FACILITY-BASED EDUCATIONAL SESSIONS | • Conducted by providers during ANC visits on birth preparedness and PPH prevention.
| | • Targeted pregnant women, and often held in a group setting to enable more participation.
| | • Women were encouraged to bring their partner of family member(s) with them. |
| COMMUNITY-LEVEL AWARENESS MEETINGS | • Conducted by community leaders, TBAs and other community-based health promoters (e.g., community health workers, safe motherhood group, etc.).
| | • Included as part of larger, general community meetings or held separately as a focused topic, such as at a women’s group meetings. |
| HOME VISITS | • TBAs or community-based health promoters visited women in their homes.
| | • Conducted education sessions with pregnant women, using pamphlets or other pictorial materials. |
| RADIO SPOTS | • Scripted to highlight the campaign’s key messages.
| | • Aired to reinforce the need for birth preparedness and use of misoprostol for PPH.
included in the contents of a clean delivery kit. Strategies are described in Figure 3 (page 7) and variations are described in the country program summaries in Section III (page 9).

**Antenatal Care (ANC):** Across all African countries, 69% of pregnant women have at least one ANC visit, which presents a valuable point-of-contact with expectant mothers. In countries with high ANC attendance, distributing misoprostol during ANC visits capitalizes on women’s existing health-seeking behavior and has the potential to reach the majority of pregnant women, regardless of where they deliver.

**Traditional Birth Attendants:** A TBA has been defined as a person who assists mothers during childbirth and initially acquired her skills by delivering babies herself or through apprenticeship to other TBAs (WHO, 1992). In settings where reaching women during pregnancy is challenging (e.g., low rate of ANC attendance) and TBAs attend many home deliveries, they can be a means to reach women who are delivering at home who might not have other contact with the formal health care system.

c. **Data collection at sites:** Data were collected using a standard questionnaire for a period of six months to over a year; collection methods varied across programs and included the point of distribution, the time of delivery and/or during follow up postnatal care (Figure 4, page 8).

d. **Data entry and management:** Data entry was performed under the supervision of the local implementing partner and verified by VSI Monitoring and Evaluation (M&E) staff who conducted the analysis.

### 3. ASSESSING PROGRESS AND SHARING RESULTS

**a. Supportive supervision:** Program management conducted monthly or bi-monthly supervisory visits during program implementation and addressed implementation challenges as they arose. Any adverse effects were documented and addressed. The VSI M&E staff conducted one or more visits to each study site to confirm that the program was being
implemented according to protocol and to facilitate any necessary changes.

b. Final technical report: VSI produced a comprehensive report on each operations research program. These included background on PPH and the history of misoprostol in the study country, methodology, results, conclusions and recommendations for future actions. For purposes of describing the OR results, VSI used the SAFE model:

Safety: Correct use of misoprostol; i.e., taking 600 mcg misoprostol orally immediately after delivery.

Acceptability: Willingness to use misoprostol in the future, recommend it to a friend, or pay for the tablets.

Feasibility: Coverage of misoprostol distribution or the proportion of the target population reached through the distribution mechanism (i.e., proportion of all women attending ANC who were enrolled and given misoprostol to take home).

Effectiveness: Births protected from PPH, i.e.,
the proportion of all births where a uterotonic was used for PPH prevention.

c. Dissemination of results to stakeholders and governments: At the completion of each research program, VSI convened a stakeholders’ meeting to disseminate results at the national level and, where possible, the district level; drafted a final technical report and policy brief; and presented results at international meetings and conferences. Additional operations research results have been published in peer-reviewed journals (Prata et al., 2012a; Prata et al., 2012b; Smith et al., 2013).
III. COUNTRY PROGRAM SUMMARIES

VSI’s operations research (OR) model was applied in seven African and Asian countries. While a unified approach was developed, its operationalization was specific to each country and its unique sociocultural context and development needs. The primary goal of each OR endeavor was to increase uterotonic coverage at delivery and to prevent postpartum hemorrhage (PPH). A set of common objectives was employed and included the following:

- To assess whether distribution of misoprostol during antenatal care (ANC) visits or at home delivery with a traditional birth attendant (TBA) were feasible mechanisms to reach women who deliver at home.
- To determine if misoprostol distribution during pregnancy via ANC or at delivery with a TBA is effective in increasing protection from PPH among women who deliver at home through increased use of uterotonic drugs at delivery.
- To provide necessary evidence that women can safely self-administer misoprostol for prevention of PPH at home births after being educated on and receiving the drug at ANC visits or from a TBA.
- To determine whether women find misoprostol to be an acceptable means of preventing PPH at home births.
- To generate evidence for the national scale-up of misoprostol distribution strategies.

The following section provides a country-by-country overview of each operations research program. Each country brief highlights the local context, research partners and elements of the misoprostol distribution strategy and community awareness campaigns. Additionally, information is provided on data collection methods and key findings and conclusions from each program. For more program-specific details, the full technical reports are available by request at info@vsinnovations.org.
Preventing Postpartum Hemorrhage at the Community Level

Bangladesh

29 upazilas (sub-districts) in the six northwestern districts of Bangladesh: Panchagarh (1), Thakurgaon (2), Dinajpur (3), Nilphamari (4), Lalmonirhat (5) and Kurigram (6). Population: 90,65,626.

Scaling up of Misoprostol for Prevention of Postpartum Hemorrhage in 29 Upazilas (2009-2011)

Context:
- Maternal mortality ratio (MMR): 194 deaths per 100,000 live births (National Institute of Population Research and Training (NIPORT), 2011).
- 77% of births occur at home and 27% of births are attended by a skilled birth attendant (NIPORT, 2011).
- 54% of women receive ANC from medically trained providers (NIPORT, 2012).

Research Partners:
- The International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B)
- Bixby Center for Population, Health and Sustainability – University of California, Berkeley
- Rangpur Dinajpur Rural Services (RDRS), Bangladesh

Misoprostol Distribution Strategy:
- ANC distribution: Misoprostol was included in a clean delivery kit (CDK), and offered to women at ANC if they were 32 weeks or greater gestation.
- Birth attendant: An RDRS trained birth attendant provided a CDK during a home delivery and assisted with using its contents.

Community Awareness Campaign:
- Community health workers (CHWs) conducted health education sessions during ANC visits.
- Pregnant women were encouraged to bring relatives (in-laws and husbands) to ANC visits to participate in the education sessions.
• **Blood loss measurement tool**: A delivery mat designed by a scientist at ICDDR,B (Prata et al., 2012b). When placed under a woman in labor, it can only absorb up to 500 ml of blood. If there is additional blood that is not absorbed by the mat, it indicates PPH.

**DATA COLLECTION AND EVALUATION:**

- **Point of distribution**: 77,337 women were enrolled and delivered during the program period; information was collected during ANC visits and a post-delivery check-up.
- **Postpartum interviews**: 3,016 (4%) of those who were enrolled and delivered during the program period were randomly selected for active follow-up (every 20th woman).
- **Verbal autopsies**: Using a standardized verbal autopsy questionnaire, 113 deaths during the program period were documented.

**KEY FINDINGS AND CONCLUSIONS:**

• Of the women who delivered during the program, 70% received a CDK during pregnancy or at delivery, demonstrating that distributing CDKs through these channels is a feasible way to reach a large number of women. Most of the women who did not receive a CDK during pregnancy delivered with an RDRS birth attendant (73%), highlighting the importance of equipping them with CDKs to ensure misoprostol is on-hand to prevent PPH.

• Of the women who received a CDK, 96% were protected from PPH either by using misoprostol at home, or by delivering at a health facility or with a skilled provider. Misoprostol used at home deliveries and distributed through CDKs increased protected births in the program by 60%.

• Almost all of the 1,893 women who used misoprostol at home and participated in the postpartum interviews reported using the drug correctly (96%), taking the correct dose at the right time.

• Over 98% of women who took misoprostol considered it useful and would recommend it to a friend.

• Almost all women who received a CDK used Quaiyum’s mat to estimate blood loss at delivery (96%). Most women who used the mat said they found it useful and would use it again in their next delivery (87%). This is evidence that Quaiyum’s mat is a feasible and acceptable means of assessing postpartum blood loss in Bangladesh, improving recognition of PPH and facilitating a timely referral to prevent delays in seeking care.

• Fewer than 1% of women experienced retained placenta, eclampsia or tears. Two and three percent of women experienced prolonged labor and obstructed labor, respectively. Only 2% of women needed to be referred during labor, delivery or postpartum.

• Perceived PPH occurred in fewer than 1% of deliveries, regardless of whether the woman used misoprostol, delivered in a health facility or with a skilled provider, or if she delivered at home and did not use misoprostol. This rate is much lower than expected based on other studies on maternal health in Bangladesh.

• A total of 113 deaths were reported in the study areas during the program time period. Eclampsia accounted for the largest proportion of deaths followed by PPH, bleeding-related causes and other direct causes. Thirty-seven fewer deaths were observed than expected in this program using the most recent MMR estimate.

• The results from this program and other PPH prevention programs were shared during a national dissemination meeting in June 2011, where the scale-up of misoprostol for PPH prevention was officially recommended. It is currently being implemented throughout the country.

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**Including Misoprostol in the [Clean Delivery Kit] is a good thing. Pregnant women are coming to the clinic because they have heard about the new CDK and misoprostol, whereas before, them had to motivate mothers to come to ANC. Now mothers are coming on their own and asking for the new CDK.”**

—Community Health Worker, Nilphamari
GHANA

DISTRIBUTION OF MISOPROSTOL AT ANTENATAL CARE VISITS FOR PREVENTION OF POSTPARTUM HEMORRHAGE (2009-2012)

Four districts: Birim South and Upper Manya Krobo, Komenda-Edina-Eguafo-Abirem (KEEA) and Sene. Population: 405,890.

CONTEXT:
• MMR: 350 deaths per 100,000 live births (WHO, 2012a).
• 24% of maternal deaths are due to hemorrhage and 42% of women deliver at home (Ghana Statistical Service (GSS), 2009).
• 95% of women attend at least one ANC visit with a healthcare professional (GSS, 2009).
• Program launched to meet government calls to demonstrate the feasibility of PPH prevention using misoprostol in the Ghanaian context.

RESEARCH PARTNER:
• Ghana Health Services

MISOPROSTOL DISTRIBUTION STRATEGY:
• ANC distribution: Women were offered misoprostol during ANC visits once they had reached 12 weeks gestation.

COMMUNITY AWARENESS CAMPAIGN:
TBAs conducted awareness meetings with community leaders and women’s groups. They also conducted one-on-one information sessions with pregnant women.
• Community health volunteers (CHVs) disseminated messages about birth preparedness and misoprostol use.
• Queen Mothers (traditional female community leaders) participated in community sensitization efforts due to their substantial community influence.
• Durbars (local community meetings) were organized by TBAs, CHVs and District Health Management Teams and brought together community members to share messages about misoprostol and its availability in health facilities.
• Megaphone announcements were made in local markets and radio spots were broadcast.
DATA COLLECTION AND EVALUATION:

• **Point of distribution:** Providers registered **11,328** women during ANC; **47% (5,345)** of these women formally enrolled in the program.

• **Postnatal follow-up:** Providers interviewed **68%** of enrolled women during routine postnatal care visits.

KEY FINDINGS AND CONCLUSIONS:

• Approximately 93% of women who delivered at home and returned for postnatal care used misoprostol at delivery. Without the availability of misoprostol, these women would not have had protection from PPH.

• For those women who accepted misoprostol at ANC, reported use was very high and correct, with 99% of women reporting at their postnatal visit that they correctly used the drug.

• Of the women who took misoprostol home from ANC and did not use it at a home delivery, the vast majority (83%) returned the misoprostol to a facility, as they had been instructed to do by the ANC provider who initially gave them the tablets. The proportion returning misoprostol was also high among facility deliveries, with 92% of the women who delivered at a facility and did not use misoprostol returning the drug.

• Over 300 TBAs and 200 CHVs educated women about the use of misoprostol and safe delivery in this program. During supervisory visits, TBAs and CHVs reported that women and community members responded positively to their messages, and that women appreciated having messages about safe motherhood brought to them by fellow members of their community.

• Two maternal deaths were reported during the program period. Further inquiry was conducted into the cause of the death and both were found to be unrelated to the program or to taking misoprostol. No referrals were made during the program.

• During the course of the program, the misoprostol tablets were recalled due to quality issues and replaced with another brand of misoprostol tablets. This recall took place in July and August 2011, and all tablets were replaced by September 1, 2011. Data were analyzed for Phase 1 (April-August 2011) and Phase 2 (September 2011-January 2012) taking into account the drug recall process. This had negative effects on program enrollment, which was significantly lower during the recall months.

• The results from this program were shared during a national dissemination meeting in March 2012, where the scale-up of this program was officially recommended.

“MANY OF THE WOMEN WHO COME TO ANTENATAL [CARE] ARE FROM FAR AWAY AND THEY CANNOT GO TO THE HEALTH CENTER TO DELIVER. MAYBE IF THEY TRY, THEY WILL DELIVER IN THE CAR. IF THERE IS NO CAR TO GO, THEY CANNOT WALK. THE MISOPROSTOL IS HELPING THEM A LOT, AND IT IS ALSO HELPING US BECAUSE THERE ARE FEWER COMPLICATIONS.”

—Community Health Nurse, Birim South District
INTRODUCTION OF MISOPROSTOL FOR PREVENTION OF POSTPARTUM HEMORRHAGE AT THE COMMUNITY LEVEL (2009-2011)

KENYA

Two districts: Kitui and Maragua. Population: 1,000,000. ■ PROJECT DISTRICTS ★ Capital

CONTEXT:
• MMR: 488 deaths per 100,000 live births (Kenya National Bureau of Statistics (KNBS) and ICF Macro, 2010).
• 56% of Kenyan women give birth at home, without access to emergency obstetric care services. In rural areas this is higher (63%), with similar rates of women delivering without a skilled birth attendant (KNBS and ICF Macro, 2010).
• 92% of women utilize ANC during their pregnancy (KNBS and ICF Macro, 2010).

RESEARCH PARTNERS:
• The Division of Reproductive Health, Ministry of Health and Sanitation
• Kenya Obstetrical and Gynaecological Society

MISOPROSTOL DISTRIBUTION STRATEGY:
• **ANC distribution:** In both program districts, ANC providers distributed misoprostol during routine visits.
• **Community midwife distribution:** In Maragua district, women received misoprostol during a home delivery with a community midwife.

COMMUNITY AWARENESS CAMPAIGN:
• Posters and pamphlets were available and distributed in the communities through ANC facilities and by CHWs.
• CHWs conducted group and one-on-one meetings with community members. These meetings reinforced ANC messages, including information about safe delivery, PPH and misoprostol, and encouraged women to attend ANC and deliver at health facilities.
• Two radio scripts in local dialects were aired.
• **Blood loss measurement tool:** The *lesso* is a pre-cut rectangular piece of brightly colored fabric worn by local women; one *lesso* completely soaked with liquid equals approximately 500 ml.
Most of the Mothers went to deliver at hospital, and those who delivered at home used [Miso] and it helped them.”

—Community health worker, Maragua district
COMMUNITY-BASED PREVENTION OF POSTPARTUM HEMORRHAGE WITH MISOPROSTOL (2009 - 2011)

MOZAMBIQUE

Three sites: Chokwe, Namacurra, and Nacala-Porto/Nacala-a-Velha. Population: 1,000,000.

CONTEXT:
- MMR: 490 per 100,000 live births (WHO, 2012a).
- 85% of women attend at least one ANC visit on average, but provincial variance exists (Instituto Nacional de Estatística, 2005).
- Program implemented in response to the Ministry of Health’s request for research to demonstrate the effectiveness of misoprostol at the community level in Mozambique.

RESEARCH PARTNERS:
- Associação Moçambicana de Obstetras e Ginecologistas
- Bixby Center for Population, Health and Sustainability – University of California, Berkeley
- Population Services International – Mozambique

MISOPROSTOL DISTRIBUTION STRATEGY:
Each site used a different strategy, depending on its level of ANC coverage:
- High ANC coverage site (Chokwe): Misoprostol distributed to women at 28 weeks gestation or greater, coinciding with their eligibility to receive niverapine to prevent mother-to-child HIV transmission.
- Low ANC coverage site (Namacurra): Misoprostol distributed at delivery by TBA.
- Average ANC cover site (Nacala-Porto/Nacala-a-Velha): Misoprostol distributed at ANC visits to women at 28 weeks gestation or greater and by TBAs at delivery.

COMMUNITY AWARENESS CAMPAIGN:
- Promotional posters, informational pamphlets and educational flip books distributed.
- TBA meetings with community leaders, women’s groups and one-on-one with pregnant women in villages.
- TBAs spoke in churches after sermons to reach both women and men with birth preparedness messages.
- Blood loss measurement tool: A pre-cut piece of cloth of standard size which women wear as a skirt,
shawl, head wrap or strap to carry a baby. One capaluna soaked with blood is equivalent to 600 ml of fluid.

DATA COLLECTION AND EVALUATION:

• Points of distribution: 11,927 women were reached through ANCs and TBAs. 
  ANC: 5,771 women attended ANC in Chokwe and Nacala-Porto/Nacala-a-Velha. 
  TBA: 4,511 women were assisted in delivery in Namacurra and Nacala-Porto/Nacala-a-Velha.

• Postpartum interviews: Providers interviewed 6,758 participants who delivered at health facilities when the participant returned to a health facility for routine postnatal care, or through active follow-up.

KEY FINDINGS AND CONCLUSIONS:

• Recall of community awareness messages about excessive bleeding and misoprostol was high among all women who completed a postpartum interview. Most women mentioned identifying excessive bleeding using the capulana, demonstrating that the capulana is a feasible and acceptable tool for assessing blood loss at the community level. Regardless of where the woman was offered misoprostol, ANC providers and health facilities were mentioned most often as sources of information about PPH and misoprostol.

• 92% of women in Chokwé and 97% in Nacala-Porto/Nacala-a-Velha whose ANC records were analyzed took misoprostol home.

• Both ANC and TBA distribution resulted in protected births at virtually all home deliveries in the postpartum interview sample. In Chokwé, 99% of the women delivering at home used the misoprostol they had received at ANC.

• TBAs used misoprostol in all of the deliveries they attended in Namacurra. In Nacala-Porto/Nacala-a-Velha, ANC distribution was complemented by TBA distribution of misoprostol. TBAs gave misoprostol at delivery to the 5% of women delivering at home who did not receive misoprostol at ANC, resulting in over 99% of home births in the postpartum sample protected from PPH.

• Virtually all the women who received misoprostol at ANC correctly self-administered the drug after delivering at home (99%). Additionally, most women delivering with TBAs in Namacurra and Nacala-Porto/Nacala-a-Velha also reported taking the correct dose at the correct time at a home delivery (99%). These results demonstrate that women and TBAs can safely use misoprostol at home deliveries once educated about the drug.

• Acceptability of misoprostol was very high among both misoprostol users and non-users across all three sites. 96% of women who used misoprostol reported that they would recommend misoprostol to a friend or use it in a subsequent pregnancy.

• There were no bleeding-related referrals, nor were there any referrals due to use of misoprostol in the postpartum interview sample. No maternal deaths were reported.

FOR THOSE THAT DELIVER AT HOME, MISOPROSTOL SAVES LIVES.” —Nurse, Chokwe
Preventing Postpartum Hemorrhage at Home Births in Five Communities Around Zaria, Kaduna (2008-2010)

Context:
- MMR: 630 per 100,000 live births, which is one of the world’s highest (WHO, 2012a).
- 65% of deliveries take place at home without trained health professionals (National Population Commission, 2009).
- Program implemented to address the Ministry of Health’s request for local evidence on the use of misoprostol by non-skilled providers.

Research Partners:
- Population and Reproductive Health Partnership (PRHP) of Ahmadu University, Zaria, Nigeria
- Bixby Center for Population, Health and Sustainability – University of California, Berkeley
- Venture Strategies for Health and Development

Misoprostol Distribution Strategy:
- Misoprostol distributed by community drug keepers to TBAs and pregnant women or members of their households. Tablets made available during the last months of pregnancy.

Community Awareness Campaign:
- Fact sheets for health providers and drug keepers, posters, head coverings (hijabs) and kettles (butas) inscribed with instructions for misoprostol use, audio-taped dramas distributed on CD and tape, illustrated booklets for non-literate audiences, interpersonal communications by TBAs and community-oriented resource persons (CORPS).
- Blood loss measurement tools: The moda, a cap used locally for fetching water, and a two-yard cotton wrapper. Each holds 500 ml of liquid when filled or soaked.

Data Collection and Evaluation:
- Points of distribution: Through TBAs and community drug keepers, 1,875 women received misoprostol and provided intake data.
- Postpartum interviews: Completed for 96% of enrolled women via active follow-up.
• **Maternal mortality audit:** Doctors on the research team investigated all cases of maternal mortality that occurred in the study communities during the program period.

**KEY FINDINGS AND CONCLUSIONS:**

- After delivery, most women reported having received information about bleeding (88%). Overall, TBAs were the most frequently reported source of information about PPH (77%), followed by midwives (52%) and health facilities (49%). The information, education and communication campaign was successful in reaching targeted women with the message about misoprostol for PPH. 88% of women reported knowing about misoprostol for PPH, with the main source of information about misoprostol being the TBA (85%).

- Across all communities, TBAs and CORPs were effective in reaching pregnant women with messages about PPH and misoprostol; TBAs were very effective in accessing the drug using the community drug keepers. 84% of enrolled women received misoprostol to use in case they delivered at home. TBAs and CORPs proved critical resources for the intervention’s success and were effective community agents for interpersonal messages to women and men.

- The use of misoprostol for PPH prevention at home births was the most important contributor to births protected against PPH. The percentage of women who received injectable uterotonic is very low in these communities (4%). With misoprostol available at the community level, 79% of the women enrolled in the program were protected against PPH who otherwise would not have been. With the use of misoprostol at home births where TBAs were able to provide the uterotonic at time of delivery, a total of 83% of deliveries were protected. This demonstrates the importance of an intervention for home births in communities where most of the deliveries take place at home.

- Among women who used misoprostol for PPH prevention, 98% reported using the correct dose and 88% reported correctly taking misoprostol orally immediately after delivery of the child. This further confirms that community-level use of misoprostol can be done safely and correctly.

- Acceptability was extremely high in all communities. 95% of women said they would take misoprostol in a future pregnancy and 96% would recommend it to a friend.

- Bleeding-related problems that developed during home births were successfully treated at home. Among those who took misoprostol at home, only one woman required additional interventions, was taken to the facility and died of bleeding-related complications. Two additional PPH-related maternal deaths were recorded among women who did not take misoprostol.

—I had nightmares while I was pregnant because I feared bleeding. I am grateful for misoprostol for protecting me.”

—Mother who experienced PPH in a previous delivery, Hayin Ojo, Nigeria
Preventing Postpartum Hemorrhage at the Community Level

**Context:**
- MMR: 460 deaths per 100,000 live births (WHO, 2012a).
- 50% of deliveries take place in a health facility (National Bureau of Statistics (NBS) Tanzania and ICF Macro, 2010).
- 96% of women receive ANC from a health professional once during pregnancy (NBS Tanzania and ICF Macro, 2010).
- Tanzanian Ministry of Health and Social Welfare recommended an operations research program to demonstrate that misoprostol distribution at ANC can address PPH.

**Research Partners:**
- Ifakara Health Institute - Tanzania
- Bixby Center for Population, Health and Sustainability - University of California, Berkeley

**Misoprostol Distribution Strategy:**
- **ANC distribution:** Misoprostol provided once a woman reached 32 weeks gestation.

**Community Awareness Campaign:**
- Pictorial pamphlets, general awareness posters, informational posters, radio, community meetings and home visits by TBAs and CHWs.
• **Blood measurement tool**: *Kanga*, a brightly colored cloth worn by Tanzanian women as sarongs and shawls. Placed under a woman’s buttocks during delivery, two standard-sized *kangas* when soaked with blood contain slightly more than 500 ml of blood.

**DATA COLLECTION AND EVALUATION:**

• **Point of distribution**: Data were collected at every ANC visit of the 12,511 women enrolled.

• **Postpartum interviews**: A postpartum interview questionnaire was administered to 6,735 women (54% of enrolled) either by providers for all women returning for a routine postnatal care visit or by research assistants through active follow-up of women who did not return for postnatal care.

**KEY FINDINGS AND CONCLUSIONS:**

• The multi-faceted community awareness campaign was successful in reaching 96% of women who participated in the postpartum interview. Most (84%) said they identified excessive bleeding using the *kanga* method. Midwives and facility-based education were reported as the most important sources of information for women’s awareness of PPH and misoprostol (85-94% across districts).

• Only 44% of enrolled women returned for an ANC visit after reaching 32 weeks gestation, limiting the number of women who were given the drug to take home. The variation in the range of ANC attendance after 32 weeks gestation across districts – 38% to 59% – indicate that it is important to consider individual characteristics of districts in scale-up strategies. Therefore, the 32-week gestation restriction resulted in fewer women being reached with the drug.

• Misoprostol played a vital role in protecting births from PPH both at home and in facilities: 91% of the 6,735 women who participated in the postpartum interview received a uterotonic at delivery (27% used misoprostol at home; 73% received a uterotonic at a health facility).

• Of the women in the postpartum interview sample who delivered at home, 88% used misoprostol after delivery. Without misoprostol, no uterotonic would have been used and these births would have been at high risk for PPH.

• The safety of misoprostol distributed at ANC for PPH prevention at home births was well demonstrated. All women who took misoprostol at home said they took the drug correctly (dose and route). Thirty women reported requiring referral for bleeding-related causes and no maternal deaths were reported.

• Most of the women who took misoprostol home from ANC used it at delivery (96% in the postpartum interview sample). Almost all women who used misoprostol would recommend it to a friend (99%) or use it in a subsequent pregnancy (98%).

*“When we had misoprostol we had no cases of postpartum hemorrhage arriving at our health center. Since the project ended, we are seeing cases again.”*—Nurse, Health Center, Ulanga District
Preventing Postpartum Hemorrhage at the Community Level

ZAMBIA


CONTEXT:

- MMR: 603 per 100,000 live births (Hogan et al., 2010).
- 47% of Zambian women deliver with a trained professional and 52% deliver at home; in rural areas up to 67% of deliveries occur at home (Central Statistical Office (CSO), 2009).
- 94% of women attend at least one ANC visit with a skilled provider (CSO, 2009).

RESEARCH PARTNERS:

- Ministry of Health, Zambia
- Bixby Center for Population, Health and Sustainability – University of California, Berkeley

MISOPROSTOL DISTRIBUTION STRATEGY:

- ANC distribution: Misoprostol was distributed to women during routine ANC visits.

COMMUNITY AWARENESS CAMPAIGN:

- Radio adverts, posters and pamphlets, and one-on-one educational sessions were used.
- Safe Motherhood Action Groups (SMAGs) brought the campaign’s messages into the community. SMAGs are community organizations affiliated with certain health centers.
- SMAGs conducted community meetings and educational sessions on the key messages comprising the program’s awareness campaign.

DATA COLLECTION AND EVALUATION:

- Point of distribution: 5,574 women attended ANC during the program period.
- Postpartum survey: A separate evaluation was carried out after the program period and included
two control districts where misoprostol was not available during the program period. 1,989 women completed the survey and 53% were from the intervention districts.

- **Verbal autopsies:** Four deaths were recorded in the intervention areas during the program period.

**KEY FINDINGS AND CONCLUSIONS:**

- 94% of women who attended ANC in the intervention areas received misoprostol.
- Uterotonic coverage was greater in the intervention areas than in the control areas, both at home births and at facility births. Almost half of the women delivering at home in the intervention areas were protected from PPH with misoprostol (49%); fewer than 1% of women in control areas reported uterotonic use at home deliveries. In addition, having misoprostol available at facilities meant that an additional 20% of women in intervention areas were protected from PPH with a uterotonic. While 66% of women in intervention areas received some type of uterotonic regardless of their location of delivery, only 20% of women in control areas received a uterotonic at delivery for prevention of PPH.
- Distributing misoprostol through ANC did not lead to more women delivering at home in the intervention areas. In fact, significantly more women in intervention areas where misoprostol was available delivered at facilities when compared to control areas. Since an important component of this pilot project was facility- and community-based education on birth preparedness and PPH prevention, the higher rate of facility delivery seen in the intervention areas could be the result of additional messages on the safety of delivering in the facility, as promoted by ANC providers and SMAGs.

- Knowledge about misoprostol was high in intervention areas. Health facilities and ANC providers were the most frequently cited sources of information on PPH and misoprostol by women in the intervention areas. While all women attending ANC in intervention areas should have received information on PPH and misoprostol, the importance that participants placed on the health facility for this information demonstrates the vital role health facilities and their staff play in educating women.
- 33% of women in the intervention area recognized SMAGs as important sources of information about misoprostol. The inclusion of SMAGs in this program was instrumental in raising initial awareness about PPH and misoprostol among women and communities, as well as for reiterating messages heard at ANC and other health facilities.
- Correct use of misoprostol by women who delivered at home was very high, with 88% of women taking it immediately after delivery and orally, and over 80% reporting that they took the proper prevention dose of three tablets.
- Acceptability of misoprostol was extremely high among women in intervention areas. The majority of women would recommend the drug to a friend (88%), use it in a subsequent delivery (90%), or be willing to purchase the drug (80%).
- Bleeding-related referrals were lower in the intervention areas where misoprostol was available for home and facility deliveries (39% versus 55% of total referrals). This may be a result of the role of misoprostol in reducing excessive bleeding at delivery as well as the subsequent need for referrals.
- Four maternal deaths were recorded in the intervention areas and six in the control. Most of the maternal deaths in control areas were bleeding-related, compared with no bleeding-related deaths in the intervention areas.

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**As men, we are the grave diggers in our communities. Since this [misoprostol] project came, we have not dug any graves for our women.”**

—Safe Motherhood Action Group volunteer, Kapiri Mposhi, Zambia
IV. CROSS-CUTTING RESULTS AND FACTORS FOR SUCCESS

This section highlights important results across the seven countries that participated in VSI’s operations research (OR) between 2008 and 2012.

The main findings are:

**Feasibility:** Community-level distribution of misoprostol and messages reach women.

**Effectiveness:** Protection from postpartum hemorrhage (PPH) can be significantly increased through community-level distribution of misoprostol.

**Safety:** Women can use misoprostol correctly during home births and experience expected, but self-limiting side effects.

**Acceptability:** Women view misoprostol as beneficial and would use it in a subsequent pregnancy or recommend it to a friend.

F E A S I B I L I T Y
Distribution of misoprostol at the community level reaches women:

- Across all seven countries, the vast majority of women eligible to receive misoprostol took the tablets home from antenatal care (ANC) visits or received it from a traditional birth assistant (TBA).
- Coverage of misoprostol distribution to pregnant women ranged from almost 70% of those enrolled and eligible to receive misoprostol in Bangladesh to over 99% in Ghana (Figure 5).
- These results show that for countries with high rates of ANC coverage, the distribution of misoprostol to women via ANC visits is a successful method of getting misoprostol into the hands of pregnant women.
- In regions where ANC coverage is low, such as Nigeria and certain health districts in Mozambique, the use of TBAs to distribute misoprostol is an effective alternative.

FIGURE 5
DISTRIBUTION OF MISOPROSTOL TABLETS TO ELIGIBLE WOMEN ACROSS ALL COUNTRIES

<table>
<thead>
<tr>
<th>Country</th>
<th>n</th>
<th>% Eligible women receiving misoprostol during ANC visit</th>
<th>% Eligible women receiving misoprostol via a TBA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>77363</td>
<td>69.4%</td>
<td></td>
</tr>
<tr>
<td>Ghana</td>
<td>5345</td>
<td>99.4%</td>
<td></td>
</tr>
<tr>
<td>Kenya</td>
<td>3812</td>
<td>98.4%</td>
<td></td>
</tr>
<tr>
<td>Mozambique</td>
<td>4292</td>
<td>98.4%</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>2441*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nigeria</td>
<td>1875</td>
<td>83.6%</td>
<td></td>
</tr>
<tr>
<td>Tanzania</td>
<td>5507</td>
<td>96.8%</td>
<td></td>
</tr>
<tr>
<td>Zambia</td>
<td>5574</td>
<td>94%</td>
<td></td>
</tr>
</tbody>
</table>

n= Number of eligible women

* Includes Namcurra district only, where TBA-only distribution occurred
**EFFECTIVENESS**

Protection from PPH can be significantly increased through community-level distribution of misoprostol:

- Among the women who received misoprostol during ANC or from a TBA and subsequently delivered at home, over 80% used the drug correctly (correct dose, route and timing) during their home delivery.

- This ranged from 79% in Nigeria to over 99% in Mozambique (Figure 6), demonstrating that uterotonic coverage can be effectively increased via community-level distribution of misoprostol.

- When women are offered misoprostol, they will subsequently use it when delivering at home, which translates into more women being protected from PPH.

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**FIGURE 6**

**MISOPROSTOL USE DURING HOME DELIVERIES ACROSS ALL COUNTRIES**

<table>
<thead>
<tr>
<th>Country</th>
<th>n</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>53897</td>
<td>86.4%</td>
</tr>
<tr>
<td>Ghana</td>
<td>1261</td>
<td>93.1%</td>
</tr>
<tr>
<td>Kenya</td>
<td>1142</td>
<td>94.9%</td>
</tr>
<tr>
<td>Mozambique</td>
<td>2353</td>
<td>99.4%</td>
</tr>
<tr>
<td>Nigeria</td>
<td>1421</td>
<td>79%</td>
</tr>
<tr>
<td>Tanzania</td>
<td>1827</td>
<td>88%</td>
</tr>
<tr>
<td>Zambia</td>
<td>281</td>
<td>82.9%</td>
</tr>
</tbody>
</table>

*Each symbol represents 10%*
Examining all deliveries captured by follow-up shows that community-level distribution of misoprostol, combined with an aggressive community awareness campaign, leads to an overall increase in uterotonic coverage.

Results show that more than 60% of all births were protected from PPH. These protected births were the result of either misoprostol use during a home birth or delivery at a health facility. For the purposes of the OR, a birth was considered “protected” from PPH if misoprostol was available at a home delivery or if the woman delivered at a health facility (Figure 7).

In most countries, such as Mozambique and Nigeria, misoprostol use during home births helped protect more than 50% of women from PPH. In Nigeria, this figure approached 83% of women who delivered during the program period.

For other countries, such as Ghana, Kenya and Tanzania, health facility deliveries protected more than 50% of births. This underscores the effectiveness of campaign messages that encouraged facility deliveries and the importance of continuing to encourage women to deliver in a health facility. Moreover, use of misoprostol can protect women both at home and in health facilities as a back-up uterotonic.

**Figure 7**

**MISOPROSTOL AND UTEROTONIC USE BY LOCATION OF DELIVERY ACROSS ALL COUNTRIES**

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of Deliveries</th>
<th>Misoprostol Used During Home Birth</th>
<th>Uterotonic Received at Health Facility Birth</th>
<th>No Uterotonic Received at Health Facility Birth</th>
<th>No Uterotonic Received at Home Birth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>77,363</td>
<td>10%</td>
<td>30%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ghana</td>
<td>3,499</td>
<td>36%</td>
<td>64%</td>
<td>3%</td>
<td></td>
</tr>
<tr>
<td>Kenya</td>
<td>2,890</td>
<td>40%</td>
<td>57%</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Mozambique</td>
<td>9,093</td>
<td>53%</td>
<td>47%</td>
<td></td>
<td>0.1%</td>
</tr>
<tr>
<td>Nigeria</td>
<td>1,710</td>
<td>83%</td>
<td></td>
<td></td>
<td>22%</td>
</tr>
<tr>
<td>Tanzania</td>
<td>6,735</td>
<td>27%</td>
<td>63%</td>
<td>5%</td>
<td>4%</td>
</tr>
<tr>
<td>Zambia</td>
<td>1,047</td>
<td>22%</td>
<td>32%</td>
<td>10%</td>
<td>23%</td>
</tr>
</tbody>
</table>

n = Number of deliveries captured via follow-up

- Misoprostol used during home birth
- Uterotonic received at health facility birth
- No uterotonic received at health facility birth
- No uterotonic received at home birth
SAFETY

Women can use misoprostol correctly and experience self-limiting side effects:

- The efficacy of misoprostol and subsequent protection from PPH is dependent upon correct use: taking a three-tablet (600 mcg) dose orally immediately after delivery of the baby and before the placenta delivers.
- Across all seven countries, the vast majority of women correctly used misoprostol (Table 1). Percentages of correct use were routinely 90% or higher and ranged from 88% in Nigeria to over 98% in Tanzania, illustrating that misoprostol can be correctly used during at home births, ensuring PPH protection.
- In general, the limited number of women who incorrectly used misoprostol either did not take the full dose (three tablets) or took the tablets at the incorrect time, but never before the delivery of the baby.
- Across all seven countries, the side effects associated with misoprostol use were limited both in type and severity.
- According to self-reports, the majority of women in most countries experienced no side effects with misoprostol use, which ranged from 48% in Zambia to 95% in Ghana (Figure 8, page 29).
- Among women who did experience side effects, the most common symptoms reported were shivering, nausea and a rise in body temperature.
- These findings are consistent with other published literature on the side effects of misoprostol use, which show shivering and pyrexia (increased body temperature) to be associated with the drug (Prata et al., 2009a; Hashima et al., 2011; Sheldon et al., 2012).
- These side effects remained short in duration and tolerable, suggesting that misoprostol remains a safe uterotonic agent, especially in resource-poor settings.

### Table 1

**CORRECT USE OF MISOPROSTOL AT HOME DELIVERY ACROSS ALL STUDY COUNTRIES**

<table>
<thead>
<tr>
<th></th>
<th>Bangladesh</th>
<th>Ghana</th>
<th>Kenya</th>
<th>Mozambique</th>
<th>Nigeria</th>
<th>Tanzania</th>
<th>Zambia</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=1893</td>
<td>n=1413</td>
<td>n=1084</td>
<td>n=1846</td>
<td>n=1422</td>
<td>n=1826</td>
<td>n=233</td>
</tr>
<tr>
<td><strong>DOSE</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Three tablets</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(correct dose)</td>
<td>96.7%</td>
<td>100%</td>
<td>99.9%</td>
<td>99.7%</td>
<td>97.5%</td>
<td>99.5%</td>
<td>80.3%</td>
</tr>
<tr>
<td><strong>TIMING</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immediately after</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>delivery, before</td>
<td>99.8%</td>
<td>99.7%</td>
<td>100%</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>88.0%</td>
</tr>
<tr>
<td>placenta was</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>delivered (correct</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>timing)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ROUTE</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral (correct</td>
<td>N/A</td>
<td>100%</td>
<td>96.7%</td>
<td>99.6%</td>
<td>N/A</td>
<td>98.1%</td>
<td>87.6%</td>
</tr>
<tr>
<td>route)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correct use of</td>
<td>96.4%</td>
<td>99.3%</td>
<td>96.6%</td>
<td>N/A</td>
<td>87.5%*</td>
<td>98.1**</td>
<td>N/A</td>
</tr>
<tr>
<td>misoprostol (correct,</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>does, timing, route)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Correct timing and route, only  ** Correct route and dose, only
**Acceptability**

Women view misoprostol as beneficial:
- Women reported an extremely high level of satisfaction with misoprostol.
- In the countries where these data were collected, almost all women would use misoprostol again in a subsequent pregnancy. This ranged from almost 90% of women in Zambia to 98% in Tanzania (Table 2).
- Women would also recommend misoprostol to a friend, while most would be willing to purchase misoprostol for future use.
- High levels of acceptability were seen across a diverse population of women in terms of geographic location and socio-demographic characteristics suggesting that the drug has a wide base for use.

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**Figure 8**

**Self-reported side effects of misoprostol users**

- **Bangladesh**: 88.2%
  - None: 6.2%
  - Shivering: 3.1%
- **Ghana**: 94.8%
  - None: 3.5%
  - Rise in body temperature: 0.5%
- **Kenya**: 90%
  - None: 6%
- **Mozambique**: 78%
  - None: 6.6%
  - Shivering: 17.5%
- **Nigeria**: 74.6%
  - None: 11.1%
  - Shivering: 42%
- **Tanzania**: 73.7%
  - None: 17.4%
  - Shivering: 4.6%
- **Zambia**: 47.8%
  - None: 9.9%
  - Shivering: 31.7%

*Percentage totals may exceed 100, as women may have reported experiencing multiple symptoms.*

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Percentage totals may exceed 100, as women may have reported experiencing multiple symptoms.
TABLE 2
ACCEPTABILITY OF MISOPROSTOL ACROSS ALL STUDY COUNTRIES
Perceptions from participating women

<table>
<thead>
<tr>
<th>Country</th>
<th>n</th>
<th>Would use misoprotol in a subsequent pregnancy</th>
<th>Would recommend misoprostol to a friend</th>
<th>Would purchase misoprostol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bangladesh</td>
<td>53897</td>
<td>N/A</td>
<td>99.3%</td>
<td>86.9%</td>
</tr>
<tr>
<td>Ghana</td>
<td>N/A</td>
<td>N/A</td>
<td>97.9%</td>
<td>71.9%</td>
</tr>
<tr>
<td>Kenya</td>
<td>N/A</td>
<td>N/A</td>
<td>95.7%</td>
<td>95.3%</td>
</tr>
<tr>
<td>Mozambique</td>
<td>6681</td>
<td>96.9%</td>
<td>95.4%</td>
<td>71.9%</td>
</tr>
<tr>
<td>Nigeria</td>
<td>1796</td>
<td>98.0%</td>
<td>98.0%</td>
<td>95.3%</td>
</tr>
<tr>
<td>Tanzania</td>
<td>3370</td>
<td>N/A</td>
<td>88.1%</td>
<td>80.1%</td>
</tr>
<tr>
<td>Zambia</td>
<td>1047</td>
<td>89.7%</td>
<td>80.1%</td>
<td>80.1%</td>
</tr>
</tbody>
</table>

TEXT BOX 2
IMPACT ON FACILITY DELIVERIES OF MISOPROSTOL DISTRIBUTION

An often-cited concern regarding the advanced provision of misoprostol to expectant mothers is that it will deter facility births. However, findings from VSI’s operations research corroborate other studies, which show that programs to increase access to misoprostol can effectively complement efforts to increase facility birth (Rajbhandari et al., 2010; Sanghvi et al., 2010).

In Zambia, VSI monitored control areas where misoprostol was not made available. Distributing misoprostol through ANC did not lead to more women delivering at home in the intervention areas. Significantly more women in intervention areas where misoprostol was available reported delivering in a facility compared to control areas (54% vs. 40%). This suggests that distributing misoprostol at ANC visits did not encourage more women to deliver at home.

Photography: VSI/Alice Cartwright ©2010
The results from these studies contribute to a growing body of evidence that community-level distribution and use of misoprostol is feasible and effective. Distribution through ANC visits and at delivery with TBAs has the potential to increase the number of women who receive a uterotonic drug for prevention of PPH at delivery. Moreover, the majority of women used the drug correctly after a home birth for PPH prevention, while symptoms associated with misoprostol use were within the normal range, self-limiting and overall did not necessitate further intervention. Additionally, misoprostol was extremely acceptable to women across all programs. Nearly all women stated they would recommend misoprostol, take it again in a subsequent pregnancy, and would be willing to pay for the drug.

In 2012, new global recommendations emerged to guide countries as they consider introducing or scaling-up misoprostol for PPH prevention. In light of the published evidence, the World Health Organization (WHO) supports the use of misoprostol for PPH prevention by community health care workers and lay health workers in settings where skilled birth attendants are not present and oxytocin is unavailable (WHO, 2012d). Moreover, new guidance on health worker roles to optimize maternal and neonatal health recommends community and lay health worker administration of misoprostol to prevent PPH at delivery, where oxytocin is unavailable. The OR described herein present alternate distribution mechanisms, including advanced provision to pregnant women, and can help advance the field with regard to the role of community lay health workers and healthcare workers to achieve equitable access to misoprostol amongst the most vulnerable and hardest to reach women.

Several facilitating factors were common across the operations research programs. By highlighting these factors, it is hoped that future successes may be realized through the effective scale-up of PPH prevention projects with misoprostol.

- **Strong governmental support**
  Across almost all seven countries, national and local government agencies strongly supported each program. Not only did most countries actively seek evidence to support the use of misoprostol, many governmental agencies partnered with VSI to implement each program. Additionally, several countries had previously integrated misoprostol into their obstetric and gynecologic treatment standards and national essential medicines list, but desired evidence on feasibility of misoprostol distribution and suggested guidelines on levels of access. This high-level support proved crucial for both planning and successful program implementation.

- **High levels of ANC coverage**
  Rates of ANC attendance of at least one visit during pregnancy were high across all countries. This enabled the distribution of misoprostol at ANC both practical and feasible. It also allowed distribution to be carried out in a medical setting with educational sessions on how to correctly use misoprostol. This suggests that such a distribution method will work in other African and Southeast Asian countries with similar levels of ANC coverage.

- **Local methods to measure blood loss**
  Key to these programs was the integration and use of local methods to measure blood loss after birth (e.g., the kanga, lesso, Quaiyum’s mat, etc). This reduced the amount of new learning or new tools that were introduced with each program. Instead, each program built upon existing methods to measure blood loss and identify PPH. Moreover, it helped in terms of the programs’ feasibility and acceptance among providers and the women participants.

- **Adaptability of program methods to local context**
  While VSI employed a standardized approach across all seven countries, every program was tailored to the particular needs and context of each country. For example, specific methods of misoprostol distribution varied by
country and were adapted to the local cultural setting. In Bangladesh, misoprostol was included in clean delivery kits, which were distributed to pregnant women during home-based ANC visits; in Mozambique, misoprostol tablets were distributed during ANC visits or via TBAs at delivery; and in Nigeria distribution was through TBAs at delivery and community drug keepers. These findings highlight the need to customize distribution methods and illustrate that such distribution is feasible when properly designed.

Just as misoprostol distribution was customized to suit local needs and cultural considerations, the outreach methods for the community awareness campaign were similarly developed. For example, in Bangladesh small health education sessions were held with families of pregnant women, while in Tanzania a wider approach that included radio adverts and pamphlet distribution was employed to complement additional one-on-one educational sessions. These campaigns contributed to the overall effectiveness of misoprostol distribution by increasing women’s awareness of birth complications, reinforcing the importance of delivering in a health facility, and encouraging the use of misoprostol after delivery. The combination of misoprostol distribution and community awareness campaigns resulted in more than 60% of all births during the operations research being protected from PPH.
REFERENCES

WORLD HEALTH ORGANIZATION 2012d. WHO Recommendations Optimizing health worker roles to improve access to key maternal and newborn health interventions through task shifting. Geneva:WHO.