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Maternal and Child Health Integrated Program

Advance Distribution of Misoprostol for Self-Administration: Expanding Coverage for the Prevention of Postpartum Hemorrhage

Program Implementation Guide
Revised, November 2013

Lindsay Grenier

Jeffrey Smith

Sheena Currie

Stephanie Suhowatsky

For information:
Jhpiego
1615 Thames Street
Baltimore, MD 21231-3492, USA
Tel.: 410.537.1800
www.jhpiego.org

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The Maternal and Child Health Integrated Program (MCHIP) is the USAID Bureau for Global Health's flagship maternal, neonatal and child health (MNCH) program. MCHIP supports programming in maternal, newborn and child health, immunization, family planning, malaria, nutrition, and HIV/AIDS, and strongly encourages opportunities for integration. Cross-cutting technical areas include water, sanitation, hygiene, urban health and health systems strengthening.

Table of Contents

Abbreviations and Acronyms

AMTSL	Active management of the third stage of labor
ANC	Antenatal care
BCC	Behavior change communication
BP/CR	Birth Preparedness and Complication Readiness
CHW	Community health worker
EmONC	Emergency obstetric and neonatal care
FAQ	Frequently asked question
FCHV	Female community health volunteer
FIGO	International Federation of Gynecology and Obstetrics
HMIS	Health management information system
ICM	International Confederation of Midwives
IEC	Information, education and communication
IRB	Institutional review board
IU	International unit
LMIS	Logistics management information system
LQAS	Lot quality assurance sampling
MCH	Maternal and child health
MDG	Millennium Development Goal
M&E	Monitoring and evaluation
MoH	Ministry of Health
MMR	Maternal mortality ratio
MNH	Maternal and newborn health
NGO	Nongovernmental organization
NSAID	Non-steroidal anti-inflammatory drug
PO	Per os (by mouth)
PPH	Postpartum hemorrhage
RH	Reproductive health
RR	Relative risk
SBA	Skilled birth attendant
SS	Supportive supervision
TAG	Technical advisory group
TBA	Traditional birth attendant
UBT	Uterine balloon tamponade
USP	United States Pharmacopeia
WHO	World Health Organization

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Foreword

Approximately 287,000 women die every year from maternal causes, the vast majority in developing countries (World Health Organization 2012). Many, many more suffer severe maternal morbidity and long-term disability. Hemorrhage, though often preventable, remains a significant contributor to these poor outcomes. It is associated with nearly one-quarter of all maternal deaths; in both Africa and Asia, it remains the single largest cause of maternal mortality (Khan et al. 2006). The vast majority of these deaths result from postpartum hemorrhage (PPH) and could be avoided by the use of prophylactic uterotonics during the third stage of labor and by timely and appropriate management.

Decades of research have proven the safety and efficacy of using misoprostol as a prophylactic uterotonic to reduce PPH. It has become an important tool in the fight against maternal mortality. While oxytocin remains the uterotonic of choice, support for the use of misoprostol in the absence of oxytocin continues to grow. Misoprostol's ability to prevent PPH has been demonstrated in multiple contexts at the community level. Incorporating the advance distribution of misoprostol into national, comprehensive PPH prevention strategies allows countries to increase their total uterotonic coverage through reaching the most vulnerable populations of women—those who are often unable to access skilled birth attendants. The ultimate aim is to ensure that the advance distribution of misoprostol is fully integrated with a country's maternal health program.

Many country programs have started with pilots or learning phases. For guidance on introducing misoprostol for PPH prevention programming, please refer to the *Prevention of Postpartum Hemorrhage at Home Birth: A Program Implementation Guide* (Sanghvi, Zulkarnain, and Prata 2009). Based on pilot findings, these programs are now ready to advocate for national expansion. This *Program Implementation Guide* is designed to help organizations, agencies, and governments (particularly Ministries of Health) scale up existing misoprostol programs for PPH prevention. These programs will pave the path for long-term sustainability through integration.

Until every birth is attended by a SBA with access to high-quality oxytocin, misoprostol will play an important role in protecting women from PPH.

We know that misoprostol reduces PPH and that reducing PPH saves lives. Saving those lives now depends on scaling up programs that get misoprostol and the information to use it correctly into the hands of pregnant women when they need it.

The case studies and field experiences in this guide come from the work of many individuals and organizations. Indonesia was one of the first countries to conduct a pilot study for community distribution of misoprostol in 2003. Since then, many countries committed to helping women unable to access skilled attendance and/or oxytocin at birth have followed suit. Currently Nepal, Bangladesh, and Zambia are working to take programs to scale nationally; South Sudan is reaching women in areas where services have never existed before; and Mozambique is engaging its professional associations to keep moving the program forward. Misoprostol is now registered in more than 30 countries for the indication of PPH, and accepted for off-label indications in others. In 2011 the World Health Organization added misoprostol for the prevention of PPH to its List of Essential Medicines.

In 2004, Dr. Mary Ellen Stanton said, "We have the opportunity to accelerate success in reduction of maternal mortality by putting the spotlight on postpartum hemorrhage—the biggest maternal killer." Now, in 2013, nine years later, the same holds true. This guide puts the spotlight on misoprostol and its contribution to preventing PPH. We have the tools to act, so act we must.

About the Guide

Advance Distribution of Misoprostol for Self-Administration: Expanding Coverage for the Prevention of Postpartum Hemorrhage has been developed to provide organizations and agencies with a step-by-step guide to participating in the improvement and scale-up of existing misoprostol distribution programs for prevention of postpartum hemorrhage (PPH). It is intended for use by organizations that have not previously implemented misoprostol programming, as well as by Ministries of Health (MoHs) and consortiums of implementing partners interested in developing a unified plan for expanding coverage. This guide recommends scaling misoprostol programming as an integrated part of a comprehensive PPH prevention strategy within the national safe motherhood program. It assumes that in many contexts implementers will not be working in isolation, but will need to partner with others to ensure uterotonic coverage at all births.

As countries move from pilots to misoprostol program expansion, more organizations will support scale-up to be able to reach the greatest numbers of women with uterotonics.

This guide is designed to provide field-based guidance to organizations interested in supporting expansion of misoprostol programs within a comprehensive PPH prevention strategy.

This implementation guide is written under the premise that users are operating in countries where misoprostol programs are already underway or have been piloted. It is expected that necessary policy changes have already been made or are nearing completion and that continued misoprostol programming is supported by the MoH. The guide assumes that in the country of implementation:

- The government has a stated interest and clear commitment to preventing deaths from PPH as a public health priority in its efforts to reduce maternal mortality.
- Initial misoprostol programming answered key implementation questions and demonstrated results. There is consensus to expand, and the government is prepared to dedicate additional financial and human resources for expansion.
- Prior implementation experience and lessons learned will be used to guide decisions regarding scale-up.
- Partners are committed to integrating misoprostol programming with existing safe motherhood structures and programs.
- Major concerns about using misoprostol for obstetric uses have been addressed.
- The necessary supporting policies are in place, or in process, for example: the drug is available for gynecological and obstetric uses in the country; policies support the community-based distribution of medications; and service provider practice acts allow distribution of the drug.
- An overarching safe motherhood or reproductive health working group is willing to be the driving force in charting the course for scale-up and in shepherding any remaining necessary policy changes.
- New implementing organizations and agencies will likely be involved in scale-up to expand coverage into new areas.

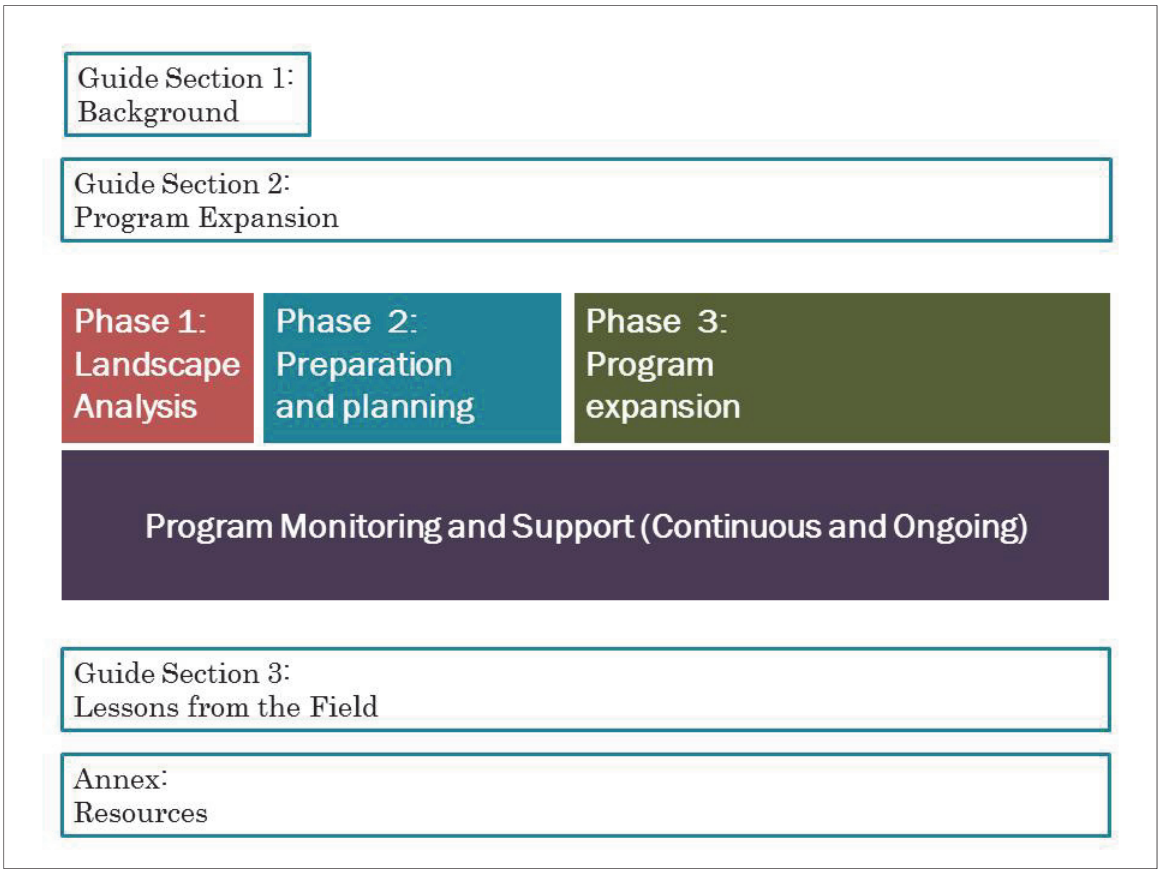
For countries planning on initiating misoprostol distribution programs, please see *Prevention of Postpartum Hemorrhage at Home Birth: A Program Implementation Guide* (2009) for additional guidance.

Those involved in developing an overarching scale-up strategy may find the World Health Organization (WHO) publication, *Nine Steps to Developing a Scaling-Up Strategy* (2010), useful.

The purpose of this implementation guide is to provide field-based guidance for country-specific expansion of misoprostol distribution. The experience gained in Nepal, Afghanistan, South Sudan, Bangladesh, Zambia, Liberia, and Mozambique, among other countries, has shaped this guide. The guide addresses all of the major areas of program design and implementation for scale-up. It includes assessing previous program design and results, standardizing materials, incorporating supportive supervision, training facility staff and community health workers (CHWs), conducting ongoing monitoring and evaluation (M&E), and ensuring drug security.

The guide is structured in four parts:

1. **Background**—providing the evidence for advance distribution for self-administration
2. **Program Expansion**, which includes a checklist and three phases of planning and implementation activities
3. **Lessons from the Field**, sharing possible program implementation pitfalls and solutions, as well as frequently asked questions (FAQs) and answers
4. **Annexes** of useful resources for program expansion



Practical solutions and resources are included to help improve on initial efforts and take a program to scale. Sample materials, tools, and resources from programs in a variety of countries, as well as advocacy materials, global guidelines, and links to seminal research can be found in the Postpartum Hemorrhage: Prevention and Management Toolkit within the *Advance Distribution of Misoprostol Program Resources* section at: http://www.k4health.org/toolkits/postpartumhemorrhage/advance-distribution-misoprostol-program-resources. (See **Annex A**.)

We know that misoprostol reduces PPH and that reducing PPH saves lives. Saving those lives now depends on scaling up programs that deliver misoprostol and the information to use it correctly into the hands of pregnant women when they need it.

Part One: Background

GLOBAL MATERNAL MORTALITY AND INCIDENCE OF POSTPARTUM HEMORRHAGE

The global maternal mortality ratio (MMR), which measures the risk of death once a woman has become pregnant, is 210 per 100,000 live births—meaning the probability that a 15-year-old woman will die eventually from a maternal cause is 1 in 180 (WHO 2012). This represents significant progress over the past 20 years, but stark regional inequities persist. A woman in Sub-Saharan Africa is still 100 times more likely to die of a maternal cause than one in a developed region. Table 1 shows regional mortality estimates. Developing countries account for 99% of the global maternal deaths, with the highest burdens in Sub-Saharan Africa (56%) and South Asia (29%). Forty countries continue to have high MMRs (defined as ≥ 300), with Chad, Somalia, and South Sudan maintaining extremely high MMRs (1,100, 1,000, and 2,054 respectively).

Table 1. Maternal mortality: 2010 WHO, UNICEF, UNFPA, and World Bank estimates

Region	MMR (maternal deaths per 100,000 live births)	Number of Maternal Deaths	Lifetime Risk of Maternal Death 1 in:
World total	210	287,000	180
Developed regions*	16	2,200	3,800
Developing regions	240	284,000	150
Northern Africa	78	2,800	470
Sub-Saharan Africa	500	162,000	39
Eastern Asia	37	6,400	1,700
Southern Asia	220	83,000	160
Western Asia	71	3,500	430
Caucasus and Central Asia	46	750	850
Latin American and the Caribbean	80	8,800	520
Oceania	200	510	130

* Includes Europe, Canada, United States of America, Japan, Australia, and New Zealand

WHO estimates that every year, nearly 287,000 women will die from complications of pregnancy and childbirth, and many more will experience long-term illness and disabilities (WHO 2012). This number remains an estimate because obstetric deaths frequently are not recorded and vital records for many countries do not adequately capture the full extent of the problem.

Maternal deaths in developing countries occur in areas with:

- Limited access to skilled health care providers for women—particularly poor women and/or those in rural areas
- Limited emergency obstetric care services established within the public health service delivery system
- Poor quality of care (De Souza 2013)
- Shortage of lifesaving commodities
- Inadequate transportation systems: poorly maintained access roads, limited access to transport, and/or climatic extremes that impact road access and functionality
- Poor referral systems

Among the complications, PPH is a major cause of both maternal mortality and morbidity. In both Africa and Asia, it remains the single largest cause of maternal deaths. PPH accounts for 30% of the total there, as compared to 13% in developed regions (WHO 2012). The considerable variability in the proportion of maternal deaths attributable to PPH suggests that deaths from PPH are largely preventable. This makes interventions to prevent PPH pivotal to the global effort to achieve the Millennium Development Goal (MDG) of reducing the maternal mortality ratio by three-quarters by 2015 (from 1990 levels).

Worldwide the prevalence of PPH is approximately 6%, with a regional high in Africa of 10.5% (Carroli et al. 2008).

Defining and Diagnosing PPH

KEY DEFINITION

POSTPARTUM HEMORRHAGE is defined as blood loss greater than 500 cc within 24 hours after childbirth.

Countries can adapt this clinical definition to measures easily understandable to the community, such as soaking two or more cloth sarongs, chitenges, or kangas (which are traditional cloths used at home births), within 24 hours.

Even with definitions easily understood by the community, it can be difficult to diagnose PPH because:

- It is difficult to measure blood loss. Blood may be mixed with amniotic fluid and sometimes with urine. It soaks into sponges, towels, and linens or spills into buckets or onto the floor.
- PPH bleeding may occur slowly, over several hours. It may not be recognized until the woman goes into shock.

In addition, the standard definition of PPH (500 cc within 24 hours after childbirth) does not necessarily indicate health outcomes. For example, severely anemic women may suffer morbidities at lower levels of blood loss, and women with high hemoglobin levels may be able to withstand 500 cc of blood loss or more without consequence.

Because the difficulty in diagnosing PPH early—particularly at the community level—can lead to delayed action, prevention is even more important. Without immediate and appropriate medical care, a woman with PPH will probably die within two hours of onset. Any woman can die from PPH, and it is impossible to predict who will have PPH. The best way to prevent PPH is through the use of medications immediately after birth. These medications, which cause the uterus to contract, are called uterotonics.

Among women experiencing PPH who survive, many will suffer severe morbidity, particularly those entering pregnancy already anemic. Preventing PPH doesn't only save lives, it protects health and limits excessive burdens on the health care system.

KEY MESSAGES

- All women are at risk for PPH. You cannot predict who will have PPH.
- If a woman has PPH, she can die in two hours if not treated.
- PPH is responsible for 25% of all maternal deaths and is the leading cause in both Africa and Asia.
- Those who survive PPH may still suffer severe morbidities as a result.
- PPH is not always easy to diagnose.
- A woman's hemoglobin level impacts her ability to withstand blood loss, but even a woman who is not anemic can die from PPH.

COMPREHENSIVE STRATEGIES FOR PREVENTION AND MANAGEMENT OF POSTPARTUM HEMORRHAGE

Most PPH cases occur within 24 hours after birth and are due to uterine atony, a failure of the uterus to contract properly after the child is born. When the uterus does not contract, bleeding from the blood vessels in the uterus is not controlled. Uterine atony accounts for 70–90% of all cases of PPH. Active management of the third stage of labor (AMTSL) reduces the incidence of uterine atony and has been a cornerstone of PPH prevention strategies.

New WHO PPH guidelines (2012) reflect recent evidence regarding the individual components of AMTSL. Earlier components of AMTSL—including controlled cord traction, early cord clamping, and uterine massage—are no longer routinely recommended. The provision of a uterotonic immediately after the birth of the baby now is highlighted as the primary component of AMTSL (oxytocin 10 IU, IV/IM when available; or other uterotonics including 600 mcg oral misoprostol). Routine abdominal uterine tonus assessment for early identification of uterine atony also is recommended.

Additional strategies exist for preventing some, but not all, other causes of PPH. In addition to uterine atony, PPH can stem from:

- Retained placenta or placental tissue
- Genital tract trauma
- Coagulation defects
- Episiotomy
- Postpartum infections
- Obstructed and prolonged labor

These last three causes can be easily addressed through improved clinical care: following good infection prevention techniques; using partographs to track the progress of labor; and restricting episiotomies to those that are medically necessary.

In many developing countries, a significant proportion of births continue to occur in the home. Reasons include cultural preferences, financial hardships, geographic barriers, and other difficulties in accessing high-quality, respectful services. In addition, births sometimes occur en route to a facility or health center. Some facilities lack a skilled birth attendant (SBA) and/or uterotonics at the time of delivery.

When every mother's life is valued, a comprehensive PPH strategy ensures a uterotonic where SBAs are available in an enabled environment, and in situations where they are not. **Table 2** presents strategies for preventing and managing PPH, with and without a SBA.

Table 2. Strategies for reduction of mortality from postpartum hemorrhage

	Without a Skilled Birth Attendant	With a Skilled Birth Attendant
Prevention	▪ Community awareness—Behavior change communication (BCC)/Information, education, and communication (IEC) ▪ Birth planning/complication readiness ▪ Promotion of antenatal care (ANC) ▪ Promotion of skilled attendance at birth ▪ Family planning and birth spacing ▪ Detection and treatment of anemia (clinical signs and symptoms) ▪ **Advance distribution of misoprostol for routine third stage use**	▪ Community awareness—BCC/BCC ▪ ANC (to include birth planning) ▪ Prevention, detection, and treatment of anemia ▪ Family planning and birth spacing ▪ Use of partograph to reduce prolonged labor ▪ Restricting episiotomy at normal birth ▪ AMTSL ▪ Routine inspection of placenta for completeness ▪ Routine inspection of perineum/vagina for lacerations ▪ Routine immediate postpartum monitoring

	Without a Skilled Birth Attendant	With a Skilled Birth Attendant
Management	▪ Community emergency planning ▪ Transport planning ▪ Referral strategies	▪ Active triage of emergency cases ▪ Rapid assessment and diagnosis ▪ Emergency protocols for PPH management ▪ Basic emergency obstetric and newborn care (EmONC): – Intravenous fluid resuscitation – Manual removal of placenta – Removal of placenta fragments – Parenteral oxytocics and antibiotics; use of tranexamic acid – Suturing of lacerations ▪ Temporizing measures while awaiting access to further care: – Bimanual uterine compression – Intrauterine hydrostatic tamponade – Use of non-pneumatic anti-shock garment – External aortic compression ▪ Comprehensive EmONC: – Blood bank/blood transfusion – Operating theater/surgery: uterine artery ligation, B-lynch procedure, hysterectomy
Supporting components: women's empowerment; respect for human rights; access to care; community support and mobilization; access, utilization, and quality of essential obstetric care services		

Pre-existing severe anemia influences the outcome when a woman experiences PPH. It is well-documented that an anemic woman is unable to tolerate the same amount of blood loss as a healthy woman. A comprehensive PPH prevention program must work in tandem with other maternal health initiatives that reduce anemia—such as malaria prophylaxis during pregnancy, treatment of hookworm, prevention of malnutrition, and iron folate supplementation.

KEY MESSAGES

- Uterine atony causes 70–90% of all cases of PPH.
- Approximately 80% of PPH can be prevented by appropriate care during labor and childbirth.
- Providing a uterotonic immediately after birth is the single most important intervention to prevent PPH.
- A comprehensive strategy addresses both PPH prevention and treatment for all births—those with and without skilled providers.
- Strategies that reduce anemia may improve the survival of women who suffer PPH.

MISOPROSTOL AS A PILLAR OF A COMPREHENSIVE STRATEGY

Misoprostol has been available for years as a drug to prevent gastric ulcers related to the use of non-steroidal anti-inflammatory drugs (NSAIDs). It is also a prostaglandin E1 analogue, making it a powerful uterotonic that has been recognized for many gynecological uses. **This guide focuses on the use of misoprostol for the prevention of PPH.**

KEY DEFINITION

UTEROTONIC DRUGS are medicines such as oxytocin, ergometrine, and misoprostol that help the uterus contract. They are especially helpful for inducing or augmenting labor and decreasing blood loss after delivery.

Why Is Misoprostol Necessary?

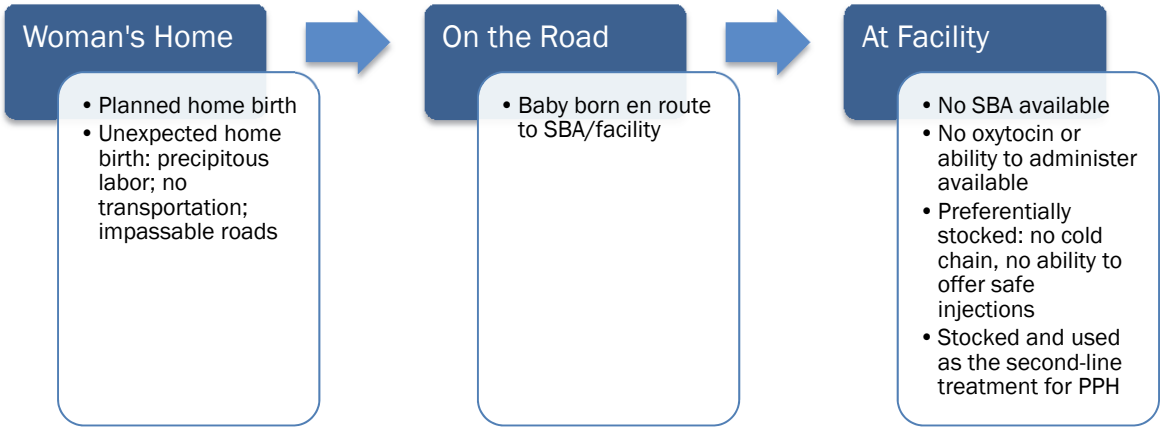
Misoprostol has become a pillar of comprehensive PPH prevention because it is cost-effective and, unlike oxytocin, does not require a cold chain or a skilled provider to administer it. These characteristics make it a valuable addition in the home-to-hospital continuum of care, providing the ability to prevent PPH regardless of place of birth. **Table 3** compares common uterotonics for PPH prevention.

Table 3. A comparison of the three most common uterotonics

ASPECT OF PPH PREVENTION	OXYTOCIN	ERGOMETRINE	MISOPROSTOL
Efficacy[1]	Acute PPH RR 0.50 Severe PPH RR 0.61 (Cotter Ness, and Tolosa 2010)	Acute PPH RR 0.38 (Liabsuetrakul et al. 2011)	Acute PPH RR 0.76 Severe PPH RR 0.59 (Oladapo 2012)
Needs skilled provider	Yes *Injection required*	Yes *Contraindicated with hypertension*	No *No contraindications* *Safe side effect profile* *Can be taken orally*
Serious side effects	Rare	Common	Rare
Contraindications	0%	15%	0%
Stability	Deteriorates in persistent heat	Deteriorates in persistent light and heat	Deteriorates in moisture if not properly packaged
Cost[2]	.07-–.45 (drug only, 10 IU ampule)	.11–.17 (drug only, .2mg/ml ampule)	.30–1.44 (3 200 mcg tabs)

Misoprostol can be distributed to women during their pregnancy to ensure that a uterotonic is available when they give birth whether that be at home, on the way to a facility, or at a facility. Many unexpected events can disrupt plans for a facility delivery with a SBA: the birth may be quick, transportation may not be available at the time of labor, or roads may be impassible due to flooding or insecurity. Once the woman reaches the birth facility, a SBA may not be available or the drugs or supplies necessary to offer a uterotonic may be out of stock. Where the availability of oxytocin is often limited due to a lack of cold storage and the ability to offer safe injections, misoprostol is also routinely stocked at delivery facilities, as has been practiced in Somaliland. **Figure 1** outlines how and why misoprostol is used along the continuum of care.

Figure 1. Use of misoprostol by location and reason



[1] All relative risk (RR) estimates are based on reviews including multiple randomized controlled trials.
[2] Cost data represent the total range reported by both suppliers and buyers in the International Drug Price Indicator Guide, Management Sciences for Health (MSH) 2012. Costs for oxytocin and ergometrine include the cost of the drug only and do not represent the associated costs of providing an injection. Costs are illustrative and may vary.

Is Misoprostol Safe?

Misoprostol has been documented to be very safe since its introduction in the late 1980s. Since then, millions of people have used up to 800 mcg daily for the treatment and prevention of gastric ulcer with no serious side effects. The few reported cases of extreme overdose recovered rapidly with supportive care (Hemmerling 2006). In 2001 The United States Pharmacopeia (USP) did an evidence-based review and determined that misoprostol is safe and effective in preventing PPH. It recommended its use as an alternative agent in preventing PPH, especially where oxytocin and other uterotonic drugs are not available (Carpenter 2001). Other recommending bodies have come to the same conclusions. Both the International Federation of Gynecology and Obstetrics (FIGO) and WHO 2012 guidelines for the prevention and treatment of PPH recommend the use of misoprostol when oxytocin is not available. It was added to the WHO List of Essential Medicines for the prevention of PPH in 2011 and is now registered in more than 30 countries specifically for the indication of PPH. In addition, off-label use is acceptable in a number of other countries, including the United States.

Common side effects associated with misoprostol include nausea, loose stool, shivering, and pyrexia (fever). All side effects are route- and dose-dependent and self-limited. Oral and sublingual routes and higher doses are more likely to cause symptoms. Concerns have primarily focused on hyperpyrexia (fever >40°C), which is most often associated with doses of ≥ 800 mcg. A 2010 study by Durocher et al. examined the characteristics of hyperpyrexia related to misoprostol 800 mcg given for PPH treatment and found that high fevers followed a predictable pattern. They often were preceded by moderate to severe shivering within 20 minutes of treatment, peaked one to two hours post-misoprostol, and gradually declined over three hours without resulting in further health complications. No deaths or sequalae have been reported linked to hyperpyrexia related to misoprostol use. A 2013 Cochrane review by Hofmeyr et al. found no statistically significant difference in maternal death or severe morbidity for misoprostol compared to other uterotonics for the prevention or treatment of PPH.

The greatest risk with misoprostol is the risk of uterine rupture when it is inappropriately taken before the birth of the baby to augment or speed up labor. Programs to date, however, have shown extremely low rates of mistimed administration with the advance distribution of misoprostol for prevention of PPH (.06%, Smith et al. 2013) and there have been no reports of uterine rupture due to misuse.

Is Misoprostol Effective?

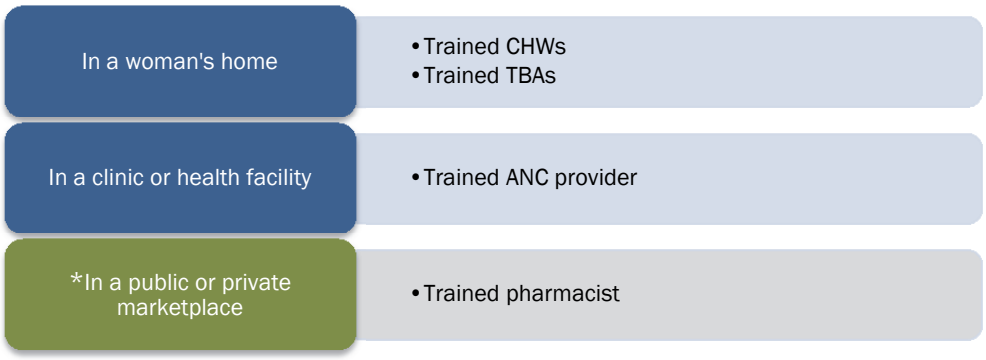
While oxytocin consistently has been found to be more efficacious than misoprostol for the prevention of PPH and remains the uterotonic of choice, support for the use of misoprostol in the absence of oxytocin continues to grow. Misoprostol's ability to prevent PPH has been demonstrated in multiple contexts at the community level. In 2006 Derman et al. found a 50% reduction in PPH and an 80% reduction in severe PPH when comparing misoprostol with a placebo in home births and at primary care centers. More recently, a randomized placebo-controlled study in Pakistan using trained traditional birth attendants (TBAs) showed a 24% reduction in PPH for women giving birth at home who received misoprostol compared to those who received a placebo. Women in the same study who received misoprostol were also almost half as likely to have a postpartum drop in hemoglobin > 3g/dl (Mobeen et al. 2011). Other studies have shown the feasibility of community-based education and distribution. In Afghanistan, 100% of women who self-administered misoprostol did so correctly, including 20 with twin pregnancies. Nine out of 10 women (92%) said they would use misoprostol in their next pregnancy. Furthermore, uterotonic coverage was achieved for 92% of births in the intervention area—compared to only 25% of births in the control area (Sanghvi et al. 2010). Similar research in Nepal found that advance distribution for self-administration led to a rise in uterotonic coverage from 11.6% to 74.2%. Those experiencing the largest gains were the poor, the illiterate, and those living in remote areas (Rajbhandari et al. 2010).

The safety and efficacy of misoprostol as an alternative to oxytocin is well-documented. Further information can be found at www.misoprostol.org and in the application for the WHO List of Essential Medicines at http://www.who.int/selection_medicines/committees/expert/17/application/Miso_Incl_1.pdf

How Is Misoprostol Distributed to Pregnant Women?

Programs to date that distribute misoprostol for PPH prevention have used a combination of strategies and distribution channels to reach pregnant women. Most commonly these include training CHWs and/or TBAs to counsel women and distribute misoprostol in their homes. Another sometimes complementary strategy is training ANC providers to counsel women and distribute misoprostol during clinic visits late in pregnancy. TBAs have been included in programs, particularly where CHW cadres don't exist, because they are already motivated to visit and counsel pregnant women. Fears that TBAs would inappropriately use misoprostol to terminate pregnancies or augment or induce labor have not been substantiated. Neither have fears that facility birth rates would decrease as a result. In contrast, many programs have seen slight increases in facility births due to the related counseling messages. Other strategies are being explored to increase access to misoprostol for women in their communities through private sector and commercial sector distribution (such as direct access via pharmacies). At this point there is insufficient evidence to recommend distribution outside a structured program that includes interaction with either the formal health system and/or community health system. **Figure 2** summarizes current and potential distribution channels. The following section discusses differences that have been noted in distribution and coverage rates using various strategies for distribution and administration.

Figure 2. Potential distribution channels



* Not recommended at this time, dependent on future research.

Until every birth is attended by a SBA with access to quality oxytocin, misoprostol will continue to have a role to play in protecting women from PPH. The only way to ensure uterotonic coverage at all births, to prevent PPH before it starts, is to put a uterotonic in the hands of every woman during pregnancy because she is the only person guaranteed to be present at birth.

KEY MESSAGES

- A single 600 mcg oral dose of misoprostol is indicated for prevention of PPH in settings where oxytocin is not available.
- Misoprostol should be administered immediately after birth of the newborn following abdominal palpation to confirm the absence of additional babies *in utero.*
- Prolonged or serious side effects are rare.
- Current program reports suggest that self-administration of misoprostol can be done safely and effectively.

Source: FIGO guidelines, 2012.

THE EVIDENCE FOR ADVANCE DISTRIBUTION FOR SELF-ADMINISTRATION

In settings where SBAs are not present and oxytocin is unavailable, WHO recommends the administration of misoprostol (600 mcg PO [by mouth]) for the prevention of PPH by CHWs and lay health workers (WHO 2012). Questions have persisted, however, about the advance distribution of misoprostol to women in late pregnancy. A 2013 article by Jhpiego, MCHIP, and Venture Strategies Innovations (Smith et al.) in the journal *BMC Pregnancy and Childbirth* reviewed programs and studies for prevention of PPH at home birth using misoprostol. "Misoprostol for postpartum hemorrhage prevention at home birth: An integrative review of global implementation experience to date" summarizes the results of all known programs in the world undertaken through 2012. The review calculated:

- Distribution rate: Proportion of pregnant women in the catchment area who received misoprostol for the prevention of PPH
- Coverage rate: Proportion of women who delivered at home in the catchment area (actual or estimated) who used misoprostol for the prevention of PPH

Results

Eighteen programs were identified as having used misoprostol for PPH prevention at home birth. Of the range of cadres and timings utilized for drug distribution, advanced distribution of misoprostol by community health agents during home visits late in pregnancy achieved the greatest distribution and coverage rates. In fact, programs employing these strategies achieved potentially more than double the coverage of those that distributed the drug through health care providers or as a part of ANC services. Programs that allowed for self-administration or administration by TBAs were the most common and also achieved high distribution and coverage rates. Only 10 of the 18 programs reported sufficient information to calculate coverage rates. The paper therefore offers recommendations on what data should be collected in future programs so that they may contribute to the global knowledge base about misoprostol use. **Table 4** summarizes findings from the programs examined.

Table 4. Distribution and coverage rates by distribution timing, cadre, and administration method among PPH prevention program using misoprostol

RATE	DISTRIBUTION TIMING				DISTRIBUTING CADRE			ADMINISTRATION METHOD		
	ANC		Home visit (Late pregnancy)	At home birth	CHW	TBA	Health worker/ANC provider	Self	TBA	SBA or semi-skilled health worker
	Any visit	Late visit								
Distribution rate	22.5–49.1%	21.0–26.7%	54.5–96.6%	22.5–83.6%	54.5–96.6%	25.9–86.5%	21.0–49.1%	21.0–96.6%	25.9–86.5%	22.5%
Coverage rate	16.8–65.9%	16.2–35.9%	55.7–93.8%	16.8–73.5%	87.9–93.8%	35.9–73.5%	16.2–65.9%	16.2–93.8%	35.9–73.5%	16.8%

Source: Smith et al. 2013.

Overall, the 18 programs reported 86,732 women taking misoprostol for prevention of PPH at home birth. Three programs—in Nepal, Afghanistan, and Zambia—tracked changes in facility birth rates, and all reported an increase in the facility birth rate in the intervention areas. Mistimed administration of misoprostol (consumption before the birth) occurred with only seven women (0.06%) among the 12,615 women for whom follow-up visit data were collected.

Table 5. Incorrect use and deaths among PPH prevention programs using misoprostol

Indicator	Number of Occurrences (total # women taking drug at home births)	Frequency (range)
Administration prior to birth	7 (12,615)	0.06% (0%-0.23%)
Deaths attributed to misoprostol	0 (86,732)	0%

Fifty-one maternal deaths were reported among all misoprostol users, 24 of which were due to PPH or excessive bleeding; the remaining deaths were due to other obstetrical causes. None of the deaths were attributed to misoprostol use. The reports include three cases of suspected (but unconfirmed) uterine rupture among women who took misoprostol after delivery.

CONCLUSIONS

High distribution and coverage rates of misoprostol for PPH prevention are possible if programs are designed to maximize population coverage and mobilize large numbers of CHWs. The programs and studies reviewed here reveal that home distribution by CHWs and TBAs enabled more women to access and use misoprostol than distribution through ANC alone. These approaches appear safe, with very few cases of mistimed administration. Limited data also suggest that advance distribution does not adversely impact national strategies to promote facility-based births. Future programs for the prevention of PPH at home birth through community-based distribution of misoprostol should ensure that data collection corresponds with the key outcomes presented in this review.

Part Two: Design and Implementation Guidance for Program Expansion

Part Two of this guide uses a checklist to assist program managers through the various phases of implementation. Following the summary checklist below, Part Two offers detailed guidance for each phase. The phases are not strictly sequential. At times, activities can be simultaneous. The checklist provides reminders for things that must be taken into consideration during program design and implementation. The specific context in which program expansion is occurring may dictate differences from what is outlined here. A Word version of this checklist is available online in the PPH Prevention and Management Toolkit. It can be adapted as necessary to become a useful planning tool.

THE CHECKLIST FOR PROGRAM EXPANSION OF ADVANCE DISTRIBUTION OF MISOPROSTOL FOR SELF-ADMINISTRATION

Summary of Phase I: Landscape Analysis

National landscape analysis:

☐ 1. Identify key governmental and nongovernmental agencies involved in the previous and/or current implementation of misoprostol programming.

☐ 2. Identify current national PPH prevention strategies and policies and evaluate adherence of strategies and policies to global evidence base:

- Understand history and evolution of comprehensive PPH prevention strategy in the country and the role of misoprostol programming within that strategy.
- Identify any ongoing policy debates and/or upcoming changes to overall strategy; if strategies/policies do not reflect global evidence base, assess potential to realize changes.
- Clarify current MoH priorities related to PPH prevention generally and the expansion of misoprostol programming specifically.

☐ 3. Review the history of implementation and results to date:

- Review available M&E results from previous and/or ongoing misoprostol programs in country.
- Evaluate results compared to those obtained with “best practice” policies.
- Identify information/research gaps.
- Identify need for ongoing advocacy to improve/change PPH prevention strategy and policies to improve uterotonic coverage at all births.
- Meet with previous/existing misoprostol program implementers, the Technical Advisory Group (TAG) and/or related reproductive health (RH) or safe motherhood working groups to discuss accomplishments and successes to date as well as setbacks and failures.
- Identify implementation strategies that may need revision as well as those appropriate for replication.

☐ 4. Identify existing assets and remaining needs:

- Identify materials developed by previous implementing agencies that can be used during expansion; assess if regional adaptation (including language) is necessary in the expansion area.
- Verify that misoprostol is registered and licensed in-country for obstetric indications and that procurement, distribution, and tracking mechanisms exist or are planned (supply may run concurrently with programming).
- Clarify if there is a current cohort of master trainers able to carry out trainings and provide supportive supervision either to a new cohort of trainers or to CHWs and facility-based providers directly.
- Clarify if there is an existing CHW cadre nationwide/in your implementation area. Gather any available information on expected CHW catchment area (number of households) and typical coverage. If CHW coverage is not high, explore whether TBAs, other community-based cadres, or volunteers are active, and whether it would be acceptable to the MoH to involve any/all of these in PPH prevention activities.
- Begin identifying funding sources.
- Clarify whether any national or organizational research ethical review approval (such as a national research council or institutional review board [IRB]) is required.

☐ 5. Compare your capacity with scope of needs and identify where partnerships may be needed.

Local landscape analysis and site selection:

☐ 6. Hold stakeholder consultations. If expansion is happening prior to finalizing supportive national policies, assess what reassurances or legal safeguards are needed from the national level.

☐ 7. Evaluate the local health system and clinical practices.

☐ 8. Carry out formative research to identify any significant cultural differences from prior implementation sites.

☐ 9. Examine components of any selection criteria.

Summary of Phase II: Preparation and Planning for Scale-Up

In conjunction with other implementers and partners:

☐ 1. Review roles and responsibilities:

- Select areas for program expansion based on established criteria and determine where each organization's geographic focus will be.
- Determine the programmatic focus of each organization, taking into account all necessary interventions under the country's comprehensive PPH prevention strategy.

☐ 2. Standardize materials and methods:

Collect materials from previous implementation in country. Standardize nationwide or regionally, as appropriate, updating in line with global guidance as indicated:

- Advocacy materials
- Training materials including clinical protocols and job aids (for ANC providers, SBAs and CHWs)
- IEC/BCC materials, including drug packaging and instructional inserts
- Supportive supervision tools

- M&E tools (See MCHIP's list of recommended core indicators and corresponding database to aid in M&E development.)

In addition to materials, standardize:

- Quality assurance methods:
  - Regular supportive supervision of CHWs and facility-based staff
  - Maternal death and "near miss" case reviews
  - Drug quality and availability
- M&E methods:
  - Content, frequency, timing, and responsibility for M&E activities
  - Methods of data-sharing and aggregation from the community to the national level
  - Household surveys capturing actual usage rates of misoprostol in new program areas

☐ 3. Design a training cascade and identify and/or develop national and/or regional trainers for both community- and facility-based trainings.

☐ 4. Secure a drug supply and ensure branding reflects the program goals.

☐ 5. Understand the procurement and distribution system and identify any bottlenecks that will impact program expansion; advocate for drugs and supplies to be part of the routine government procurement and logistics systems.

In your program expansion area:

☐ 6. Meet key province or district officials to introduce the program and orient them to the proposed PPH prevention activities. Present justification for the program expansion based on PPH prevention need and findings from previous implementation. Solicit their input and suggestions.

☐ 7. Select local health system counterparts at the province, district, and township levels who will participate in the program. Identify key community stakeholders.

☐ 8. Select local community counterparts (CHWs). Working with health system counterparts and key community stakeholders, determine which existing cadres of CHWs will be mobilized for PPH prevention activities. If no such system or cadre exists or their coverage is limited, make plans to develop an integrated system as part of community-based health care that addresses recruitment, training, supervision, and retention (if there is meant to be a standardized system countrywide, support development of that system).

☐ 9. Orient counterparts and the community to the planned program expansion; present justification for the program expansion based on PPH prevention need and findings from previous implementation.

☐ 10. Determine whether the previous system(s) used to identify and register pregnant women for the program need to be adapted so that no woman is left out and there are no missed opportunities to reach eligible women (community mapping).

☐ 11. Take steps necessary to ensure that local[3] procurement and distribution system of misoprostol will support program activities.

☐ 12. Develop the budget and identify funding sources among partners that will fund activities.

[3] Or closest as possible if drug not available locally.

Summary of Phase III: Program Expansion

- ☐ 1. Print all of the training materials, IEC/BCC materials, counseling materials, identification forms and registration forms.
- ☐ 2. Orient and train SBAs on: program orientation; PPH prevention for a facility-based birth; PPH management for women who have taken misoprostol at home before coming to the facility; and PPH management.
- ☐ 3. Orient and train ANC providers and CHWs in how to: identify and counsel pregnant women; record the home visits; distribute the pills; follow up a postpartum woman and newborn; monitor for and report any adverse incidents; and record outcomes for the birth and history of misoprostol use.
- ☐ 3. Ensure branding and packaging are specific to program needs (e.g., brand name identifies the drug for PPH prevention and is in a three-pill pack).
- ☐ 4. Using the community mapping system developed in Phase II, begin to census and register pregnant women in the program area.
- ☐ 6. Begin registering and counseling women.
- ☐ 7. Distribute the drug to pregnant women who are registered, have been counseled, and are at least eight months pregnant.
- ☐ 8. Conduct final postpartum visits for all registered women who have delivered.
- ☐ 9. Conduct supportive supervision activities.
- ☐ 10. Conduct and supervise all M&E activities. (See next Program Monitoring and Support section for detail.)
- ☐ 11. Recognize/reward high performers and program champions.

Summary of Program Monitoring and Support (Continuous and Ongoing)

- ☐ 1. Strengthen the supportive supervision system:
  - Design supportive supervision activities and tools.
  - Identify and train supervisors.
  - Determine the ideal frequency of activities.
- ☐ 2. Review guiding principles:
  - Balance data needs with collection burden.
  - Collect data to inform quality improvement.
  - Identify opportunities to monitor progress toward equity.
- ☐ 3. Develop a M&E plan:
  - Select indicators for program monitoring and quality improvement.
  - Identify data sources.
  - Set targets.
  - Secure ethical approval for any research.
- ☐ 4. Implement the M&E plan:
  - Ensure data quality and management, and reinforce/adapt training as necessary.
  - Routinely analyze data and share reports.
  - Hold regular meetings with the stakeholders for continual feedback.

☐ 5. Analyze, share, and use results:

- Enter aggregated data in online misoprostol database.
- Use lessons from the field, program results, and client feedback to improve the program; share them with other implementing partners.

PHASE I: LANDSCAPE ANALYSIS

Taking Pilots to Scale[4]

In many countries, innovators and early adopters have already taken the initial steps in developing policies and programs for the advance distribution of misoprostol to prevent PPH. Some are now ready to take those innovations to scale and expand programming to bring misoprostol to all women who need it. Before expansion, it is helpful to perform a landscape analysis to "take stock" of the current situation. There are two distinct parts to this activity: 1) a national assessment; and 2) a local assessment. The purpose of the landscape analysis is to provide the background needed to make informed choices about how to proceed with scaling up existing programs. For organizations contemplating new involvement in misoprostol programming, this is a critical step in deciding to move forward and in understanding what their relative contribution may be.

The national assessment may be completed by a consortium of interested parties and will help identify existing resources, strengths, and successes to date. It also can pinpoint any needs for continued advocacy and change in policy, strategy, or implementation tactics. It should identify how program activities can be integrated with existing maternal health structures to avoid vertical programming. If the opportunities and needs that emerge from this analysis are a good match for your organization's abilities and interests, the next phase is to engage in a local landscape analysis in the proposed program expansion area.

The local assessment should be performed prior to final site selection, possibly in multiple locations simultaneously. Its purpose is to ensure that resources are used wisely by choosing expansion areas with both a high need for the program and a high chance of success. In addition, it will provide the insights needed for specific regional program planning, such as the need for translating existing materials into a local language or mobilizing additional CHWs to ensure high coverage.

A. National Landscape Analysis

Identify Key Partners

The first step is to identify the key parties involved in previous and/or current implementation of misoprostol distribution for the prevention of PPH. This will likely include:

- Relevant departments in the MoH (such as safe motherhood, RH, community development, and drug management)
- A RH or safe motherhood working group and/or the TAG specific to PPH or the use of misoprostol for obstetric indications
- Implementing partners such as nongovernmental organizations (NGOs) experienced in community-based maternal health activities

[4] If misoprostol programming has never been implemented in your country, please see the 2009 *Prevention of Postpartum Hemorrhage at Home Birth: A Program Implementation Guide* for guidance on initial steps.

There are many additional stakeholders, but these will be the key informants for the remainder of the landscape analysis. For expansion to succeed, the ongoing guidance and support of a functioning TAG or highly proactive working group is needed. Assess the dedication and motivation of the relevant working group to integrate misoprostol programming as part of the analysis.

Identify National PPH Prevention Strategies and Policies

The next step is to identify current misoprostol program strategies and policies within the national comprehensive PPH prevention plan and compare them to the global evidence base (suggested resources follow each item). In particular identify:

- Concurrent strategies for reducing PPH in facility-based births (the PPH Toolkit and *WHO Recommendations for the Prevention and Treatment of Postpartum Hemorrhage* for more information)
- Clinical protocols for preventing and treating PPH in facility-based births (WHO's *Managing Complications in Pregnancy and Childbirth: A Guide for Midwives and Doctors*)
- Allowed and/or preferred **distribution** methods of misoprostol
  - Personnel, location, and timing (Smith et al. Misoprostol for postpartum hemorrhage prevention at home birth: An integrative review of global implementation experience to date)
- Allowed and/or preferred **administration** methods of misoprostol
  - The pregnant woman herself, a trained health worker or CHW (Smith et al. Misoprostol for postpartum hemorrhage prevention at home birth: An integrative review of global implementation experience to date)
- Protocols for administration of misoprostol (FIGO *Prevention of PPH with Misoprostol Guideline*)

In addition, identify and/or clarify current MoH priorities related to PPH prevention generally and the expansion of misoprostol programming specifically: Have specific coverage targets already been developed? Are there specific geographic areas already prioritized for program expansion? If not, this will be an activity to complete in Phase II.

At the same time, explore the history and evolution of the national PPH prevention strategy and misoprostol's place within that strategy. This is particularly useful when the comparison of current policies to the global evidence base identifies areas where change may be indicated to improve total uterotonic coverage. An understanding of key players' priorities, key concerns, and previous policy debate can help inform an approach to change. Lastly, identify any ongoing policy debates and/or upcoming changes to the overall PPH prevention strategy that may impact the expansion of misoprostol programming.

BEST PRACTICES

Current evidence indicates that the highest uterotonic coverage of all births is reached when misoprostol is distributed during late pregnancy by a trained CHW to pregnant women for self-administration at the time of birth.

Source: Smith et al. 2013.

Understand the History of Implementation and Results to Date

Once strategies and policies are understood, the next step is exploring how they were translated into action. This part of the landscape analysis goes beyond high-level national strategies to the particulars of program implementation and the results obtained.

Locating and examining available M&E reports or summaries early in the landscape analysis process may help frame additional areas of inquiry. It also may help support ongoing advocacy activities. Comparing results with those obtained with "best practice" policies can provide important justification for program expansion or changes to implementation policies. For example, in Liberia, the pilot phase was designed to counsel and distribute misoprostol for self-administration through two channels: ANC during visits late in pregnancy; and the small number of district reproductive health supervisors (who are not considered to be CHWs). The distribution and coverage rates with this design fell short of the MoH expectations. Prior to scaling up, the Ministry strategically redesigned the program approach to mobilize the existing CHW cadre of Trained TBAs (TTBAs) as the key community-based distribution channel. Comparing their original implementation model to best practices allowed them to use the pilot as a learning phase and justify changes in the design in order to meet their coverage targets. Evaluating pilot results provides the opportunity to revisit the overall goal and adjust distribution timing, distribution cadre/s, and administration methods accordingly.

Identifying information/research gaps also is vital so that those gaps can be closed before or during expansion. For example, although the pilot in Madagascar was conducted for six months in one district as planned, it was expanded as a pilot into another district to continue the more extensive M&E in order to fully answer questions on safety, coverage, and acceptability.

KEY MESSAGE

The goal of using misoprostol in the prevention of PPH is to increase the total uterotonic coverage of a population at birth. To understand progress toward that goal, policy-makers and program implementers need to know:

1. To what percentage of pregnant women the drug was distributed
2. What percentage of those women appropriately took the drug immediately following delivery
3. What percentage of all women in the catchment area were protected from PPH, either at home birth (through the use of misoprostol) or during a facility birth (through the use of a uterotonic as part of AMTSL)

Beyond the M&E information available, in-depth discussions with previous implementers will help identify key accomplishments and successes to date as well as setbacks and failures. Together, walk through the previous implementation plans and identify strategies appropriate for replication as well as those that should be reconsidered or adapted. If there was or is more than one implementing partner, consider holding a one-day workshop where everyone can discuss these issues together and present their personal experiences with implementing the national strategy. The TAG or other identified safe motherhood/RH working group may be a good mechanism to coordinate these types of discussions.

The box below presents some of the key components of implementing misoprostol distribution programs. Identifying key lessons learned related to these areas will help pinpoint where implementation changes may lead to greater success.

PROGRAM COMPONENTS TO ASSESS FOR REPLICATION

- Human resources – Program staff, facility-based providers, CHWs:
  - Initial and refresher training: timing, content, and instructional design
  - Roles and responsibilities
  - Incentives and motivations
- Budgeting and resource management
- Drugs:
  - Procurement and supply chain for oxytocin and misoprostol
  - Tracking availability, use, and distribution
  - Method for packaging misoprostol into three-pill packs with PPH prevention branded name and instructions for use
- Community sensitization and involvement
- Supportive supervision and quality assurance
- Information system, monitoring, and research
- Materials and tools for use in above areas

Identify Existing Assets and Remaining Needs

A basic understanding of the materials available, status of drug approval and supply, and the availability and existing capacity of trainers and CHWs will be essential to determine the overall scope of work involved in program expansion.

Program expansion efforts should build off previously developed program materials. Collect existing IEC/BCC and training materials, then assess if there are gaps and if any adaptation will be necessary for your projected implementation area. To the extent possible, these materials—along with quality assurance, supportive supervision and M&E tools and procedures—should be standardized nationwide. As an example, when the program moved from pilot to expansion in Afghanistan, IEC/BCC materials and M&E tools were simplified and integrated into the routine health service delivery system.

This will be addressed further in Phase II.

CHECK FOR EXISTING MATERIALS

- Training materials for facility-based providers (ANC providers, SBAs) and CHWs
- IEC/BCC materials for use with community members; BCC/advocacy materials for facility-based providers and local/regional stakeholders including MoH staff
- Instructions for use inserts for drug packaging
- Job aids for CHWs and facility-based providers
- Supportive supervision tools
- M&E tools

It is important to verify that misoprostol is on the country's List of Essential Medicines, registered and licensed in country for obstetric indications. Confirm that misoprostol procurement, distribution, and tracking mechanisms exist or are planned. Some countries may make the policy decision to move ahead with expansion while these activities are in process. If misoprostol is not on the list, verify that mechanisms are in place to allow its purchase and use in public sector programs. It is acceptable in many countries to use a drug off-label. Another option would be to inquire with UNFPA about supplying misoprostol until it is added to the list. Because misoprostol is in the WHO List of Essential Medicines, UNFPA can potentially help with procurement.

If there is no workable, acceptable path to procure misoprostol, program expansion may be ill-advised until more progress is made to obtain supplies of the drug for obstetric uses. Advocates will need to focus efforts to have it included on the List of Essential Medicines or obtain a waiver for its use in public sector programs.

Another asset to consider is the existence of a CHW cadre. Gather any available information on typical coverage and expected size of catchment areas (number of households) for CHWs, which might vary in different geographic areas of the country. If coverage is not high,

explore whether TBAs or other community-based cadres or volunteers are active and whether it would be acceptable to the MoH to involve any/all of them in PPH prevention activities. During initial analysis to develop the learning phase of the PPH program in South Sudan, it was discovered that there was no pre-existing CHW cadre. TBAs, however, did exist. The MoH agreed to train and use the existing network of TBAs transitioning their role to be "Home Health Promoters" who are responsible for counseling and misoprostol distribution. This repositioning of the gatekeepers of delivery services minimized delays in selection and recruitment and led to stronger linkages between the TBAs and formal health care system. For expansion planning, it would be useful to know that the new CHW cadre of Home Health Promoters has not been recruited and trained in all communities and needs to be supported. In contrast, Nepal has a well-established group of nearly 50,000 CHWs called female community health volunteers (FCHVs) who provide health information and some limited services. FCHVs were able to integrate advance distribution of misoprostol into their work because they already were identifying pregnant women, providing education on birth preparedness and complication readiness, and promoting ANC and skilled attendance at birth.

A cohort of master trainers needs to be identified to conduct trainings and provide supportive supervision for both CHWs and health facility staff. Both trainers and CHWs will be critical human resources for program expansion. If systems to develop and train CHWs and master trainers do not exist, or are not functioning, they will need to be created in Phase II.

It is important to determine whether any national or organizational research ethical review approval (such as a national research council or institutional review board [IRB]) for your activities is required. This will depend on the nature of research envisioned as part of program expansion. Routine program monitoring may not necessitate ethical review, but keep in mind it is almost always a prerequisite for publishing program results. If the results will be used only internally by program stakeholders, then this type of review probably is not required. If programs plan to share their experiences with PPH prevention program expansion through journal publications and presentations at scientific meetings, ethical review should be explored and included in planning. Discuss the need for ethical review with the MoH, working group, and internal organizational stakeholders early in the planning phase as approval may take two to three months.

Finally, if not already done, verify support from policymakers and begin to identify funding sources. Determine what degree of expansion is feasible given budget commitments.

Determine Capacity and Next Steps

Once the landscape analysis is completed, a picture should emerge of what inputs are necessary to move forward with program expansion and what the scope of work will be for program design and implementation. At this point, your organizational capacity can be compared with the description of work that needs to be done. Are there areas where it will be necessary to partner with other organizations? For example, if improvements need to be made to the supply chains for oxytocin and misoprostol, do you have the capacity to address that?

Because the goal is uterotonic coverage at **all births**, other components of the comprehensive PPH prevention strategy also need to be considered. For example, misoprostol program expansion should ideally coincide with strengthening of PPH prevention and management in facilities. If you do not have experience conducting competency-based in-service maternal and neonatal health (MNH) clinical trainings or developing quality assurance methods for facility-based services, consider partnering with another organization that does. In this way, programming can simultaneously strengthen the health system while supporting women who cannot access a SBA yet.

B. Local landscape analysis and site selection

Local Stakeholder Consultations

While activities aimed at sensitizing various groups to the program will take place in Phase II, it is important to "take the pulse" of key local stakeholders prior to initiating program expansion. This will help to identify strong opposition and potential barriers as well as likely program champions. All other things being equal, in the choice between multiple sites for program implementation, the likelihood for success, and thus impact, will be greater when you select an area whose priorities and objectives align with the program's.

In some countries, the MoH may be ready to expand programming before finalizing the national policies needed to support program activities. Stakeholders otherwise supportive of the programs aims may feel their hands are tied if this is the case. If such barriers exist, assess what, if any, reassurances or legal safeguards are needed from the national level for local MoH officials and providers to participate in and support the program.

Sample local or regional stakeholders include:

- Regional, provincial/county, or district departments of the MoH, down to the lowest administrative unit (down to sub-district levels and facility levels)
- Local chapters of national professional associations for physicians, obstetricians, midwives, and nurses (if nurses have a significant role in providing obstetric care)
- Medical directors/lead clinicians in local health facilities/maternity wards, including those from the private sector as appropriate
- Supervisors and representatives of the local CHW system, if one exists, and/or TBAs
- Key community leaders
- Local and international NGOs working on maternal health in the area that would be influential in obtaining community-level support and already working with women's groups or CHWs

Evaluating the Local Health System and Clinical Practices

Understanding current practices and available resources will aid implementation area selection and initial program planning on many levels. How the findings influence site selection may differ depending on individual program strategies or objectives. For example, some countries may prioritize those areas with the fewest services and highest unmet need, while others may prioritize areas where there is already a strong facility-based health system to work with that can provide supervision to the program and quality referral services. Gather information for prospective program implementation areas on:

- Health facility availability: the number, names, location, and type of each health facility in the area (including private maternity care clinics); location of the nearest facility that can provide emergency obstetric and newborn care (EmONC) to treat PPH cases
- The quality of services available in each health facility: general infrastructure; availability of supplies and equipment; current clinical practices related to the prevention and management of PPH; hours of operation and staffing
- Availability and numbers of SBAs and frequency of staff transfers/absences (to help plan for initial and refresher training)
- Understanding of the local commodity situation: what is available; how do local procurement and distribution function; what are common causes of stock-outs

In South Sudan, this evaluation led to increased program activities around introducing and supporting the use of AMTSL with oxytocin (or at a minimum administration of a uterotonic) in facilities where it was found to be virtually non-existent.

Identifying Significant Cultural Differences from Prior Implementation Sites: Formative Research

While the goal is to replicate successful materials and strategies from prior program implementation, regional adaptations may be needed if significant cultural or language differences exist. Differences requiring significant changes to the program likely will be obvious and well-known, but not always. Another example of the need for adaptation comes from the pilot in Madagascar. Findings from the pilot identified the traditional practice of drinking a tea with uterotonic properties during labor and birth, which may be dangerous if taken with misoprostol. In this case, expansion partners may want to conduct formative research to better understand this practice and develop appropriate messages about tea consumption by women who take misoprostol. It is important to evaluate this likelihood, as the need for adaptation will impact both the budget and implementation timeline and may thus impact final site selection as well.

Formative research often uses focus group discussions, in-depth interviews with key informants, and participatory observation as methodologies. The primary goal in this phase is to identify if cultural differences are substantial enough to warrant changes in program implementation. You may want to start by performing a few in-depth interviews with those likely to be familiar with the local norms related to pregnancy and labor in both the prior implementation site and current target site. The need for additional formative research can then be determined from those findings. Additional key informants may include community and religious leaders, both of whom would be in the position to encourage or disapprove of the misoprostol program.

This may be all that is needed during the landscape analysis. If, however, substantial differences are suspected or identified in an area already chosen for expansion efforts, then further formative research will be needed to gather information about the underlying knowledge, beliefs, attitudes, and practices of women and their families as they relate to pregnancy, delivery and bleeding after delivery. The type of person who should be included in a focus group will vary; however, some typical participants are listed in the box below. Decision-makers such as men and mothers-in-law can be included. A sample of focus group discussion questions for different participants can be found in Annex B of the 2009 implementation guide.

POSSIBLE FOCUS GROUP MEMBERS

- Women who have recently delivered
- Women who recently delivered and experienced a complication
- Women who recently delivered and experienced PPH
- Men with children
- Older women with daughter-in-laws who have recently delivered
- TBAs
- CHWs
- Midwives or other service providers

Findings can help identify and address differences and ensure that the information, counseling, and drug interventions are culturally appropriate and accepted by the community. The advantages and disadvantages of localizing materials should be carefully considered, given the time and costs required.

Additional Implementation Area (Site) Selection Considerations

Site selection will depend on a number of factors. Some additional factors to look at when deciding on which implementation areas to select include:

- Will implementation in this area reach the most underserved women who are at highest risk?
- Does it have a higher percentage of home births than the national average?

- Are there physical barriers—such as very poor roads, boat access only, or many isolated communities? Use of misoprostol in these settings could buy a woman more time if she experienced PPH and had to be referred.
- Is the area primarily rural? Rural women have less access both to facilities and to SBAs.
- Are there other factors such as security concerns or lack of transportation that limit the ability of women to be transported to facilities for delivery and/or emergencies?
- Does the area have funding that it can contribute to the program?
- Are there donor programs in the area that could contribute resources, such as paying for the adaptation of materials or buying the medication?
- Are there NGOs already working on maternal health issues in the area that could support the program?
- Is there an existing CHW cadre/system? Is it functioning well? Do CHWs already provide MNH information or identify pregnant women?
- Who is available to be trained as trainers (of both CHWs and providers) and supervisors under the program?
- Will conflict, civil unrest, or seasonal weather (such as a rainy season) affect distribution?

KEY MESSAGES FOR PHASE I: LANDSCAPE ANALYSIS

- If programs using the advance distribution of misoprostol have not previously been implemented, refer to the 2009 implementation guide: *Prevention of Postpartum Hemorrhage at Home Birth.*
- The purpose of the landscape analysis is to provide the information needed to make informed choices about how to proceed with scaling up misoprostol programming to achieve the greatest distribution and coverage.
- Evidence indicates that the highest distribution and coverage rates are achieved when CHWs/TBAs distribute misoprostol for self-administration. Review national program results to date and existing PPH prevention policies and strategies to identify additional policy changes needed to maximize distribution and coverage.
- Advance distribution of misoprostol should be implemented as part of a comprehensive PPH prevention program and be integrated with other maternal health initiatives currently being implemented in a country. Avoid creating a vertical program.
- Expansion efforts should capitalize on materials and processes developed previously and take advantage of lessons learned during initial programming.
- A local landscape analysis should be performed before final site selection and used to prioritize expansion areas as well as aid in initial program planning.

PHASE II: PREPARATION AND PLANNING FOR SCALE-UP

This phase is divided into two parts:

1. Activities requiring coordination with previous or current implementers and partners—to ensure that materials, procedures, and policies are standardized to the extent possible throughout the country and that individual organizations' efforts are complementary and well-coordinated.
2. Activities specific to your implementation area that require locally individualized strategies or action.

A. Activities in Conjunction with Other Implementers and Partners

Review Roles and Responsibilities

If working with other organizations in a country-wide expansion effort, you will need to determine the relative roles and responsibilities of each organization. There are two main components to consider:

1. Geographic focus; and
2. Programmatic focus.

Programmatic focus should consider the full spectrum of necessary interventions to implement a comprehensive PPH prevention strategy. These decisions may need to be made in parallel because an organization's programmatic focus or ability may impact its geographic intervention area. For example, if an organization is unable to ensure that facility-based providers can perform AMTSL and manage PPH to standard, they will need to partner with an organization capable of implementing in-service trainings and facility-based quality assurance methods. Geographic focus of the first organization therefore may be influenced by the geographic focus of the supporting organization. Final site selections should be coordinated among implementing agencies to best achieve national targets and objectives and balance any competing priorities.

KEY MESSAGE

AGREE ON GEOGRAPHIC AND PROGRAMMATIC FOCUS OF PARTNERS

When planning expansion of misoprostol programming, remember to integrate activities with existing maternal health programs and to address all aspects of the national comprehensive PPH prevention strategy in conjunction with partners.

Misoprostol programming needs to look beyond distribution to encourage antenatal care, promote skilled care at birth, ensure timely referrals in case of complications, and provide PPH treatment at health facilities—all of which rely on the existing health system.

Standardize and Field-Test Materials and Methods

Ideally all technical materials and programmatic methods should be standardized nationally, but this is not always possible. It is likely that as the MoH prepares to move the program from pilot to the expansion phase, all materials—IEC/BCC materials, M&E tools, and training packages—will be simplified/adapted. A national review of materials involving all expansion partners may be needed because the program has a smaller and less intensive research component and it needs to be fully integrated with the normal health service delivery system. In Afghanistan, this adaptation process occurred, and some of the health messages were adapted and simplified.

The local landscape analysis in Phase I should have provided the information necessary to determine if regionally specific materials are needed. In this case, if not completed during phase I, new formative research may be needed to guide material adaptation, particularly of IEC/BCC messaging and drawings and product packaging. In any case, any time materials are changed and/or introduced in a new area, they should be field-tested before finalization to ensure they are understood and achieve their objectives.

Materials available for adaptation are listed in **Annex A,** and samples in various languages are posted on the PPH Prevention and Management Toolkit online: (http://www.k4health.org/toolkits/postpartumhemorrhage). They include:

- Advocacy materials
- Training materials, including job aids for:
  - Facility-based providers such as SBAs who manage births and PPH cases (**See Annex B** for course overview.)

  - CHWs and/or others distributing misoprostol to women (See **Annex C** for course overview)
- IEC/BCC materials:
  - Counseling provided directly to woman and her family (See **Annex D** for key counseling messages)
  - Drug packaging
- Supportive supervision tools for use with:
  - Trainers
  - Facility-based providers
  - CHWs (See **Annex E.**)
- M&E tools (See **Annex F** for overview of core indicators and data sources and **Annex G** for an example of a CHW pictorial form.)

If adaptation will occur, materials need to retain the essential content summarized in **Table 6**.

Table 6. Overview of PPH prevention materials and content

MATERIALS	KEY CONCEPTS AND CONTENT
Instructional Design	▪ Take literacy levels into account, such as difference courses for literate and non-literate CHWs. ▪ Use participatory methods that engage adult learners and build off their existing knowledge and experience—such as group discussions, role plays, exercises, demonstrations, brainstorming, and games. ▪ Use the same materials in the trainings that will be used by the CHWs on-site; likewise, use the same job aids that providers will use at their workplace. ▪ Trainings should be competency-based. Participants must score 85% on any knowledge assessments and perform all of the steps and tasks on skills checklists correctly to successfully complete the course.
Key Content for SBA Trainings (See **Annex B** for sample training agenda.)	▪ AMTSL using oxytocin; if indicated in-country, clinical protocols for facility use of misoprostol when oxytocin is not available ▪ Management of PPH with women who have taken misoprostol at home or en route ▪ Management of misoprostol stock for distribution and use of drug log if applicable ▪ Management of unused pills brought to a facility delivery ▪ Data collection for M&E at the facility level, with practice using forms and registers ▪ Management of PPH for any birth (Note: Part of a comprehensive PPH strategy; may stand alone as a separate training and should focus on simplified protocols)
Key Content for CHW Trainings (See **Annex C** for sample training agenda.)	▪ Causes and prevention of PPH ▪ Appropriate use of misoprostol to prevent PPH ▪ Counseling techniques to transmit attitudes, knowledge, and skills needed to promote misoprostol use to pregnant women and their families ▪ Community mapping and enrollment of pregnant women ▪ Particulars of acquiring, distributing, and tracking the drug specific to their role ▪ Data collection for M&E, with practice using forms and registers

MATERIALS	KEY CONCEPTS AND CONTENT
Counseling Materials for Women and Their Families (See **Annex D** for key messages.)	▪ They should be in a visual format, appropriate to literacy levels and primarily pictorial. ▪ Include reminder cues for action that can be left with the family. ▪ Content to include: – Encouraging the pregnant woman to attend ANC with a skilled provider – Describing the benefits of giving birth with a skilled provider, including prevention of PPH through the use of oxytocin – Explaining the danger signs of pregnancy and labor – Urging the woman and her family to have a birth preparedness plan – Explaining what PPH is in terms that the woman can readily understand – Telling her what causes PPH – Telling her that if she delivers without a SBA, or if oxytocin is not available, she should consider taking misoprostol **In addition, messages on misoprostol should be clear and include:** ▪ Where to store misoprostol ▪ When to take misoprostol ▪ How to take misoprostol ▪ When not to take misoprostol ▪ What side effects to expect from taking misoprostol ▪ What to do about side effects ▪ What to do if bleeding continues after taking misoprostol ▪ How to return the misoprostol if it is not used
Drug Branding and Packaging	▪ The drug should be branded with a name that reflects its purpose for the prevention of PPH. ▪ This name, rather than misoprostol, should be used in all communications with women and their families. ▪ The packaging should include clear instructions for use and contain three tablets.

When reviewing existing materials, consider available qualitative and quantitative data available from the initial implementation:

- Did advocacy materials address main concerns? Were they successful in turning opinion?
- Were training materials clear and easy to use? Did they accomplish their objectives?
- Did IEC/BCC materials lead to the acceptability and correct use of misoprostol by community members?
- Were supportive supervision tools valued by both mentors and those being mentored? Were they seen to improve performance? (See section on Program Monitoring and Support for additional guidance.)
- Were M&E tools clear and easy to use? Did they provide the information needed to assess success and improve the program? (See section on Program Monitoring and Support for additional guidance.)

Edit materials and tools judiciously, doing so only when the benefits outweigh the disadvantages of having multiple versions in circulation. Sometimes having one imperfect tool in use by everyone is preferable to having many versions striving for perfection.

TIPS FOR ADAPTATION OF MATERIALS

- If other manuals and counseling materials exist, try to replicate the same artwork to have consistency with other safe motherhood messages.
- Pictures used in the training and counseling materials should be the same.
- Field-testing is an important phase before mass-producing; all messages should be translated into local dialects using local people as translators (teachers and village leaders, for example) as much as possible.
- Double-check that the essential meaning of the message has not been lost by reverse translation—from the original language into the local language and then back again.
- Create a dictionary of local words that are used for the same meaning so that CHWs can know them all.
- If possible, have someone like a sociologist or an anthropologist review the materials to make sure the cultural norms and values are well-represented.
- Use artwork that shows familiar faces, dress and settings.

In addition to materials, standardization of M&E and quality assurance methods should be discussed including those related to:

- Frequency and timing of M&E activities
- Methods of data-sharing and aggregation from the community to the national level
- Household surveys capturing actual usage rates of misoprostol in new program areas
- Regular supportive supervision of CHWs and facility-based staff
- Maternal death reviews and "near miss" case reviews
- Drug quality and availability

More information pertaining to these activities can be found in the Program Monitoring and Support section.

Other materials that may be helpful are listed in **Annex A** and posted online in the PPH Prevention and Management Toolkit, http://www.k4health.org/toolkits/postpartumhemorrhage:

- Advocacy materials, such as community orientation presentations
- Clinical protocols
- Job aids
- Field team job descriptions

Develop National/Regional Trainers

Once training materials are finalized, trainers must be developed to carry out the training/updating of health facility staff and CHWs during Phase III. The number of tiers and nature of this training cascade may differ by country. In some countries there are already established training centers and trainers, who usually work with the MoH. These may be centralized, and focused on creating "master trainers" or "trainers of trainers" or regionalized and focused on directly training health facility staff/CHWs themselves. Together with partners, identify what training system resources already exist in-country and make a decision regarding how a sustainable training cascade will be structured. Ideally training should strengthen or use any existing MoH training system to build capacity and promote sustainability. All trainers need to be effective in using competency-based approaches with emphasis on skill development and opportunities for "hands-on" practice.

The best-case scenario is to use master trainers with a great deal of experience who:

- Have an understanding of group dynamics
- Know how to train people with low levels of basic education
- Can model strong interpersonal communication skills that the participants can replicate when working with pregnant women
- Ensure that local words for bleeding, vomiting, pain, etc. are used in the training so that the training context is culturally appropriate
- Include participants' experiences in role plays and discussions, valuing the participants' contribution to the learning process
- Are willing and able to travel to the field to provide post-training follow-up and supportive supervision

When determining the number of trainers needed, remember to account for the anticipated number of people to be trained; time needed to fulfill supportive supervision responsibilities; and future trainer attrition.

There are many options for training of trainers, and you can obtain technical assistance from other countries that have already done this (such as Afghanistan, Nepal, and Indonesia in Asia and Zambia, South Sudan, Mozambique, and Nigeria in Africa). You also can request assistance from institutions such as Jhpiego and VSI that have spearheaded training around the world, or others with training systems development expertise.

Drug Supply and Branding

The two largest manufacturers of misoprostol are Cipla and Searle. Other common names and where they are manufactured are in **Table 7** below (VSI 2013):

Table 7. Misoprostol manufacturers and name brands

Drug Name	Where/Who Manufactured
Ace Miso	Acme Formulation
Alsoben	South Korea/Unimed
Cytomis	Incepta
Cytotec	Searle and Pfizer
Cityl	Colombia/Tecnoquimicas
Cyprostol	Austria
Cytolog	India
Gastotec	Korea
Gastrul	Indonesia
Gymiso	France
G-misoprostol	GPL
Isovent	Square
Kontrac	Fourrts (India) Ltd.
Misoclear	Acme Formulations
Misofem	Naari; FamyCare
Misoprost	India/Cipla; Ohm Pharmaceutical
Misoprostol	Servimedic; Zizhu Pharmaceuticals; Ba Dinh Pharmaceutical Company
Misotac	Sigma
Misel	Korea
Prostokos	Brazil/Hebron
S.T. Mom	Zafa
Texyto	China/Zizhu Pharmaceuticals
Ummal-gargaar	Sigma
U-Miso	Taiwan
Vagiprost	Egypt/Egyptian Co. for Chemicals & Pharmaceuticals
Vanprazol	Cipla
Zitotec	India

In addition to these sources, the drug can be manufactured locally where national pharmaceutical manufacturing capacity exists. The decision about where to purchase the drug should be evaluated with regard to economic factors, because sometimes local taxes and tariffs make the importation of drugs more expensive than local manufacture. Regardless of the decisions made with respect to supplier (local or international), quality control measures must be enforced.

If misoprostol was not previously registered, it is very important to evaluate the local name used during initial implementation. This name should reflect that it is used to support the health of women and prevent PPH. If this was not done during the pilot phase, it should be done now. This step is so important because one of the common worries about misoprostol is that it will be misused as an abortifacient. Establishing a new brand allows the program to promote the drug for its intended purpose—preventing PPH at home births. This needs to be done before registration of the product because names cannot be changed afterward.

There are many ways to identify a brand name. In the Indonesia experience, a team with members from the local university, representatives of the district level of the Ministry of Health, and service providers was asked to consider the topic of branding during the early phase of program implementation. After a field-test of four initial options with district village midwives, all were discarded in favor of a fifth: "*PAS-Bayet al*" *PAS* stands for *Perdarahan Atasi Segara* or "immediate response to hemorrhage" after a baby; however, "*PAS"* is also an independent Indonesian word that indicates that something fits just right, and thus the connotation was that taking the drug fit in just right with having a baby safely. In Nepal, they chose the name *Matri Suraksha Chakki,* which means Mother's Protection Tablet. It is a very important step to select a suitable and appealing name that conveys its purpose. If there are commercial sector branding services available in-country, they may serve as a possible source for technical assistance to ensure that the name is appropriate.

Identify National Procurement and Distribution Bottlenecks; Plan for Drug Arrival to Coincide with Initiation of Trainings

Consistent availability of quality misoprostol may remain a problem even after the policy hurdles to allow the import and use of the drug are overcome. This challenge should be assessed and addressed early in planning. It is essential to identify the main procurement actors (government, NGOs, UNFPA, private commodity distributors, social marketers), determine how each will be involved, and what lead times are needed by each. For example, government tender processes often take six to 12 months. This must be taken into consideration when planning the program rollout, as the drug must be available in the intervention areas immediately following the first trainings.

A separate procurement system may have been set up for the purpose of the pilot program. Once a country is committed to scale-up, advocate for the inclusion of all drugs and supplies used in PPH prevention programming to be included in the routine government procurement system. The importance of availability of uterotonics to prevent PPH is being given global attention through the UN Commission on Life Saving Commodities, which has included oxytocin and misoprostol on its list of lifesaving maternal health drugs.[5]

Accurate forecasting and quantification of misoprostol prior to procurement is key to successful program implementation. The total amount of product procured must meet the national need for use in programs. If it does not, it can result in: 1) stock-outs when the product is procured in quantities insufficient for the programs, or 2) the need to recall and destroy expired product when too much is procured. Either of these results can have significant financial implications for the programs, in addition to interrupting distribution. An example of the VSI forecasting tool and a JSI DELIVER *Quantification of Health Commodities: A Guide to Forecasting and Supply Planning for Procurement* are useful resources, both found in the PPH Toolkit.

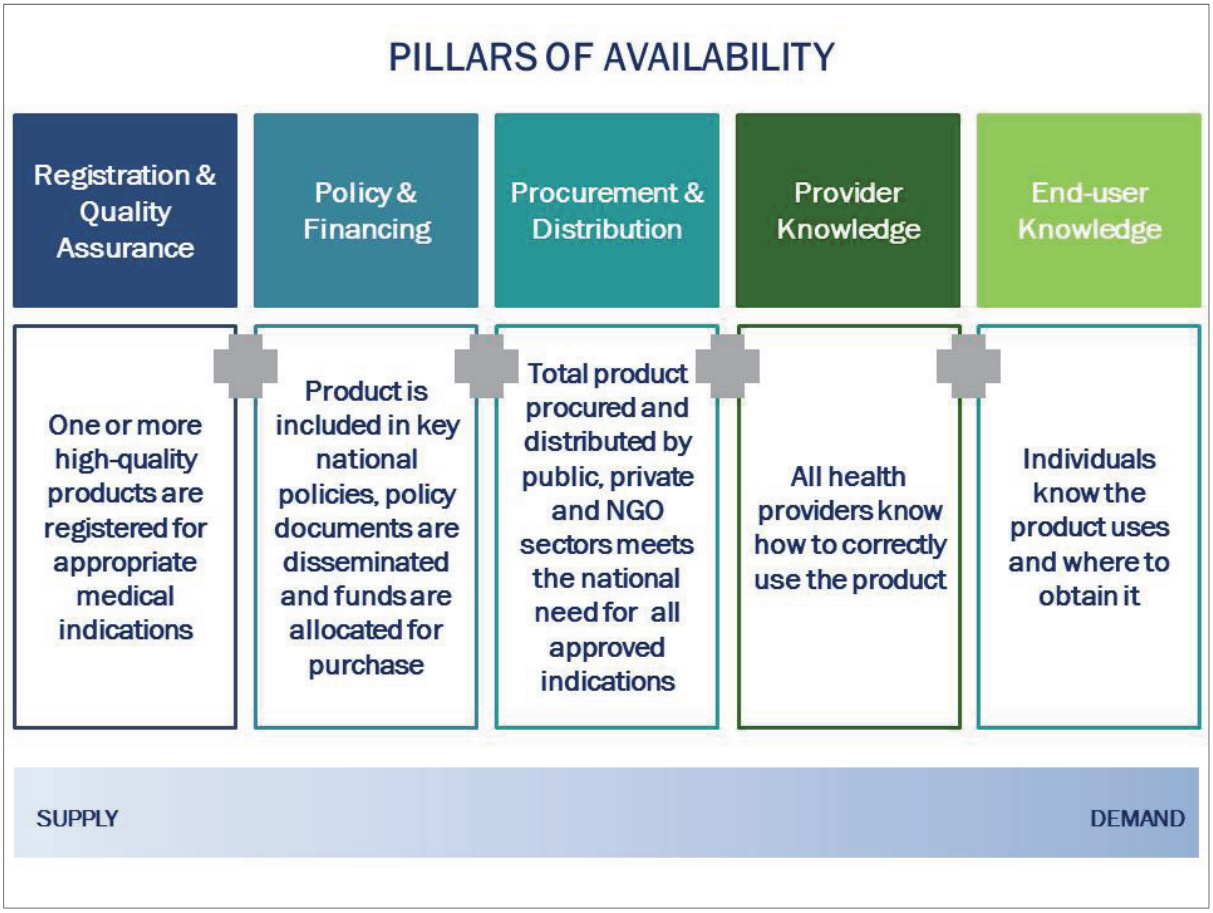
To ensure timely distribution once misoprostol arrives at the central medical stores, it is important that policies and procedures for ordering misoprostol in the public sector are in place and are clear. Ordering of misoprostol from the central medical stores by facilities or districts will require inclusion of misoprostol in ordering forms. Many countries have combined "pull" and "push" systems for ordering drugs. Regardless of the system, it is very

[5] United Nations Commission on Life-Saving Commodities for Women and Children. Life-saving commodities. http://www.everywomaneverychild.org/resources/un-commission-on-life-saving-commodities/life-saving-commodities

important that personnel responsible for ordering or distributing misoprostol have the most updated guidelines or job aids referring to the use of misoprostol. This includes who can use misoprostol and at which level of the health care system. For example, in a "push" system, the district medical stores pharmacist needs to know that misoprostol is being used to prevent PPH at home births, and is being distributed by CHWs attached to peripheral health centers or health posts. Under this system, the supply of medicines to these facilities will always include misoprostol. The following list covers key questions to ask to ensure misoprostol can be procured and distributed:

- Is misoprostol included in the national List of Essential Medicines (or extended list)?
- Is misoprostol included in the list of RH or MCH essential drugs for the next government tender process?
- What is the timeline for the tender process in the country?
- Was misoprostol included in the forecasting and quantification of RH or MCH drugs?
- Who can purchase misoprostol?
    - Consider all possibilities in the country (organizations that procure medicines for the public or private sectors): Government; NGOs, UNFPA, etc.
- Are policies and procedures for ordering misoprostol clear (ordering by districts, or facilities) after the drug has arrived in the country?
- How is the drug distribution system in the country organized (push, pull, or combined system)?
- Is misoprostol included in the standard drug ordering forms and in the logistics management information system (LMIS)?
- Are pharmacists in the central and regional/district/provincial medical stores aware (or have a copy) of national guidelines or job aids referring to the use of misoprostol?
- Is incoming misoprostol tested for quality and does it have an expiration date of at least two years from arrival in country?

VSI has developed an availability framework for misoprostol illustrated below based on five thematic areas or "pillars" that assesses factors influencing product availability. It includes the conditions that must be satisfied to achieve availability of misoprostol to all women every day. The same thematic areas can be used to structure an assessment methodology for determining strengths and weaknesses related to product availability. See the *Availability Case Study: Misoprostol in Tanzania* (2012) found online in the PPH Toolkit for an example of its use.



Source: VSI.

B. Activities in Your Program Expansion Area

Meet Key Local Officials to Introduce Program

Once the program implementation area is selected, it may be helpful to obtain MoH approvals to work in selected districts. Formal introduction and approval from the central level can help build support at the regional, provincial, or district level.

An introductory meeting with provincial or district officials is needed to orient them to the proposed PPH prevention activities. Any MoH staff responsible for maternal health, CHWs, logistics, and M&E (or health management information system [HMIS]) should be invited. During the meeting, present justification for the program expansion based on PPH prevention need and findings from previous implementation. Solicit their input and suggestions, especially on the planning for the remaining activities outlined in this section. For example, district health officers can identify other upcoming maternal health trainings to which PPH prevention training could be added—reducing costs and disruption to services. Strong, local MoH ownership from the start is essential for addressing bottlenecks, mobilizing human resources, promoting sustainability, and responding in the case of adverse events.

Select Local Health System Counterparts

It is critical to have counterparts within the public health system who will be responsible for the day-to-day management and oversight of the program. These may include provincial or district MoH representatives, SBAs, pharmacists, and community members. In Indonesia, there were counterparts at all levels of the health care system, from the central to the provincial and district levels. Your country health system will guide the most appropriate placement of counterparts and local MoH officials can be consulted in the selection process. Counterparts do not have to be physicians; they can be nurses, midwives, or public health managers. The counterparts will have roles to play over the long term, so it is important to have a clear job description that outlines what each person will do in support of the

misoprostol program. Example job descriptions for field coordinators, CHWs, CHW supervisors, and pharmacists can be found in Annex A of the 2009 implementation guide.

Select Local Community Counterparts (CHWs)

CHWs are the workforce that will be mobilized to communicate information, conduct counseling, identify pregnant women in their recruitment areas, distribute the drug, and conduct postpartum interviews. The complexity of this step depends on whether or not there is an existing structure for CHWs and/or community-based health care. Because the ultimate aim is to integrate misoprostol programming with existing community-based maternal health interventions, it is not advisable to develop a separate cadre solely to implement this program. In situations where there is a functioning CHW system, that system should be utilized. It is important to understand the expected CHW catchment area (number of households) and typical CHW coverage in your program implementation area. If coverage is not high, explore whether TBAs, other community-based cadres, or volunteers are active. Earlier in the landscape analysis in Phase I, you would have gathered information on whether it would be acceptable to the MoH to involve any/all of these cadres in PPH prevention activities. Based on that information and local feedback on how best to maximize distribution through existing community-based mechanisms, the numbers and types of CHWs available to your program can be confirmed. At the local level, also gather information on turnover among CHWs to be able to plan refresher training.

If there is no active local system, but there is a national blueprint for the roles, responsibilities, and training of CHWs, programmatic efforts should support development of CHWs following that blueprint. If no such blueprint or system exists, consider partnering with others to create an integrated system as part of community-based health care which addresses recruitment, training, supervision, and retention. Planning then needs to account for additional time and resources to develop the CHW system. For additional guidance on developing a CHW system, refer to http://www.chwcentral.org/.

If additional CHWs need to be developed, or only a subset will be trained in PPH prevention using misoprostol, there are a number of criteria commonly used to identify who would be good candidates. These are dependent however on the local context. For example, literacy with an eighth grade education maybe a usual criterion, but many countries like Nepal and South Sudan have many non-literate community health volunteers in successful programs. Program materials and training processes need to be adjusted according to literacy levels. Sometimes literate and non-literate CHWs are given different responsibilities. The box below shows common criteria for selecting CHWs from around the world.

KEY DEFINITION

CRITERIA FOR SELECTING CHWs TO UNDERGO TRAINING IN PPH PREVENTION USING MISOPROSTOL PROGRAMS

- Usually female; can be male if culturally appropriate
- Willing to work for no remuneration
- Willing to visit pregnant women house to house
- Previous experience in other public health programs
- Acceptable to the community
- Have a basic education level
- Have time available for training and follow-up

Orient Counterparts and the Community (Sensitization)

When expanding into a new implementation area, sensitization through a series of meetings with all of the parties involved will open dialogue and build consensus. The purpose is to lay a foundation of knowledge and awareness, which will prevent any misunderstandings as the program unfolds. It is an opportunity to present justification for the program expansion based on local PPH prevention needs and findings from previous implementation. Its

purpose is not to create demand for the new program, although this might be a secondary effect when meetings are held at the community level. Sensitization efforts:

- *Must be conducted at all levels*, from national levels down to village levels. If the program is being carried out on a limited basis, such as on a province basis, then sensitization begins at that level.
- *Must be transparent*. In meetings and discussions, program officers must be willing to discuss any risks or drawbacks in the program. Because there are sensitivities about misoprostol being used as an abortifacient, the program team must be willing to answer these questions if raised. Keep the focus on the use of the drug for PPH prevention and not the other gynecological uses.
- *Must be consistent*. The messages that are shared during these meetings are the same as those in the information and counseling materials that the individual pregnant woman will get—signs and symptoms of PPH, how misoprostol works, support for delivering with trained providers, and support for AMTSL as the most effective PPH prevention tool. At the village level, the drug should be referred to by its branded name associated with the PPH prevention program and not the generic name of misoprostol, which might raise questions about use as an abortifacient.
- *Must be thorough*. If at the village level not enough questions are raised, program managers must raise the issues themselves. This includes discussion of side effects, costs, and success rate.
- *Must be repeated throughout the program*. As data become available on a local basis, they must be shared. As more areas become integrated into the program, they need to have the same access to information as earlier programs did. Also, as contact people who previously were informed move to other positions, it is necessary to continue the socialization process with their successors.

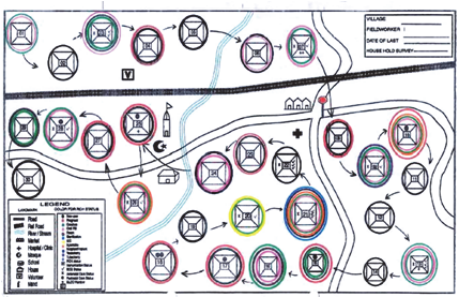
Depending on the audience, materials that may be used during sensitization efforts include:

- Fact sheets on frequently asked questions
- References for research that has been conducted on the efficacy of misoprostol.; an outline of why misoprostol is needed for prevention of PPH in their region; this outline should include data on how many women experience PPH, the MMR for the region (if possible), the state of EmONC services, and any identified cultural barriers that contribute to PPH
- Results from prior implementation in-country, including success stories with human interest, which can be emotionally powerful

Review Community Mapping Techniques

A community map is a simple, graphic representation of major landmarks in a community; the location of all households; and key information about each household. In areas of difficult terrain, they may also indicate the best/most efficient path from house to house. They are a basic management tool for planning, monitoring, and evaluating CHW activities.

Community map of pregnant women in a village in Afghanistan



Source: Jhpiego.

For this program, each community map should clearly show: each pregnant woman; which counseling visits have already been made; when misoprostol should be distributed; and to whom it has already been distributed. For postpartum women, it should indicate where they gave birth; if they took the misoprostol; and if they experienced an adverse event or complication requiring a referral.

Although the maps are primarily tools for the CHWs to complete their work effectively, they can also be a way to visually share M&E results with the community. Other benefits include:

- Easy to understand. Maps are easily interpreted and their use easily explained to new workers, even those with little or no schooling.
- Lend status to their users. Maps visibly symbolize the work CHWs are doing. Because village women can seldom display visible signs of their contributions, the maps become a source of pride and status for them.
- Accountability. Maps are results-oriented and convey accurate data while at the same time linking abstract data and real people.

Mapping is often part of a CHW's existing maternal health responsibilities. Many additional metrics (such as immunization status) may be recorded on the same map. Review the community mapping techniques already in use by local CHWs and/or those used during the PPH pilot or learning phase:

- Is there high confidence that all pregnant women were identified?
- Are the symbols being used clear and easy to draw, understand, and remember? It is best to have all CHWs record information using the same graphical representation so that anyone involved in the program can read any map.
- Is all required information represented?

CHWs should initially draw maps by going door to door. Thereafter, information should be continually updated as CHWs make their household visits. There are many strategies to identify new pregnant women: ask around during weekly market days, ask other women during household visits, and work with providers at health posts to ensure those attending ANC are included on the map.

Because this program is about reaching out to the women who are more likely to deliver at home without a SBA, mapping techniques should include identifying those who live far away from facilities, the poorest communities, and under-served or geographically isolated areas.

Review Local Procurement and Distribution System

Take any steps necessary to ensure the local procurement and distribution system of misoprostol will support program activities. Review procurement requirements and budget enough time for drugs to arrive to the program area. Ensure that pharmacists who will distribute the drug to the program are sensitized to it and have a copy of national guidelines or job aids referring to the use of misoprostol. Review local forecasting mechanisms and the re-ordering process to avoid stock outs as the program rolls out.

Develop a Program Budget

Cost considerations are always important in decisions to scale up public health measures. Fortunately, the overall cost of the use of misoprostol to prevent PPH at home births is relatively small, as there is no need for extensive infrastructure to implement the program.

Budget elements for misoprostol program expansion should include the following:

- Stakeholder meetings
- Meetings held for the sensitization process
- Adaptation, production, and distribution of IEC/BCC, training, counseling, supportive supervision, and M&E materials; depending on the quantity, district or provincial storage may also be required
- Purchase of adequate drug supply and packaging specific to the PPH prevention program

- Initial and refresher training for the personnel implementing the program—including per diem for the participants, transportation costs, rental of facilities, and honoraria for the trainers(Note: consider budgeting similar rates as offered by government if participants are government providers or CHWs)
- Transportation costs for supervision
- Staff salary and benefits costs (which are shared across other programs)
- Purchase of computers, tablets, and/or smart phones for M&E
- Funding to carry out household surveys in a sample powered to determine usage rates of misoprostol that had been distributed and outcomes of users

Factors that influence the overall cost of the misoprostol program include:

- The procurement option chosen for supplying the misoprostol, particularly if there are high tariffs on imported drugs; local manufacture may be less expensive if an option
- Incentive schemes for CHWs for their role
- The use of a dedicated training infrastructure and trainers for health activities already in existence
- The necessity and range of liability payments if a woman experiences an adverse event after taking misoprostol
- Limited geographic scope, which will reduce costs for transportation, fuel, etc.
- Existing costs for health staff personnel; if labor costs are high, this will impact the program

Where feasible, programs should try to harmonize any rates and fees with current government policies because most expansion programs will use the existing government public health and CHW systems. Coordination on these kinds of costs is strongly encouraged with other expansion partners. Differences in training fees, transportation allowances, CHW incentives, and per diem rates can create implementation and motivation issues.

In determining what resources are available for this program, managers should approach donors, local philanthropic organizations, and other nongovernmental sources for funding.

PHASE III: PROGRAM EXPANSION

By now, all of the tools are in place; counterparts have been chosen and oriented; and the community has begun to hear about the program through sensitization efforts. Trainers have been developed and are ready to begin training. The procurement and distribution system is ready to provide a steady supply of misoprostol as needed. It is time to roll out and monitor the core interventions; train facility-based providers and CHWs; identify all pregnant women in the area and begin providing information and counseling; and, finally, distribute misoprostol to any registered women who have completed counseling and are eight or more months pregnant.

Train Facility-Based Providers and CHWs

After the master trainers are prepared, training can roll out to those who will interact directly with pregnant women. Recognizing that there are resource constraints and different settings available for training, program managers should try as much as possible to create an environment conducive to learning (not too noisy or hot) and to provide appropriate teaching aids. When doing the actual training, trainers must ensure that all of the materials being used are the ones that the CHWs will then use on-site. It is helpful to have both program and CHW supervisors (e.g., MoH central, regional, and district officials) participate in the training for CHWs, so they have a full appreciation of the expectations and

capabilities of the CHWs they will be supervising. It also may be helpful for them to attend training for facility-based providers.

Package and Distribute Misoprostol

If not done by the manufacturer, the drug doses should be overbranded and packaged for distribution within the misoprostol program in Phase III. Local packaging will reinforce the message that this drug is to prevent PPH and differentiate it from any other uses. Packaging must also take into account safety precautions and M&E needs. Guidance for packaging includes:

- The standard dosage for prevention of PPH is three tablets of 200 mcg per tablet, for a total of 600 mcg.
- Each dose should be independently packaged into small blister packs.
    - If a three-pill pack is not available, secondary packaging can consist of a small plastic bag with a zip-lock seal, accompanied by the instructions for use and graphics from the counseling materials.
- Each pack (or bag) should be tagged with a number, which then should be registered to district distribution sites; when the provider or CHW dispenses the drug, she should note the number for tracking purposes. This number should include the batch number of misoprostol if different batches of the drug are in the country. This will help with quality monitoring of the drug.
- The external packaging design should reinforce the public health messages behind taking the drug. In Indonesia the packaging was red—as a reminder of danger—and yellow because it contributed to the graphic look of the package.
- Distribution of misoprostol should comply with stock management norms about the expiration dates already in place in-country. To avoid stock-outs, set restocking protocols based on average caseloads of the CHWs and how difficult it is for them to access the distribution point.
    - For example, if a CHW generally sees three pregnant women a month to distribute misoprostol and can come to the restocking point only every other month, you may choose to supply nine doses at a time and recommend restocking when three doses are left.

Complete Community Mapping and Register Pregnant Women

At this point in the program, CHWs have been selected and trained, and implementation areas are selected and sensitized where the program will begin. Misoprostol is stocked and ready for distribution, and sufficient supplies of counseling and education materials are available. Using the methods reviewed in Phase II, the CHWs will identify pregnant women on a community map and register newly pregnant women as part of their overall maternal health responsibilities. Because of the shift from pilot to expanded implementation, enrollment is no longer required and registration should be part of integrated CHW work. The registration form should include:

- The pregnant woman's full name (including local or nickname if commonly used); her husband's full name; her address or house number; and her age and the year she was born
- The last month she had her menstrual period and when she knew she was pregnant
- The estimated date of delivery and when the pregnant woman will be eight months pregnant, as this is when she will receive her dose of misoprostol[6]

[6] Methods for determining the estimated date of delivery and the date by which misoprostol can be distributed are included in the CHW trainings found in the PPH Toolkit.

- If she is getting ANC and with whom; if she plans to deliver at home or at a facility; and what kind of provider she will use
- Signed consent to receive misoprostol (if necessary)

If the woman is in her eighth month of pregnancy at the time that she is registered, the CHW should tell the woman about misoprostol and give her the pills if she wants to use misoprostol. This should be done even if the woman is planning to deliver at a health facility to ensure that a uterotonic is available at birth.

The registration forms are very important and serve as the basic record for the entire program. It is possible to make them pictorial if needed. (See **Annex G** for an example from South Sudan.) The forms should be filled out in ink and kept in a weather-proof envelope. The CHWs also need to take care that the pregnant woman is not being doubly registered (for example, at her own home but also at her mother-in-law's home). In some countries, once the registration is completed, there are local regulations that it must be filed with the local midwife (SBA) or health center. If this is the case, the CHW needs to make two copies, one for herself and one for the health counterparts.

In some country contexts, multiple distribution channels may be used, such as through TBAs and/or ANC providers at health facilities. If ANC providers in addition to the CHWs are educating and registering pregnant women for advance distribution, ANC providers will need to complete the registration process at the health facility, collect signed consent (if necessary), inform the women when to return to receive her dose of misoprostol, and/or distribute misoprostol if the woman is already eight months pregnant. In this situation, the ANC provider also should confirm that the pregnant woman is not being doubly registered.

Begin Counseling Registered Women

Counseling is the core of the entire approach to home-based PPH prevention. The program is not about just taking the pills but about providing information to pregnant women and their support members so they are informed, are aware, and can respond if they encounter PPH during their delivery.

Counseling sessions should include time for the CHW to encourage the woman to ask for any other information or to explore questions that she has about her pregnancy and delivery. CHWs should ensure that if they are not able to answer a question, they bring it up to their supervisor and get back to the pregnant woman with the correct information.

There are generally four points of interaction between the CHW and a pregnant woman for the purposes of misoprostol counseling and distribution. They are:

1. Registration—done by a CHW when she identifies a newly pregnant woman in her catchment area as part of their general maternal health responsibilities
2. The first counseling visit when PPH and misoprostol are discussed
3. The second counseling visit at approximately eight months when the pregnant woman receives misoprostol
4. A postpartum visit within 24 hours and then another within seven days

Sometimes these visits can be collapsed, for example, if the CHW has not registered many pregnant women and thus can combine registration with the first counseling visit. Sometimes, a woman is not identified until she is in her eighth month, and thus her first counseling visit and the visit to receive the medication are combined. Because the ultimate goal is to integrate misoprostol programming with the full spectrum of community-based maternal health programming, the content of these visits may also be included with other CHW activities. For example, if CHWs are already responsible for an immediate postpartum

visit soon after birth to check on the newborn and mother, the postpartum interview can be obtained during that visit.

During counseling, the CHW should direct her information not only to the pregnant woman but also to her support person. Typical support people include her husband, mother or sister, mother-in-law, or a neighbor. The support person can help the woman remember to take the medicine right after the baby is born and also be aware of any side effects. The other important reason to include the support person, especially if he or she will be responsible for care-seeking decisions (such as the husband or mother-in-law), is so that the person can understand the danger signs in pregnancy and how quickly PPH can cause death.
A successful counseling visit should:

- Happen in the woman's home.
- Include her support person.
- Be convenient to her schedule so she has time to listen and ask questions.
- Take between 30–60 minutes and include time for questions and clarification.
- Use visual aids such as flip charts and cloth models.
- Be interactive and respectful. The pregnant woman should be engaged in a discussion rather than "talked at" and her beliefs should be respected. Role plays are a good way to explore and practice emergency situations.
- Use the interpersonal skills learned in training.

See **Annex D** for the key messages to be conveyed to the pregnant woman and her support persons.

> "After I took the misoprostol, I began to shiver and I started to become a little scared. Then I remembered what the CHW had taught me about side effects. So I drank some warm tea and was soon okay."
>
> —A woman who has participated in the misoprostol program

During visit when the woman is eight months pregnant, the CHW should:

- Give the woman and her support person, if present, all of the information that she gave to them on her first visit to the home.
- Ask the woman and her support person to repeat the information to her in their own words.
- Repeat any additional information that the woman did not remember, and correct any misinformation in the same way that she did at the first visit.
- Obtain the woman's signature that she has understood the information and is planning to take the misoprostol.
- Give her information on how to store and when to take the tablets.
- Ensure that the woman and her support person understand this information, especially when to take the misoprostol.
- Request the pregnant woman and support person to repeat back the information again about when to take the misoprostol and how to store it.
- Give the woman the misoprostol only if she and her support person can repeat the information completely and correctly.

CONFIRMING WOMEN'S COMPREHENSION OF MISOPROSTOL USE FOR PPH PREVENTION

The CHW will know that the woman understands the information about PPH and misoprostol if the woman can tell her:

- The danger signs for PPH
- The causes of PPH
- How to store the misoprostol tablets
- When to take the misoprostol tablets
- Side effects and what to do if they occur
- What to do if bleeding does not stop after taking the misoprostol

The CHW should make sure that the woman and her support person understand that they should not give the misoprostol to any other pregnant woman for her to use. If the woman does not use the misoprostol, she should return it to the CHW when she visits after the baby is born. If the woman does not want to use misoprostol, the CHW should record the date of the visit and the reason why the woman did not wish to use the drug. If the woman is no longer pregnant, the CHW should record the date of the visit and note the reason if known (for example, spontaneous abortion, premature childbirth, or incorrect calculation of estimated date of childbirth and has already given birth).

Sometimes when doing the eighth-month visit, the CHW finds that the woman who was registered is no longer at her original address. In this case, the CHW should talk to community members and elders to find out where she is living. If she has moved to another village or homestead within the CHW catchment area, the volunteer should visit her at her new address and write down her new information. If the woman has moved to a village or homestead that is not within her area, the CHW should inform her supervisor of her new location.

If, during home visits to other registered women, the CHW meets a pregnant woman who is new to the community, the volunteer should ask the woman if she received information or misoprostol in another village or homestead.

If the woman has not received information, the CHW should:

- Register her.

If the woman has received only information, the CHW should:

- Ask her to repeat the information.
- Give her any additional information needed.
- Correct any misinformation, and give her misoprostol if she wishes to use it.
- Add the woman to her registration form.

If the woman has already received misoprostol (possibly from another CHW), the CHW should:

- Check that the medicine has been kept in good condition.
- Ask her to repeat the counseling and information she received.
- Give her any additional information needed.
- Correct any misinformation.
- Add the woman to her registration form.

KEY MESSAGE

GIVE MISOPROSTOL ONLY TO WOMEN WHO UNDERSTAND THE INFORMATION THEY RECEIVED

Do not give misoprostol to a woman who has not been given all of the information about PPH and how to use misoprostol.

Before giving it to any woman, be sure that she can repeat back to you all of the information on how to store and use misoprostol correctly.

Distribute the Drug to Pregnant Women

Drug distribution will vary from country to country. Stock at each level should depend on the average number of deliveries expected, and at least one full month of stock on hand should be maintained at all times. The following is an example of protocols developed in Afghanistan:

> Misoprostol is distributed from the national or central level warehouses out to the provincial and district health systems. The coordinating supervisor for the region receives the drugs and then distributes them to each community health worker according to the number of pregnant women she has registered, or the midwife at the local health center can give the community volunteer 20 doses of misoprostol. The supervisor re-orders stock depending on the average number of pregnant women or deliveries they are experiencing a month, but always keeps one month of stock on hand. (A sample "Drug Request and Receive Form" from Afghanistan can be found in Annex E of the 2009 implementation guide.)
>
> When the volunteer has five doses of misoprostol remaining, she should give her record form to the midwife at the local health center. The midwife will then give her 15 more doses of misoprostol, to keep her stock at 20. If the volunteer has less than five doses of misoprostol remaining, the midwife will give her enough doses to total 20 doses. Since a CHW will distribute the medication over a certain time period, she should make sure to keep the pills in a safe, locked, dry place in her home where there is no possibility of the pills being damaged or stolen.

The drug should be distributed to each registered pregnant woman after she has received counseling and is in her eighth month. The CHW should observe the pregnant woman's house and make recommendations for where a safe place would be to store the drug. The drug should be stored away from children and under lock and key. It is important that the support person for the woman know where the drug is kept and where the key is kept so he or she can give the woman the dose within five minutes after she has delivered her baby.

During the follow-up postpartum visit, the CHW will make sure to record when and how the drug was taken and if there were any side effects. (**Annex G** presents a pictorial version of the record form.) Sometimes women forget to take the drug. If that is the case, the CHW should return to the supervisor any misoprostol that she collected from a registered woman after delivery. The supervisor will inspect the misoprostol to see if the pills are broken, discolored, or wet. If they are, he/she will destroy the misoprostol. If the misoprostol is in its original packaging and is not damaged in any way, the supervisor may return it to his/her inventory.

Conduct the Final Postpartum Visit

The very last step in the full implementation of Phase III is to conduct the final postpartum visit. The CHW should visit the woman soon after birth to check that the woman and her newborn are both well and to assist in a referral in the event that there are any problems.

During the visit, the CHW should verify if the woman used the misoprostol correctly and take back the misoprostol if she did not use it. (The CHW should keep all returned misoprostol separate from her other misoprostol so that it can be returned to her supervisor

as was explained in the section on drug distribution). The following information should be recorded on the postpartum visit form:

- Date of the visit
- Date of childbirth
- Place of childbirth
- Whether the woman was attended by a SBA
- When the woman took the misoprostol (before birth, after the birth of the baby but before delivery of the placenta, after birth of the baby and delivery of the placenta)
- Any side effects the woman had
- Whether the woman thought she had more bleeding than normal
- Whether the woman went to the health center or hospital after the birth, and why
- If the woman would take misoprostol again

Please see **Annex G** and the PPH toolkit for examples of postpartum visit forms.

Recognize and Reward High Performers

Although advance distribution of misoprostol is integrated into ongoing maternal health responsibilities, already busy facility-based providers and CHWs may perceive the PPH prevention activities as additional work. Maintaining motivation therefore is important to sustain the program's quality, distribution and coverage over time. People are motivated by many different things, not the least of which can be feeling as though they are part of something larger that is doing something to help others in their community. Most people also respond positively to recognition for their contributions. This applies to everyone involved in the program from those who were tasked with supporting and supervising CHWs to the CHWs themselves, to health facility staff who may be responsible for some aspect of M&E.

Explore what would be of value to the various people involved in the program and feasible to procure. Often programs choose to provide items as rewards that also help people in their work or identify their contribution. For example, CHWs may receive bicycles to assist with household visits, or t-shirts, bags, or nametags, which identify them as trained CHWs. Public recognition is also often valued. Identify the metrics used to determine "high performers" early on and make them known to those working with the program so that they have clear expectations and goals.

It is important to recognize and remember that most people will have had busy jobs and busy lives, before adding on the additional tasks associated with getting misoprostol into the hands of women. Knowing that their contribution is helping to make a difference and is recognized and appreciated helps make that work meaningful and continues to motivate people to stay engaged.

PROGRAM MONITORING AND SUPPORT

This section describes key monitoring and quality improvement measures to support problem-solving and decision-making during the implementation phase. Although this section follows program expansion, monitoring and support run through the entire planning and implementation process. They should be considered early and often and integrated with other program planning activities:

- Phase I – Review not only the results of previous implementation, but the performance of the previous program monitoring and support.
- Phase II – Consult with the MoH, implementing partners, and other key stakeholders to develop an M&E framework and supportive supervision system with accompanying

standardized materials (data collection and supportive supervision [SS] tools) and procedures (the frequency, timing, and responsibility for conducting M&E and supportive supervision activities as well as the method for aggregating data at a central level across PPH prevention implementing partners).

- Phase III – Train those involved with program monitoring and support according to their responsibilities; start collecting and analyzing data and conducting supportive supervision activities.

Throughout the phases, ensure that national/regional/district-level staff and partners have an opportunity to discuss the M&E processes, priorities, and any concerns. To mitigate the financial and human resource burdens of M&E and supportive supervision, and to aid long-term sustainability and integration, program monitoring and support should be integrated into existing government systems instead of developing a "vertical" monitoring and support system. Program monitoring and support will likely need to be simplified from the introductory research phase to be integrated into government systems for expansion. During the revision process, understanding how the government systems at the district and community levels currently support M&E and supervision will help revise tools and processes realistically, as well as address any issues identified in the pilot phase. Prioritizing development principles in conjunction with the most essential M&E and SS activities with the MoH and partners ahead of time will be helpful in planning for expansion.

KEY MESSAGE

Build on existing government systems,
and ensure consistency across all PPH prevention projects.

Strengthen Supportive Supervision Systems

Supervision systems in developing countries tend to be weak as a result of scarce human resources, limited transportation options, and competing priorities. Strengthening the existing supportive supervision system for CHWs as well as health care providers at facilities is a contribution that program expansion can make to the overall functioning of the public health system.

Supportive supervision can be helpful at many levels to:

- Help new trainers develop their facilitation skills and master the training material
- Strengthen new supervisors' supportive supervision techniques such as coaching skills (See Toolkit for coaching skills checklist.)
- Reinforce new knowledge and skills of facility-based health care providers
- Reinforce new knowledge and skills of CHWs/TBAs

It may not always be necessary to provide supportive supervision to trainers and supervisors if they are experienced in these roles; quarterly or biannual meetings may be sufficient to share experiences, solve problems, and practice skills together. It is, however, imperative to provide ongoing support to health care providers and CHWs to fully realize the benefits of training and for quality assurance purposes. It can also be highly motivating for providers and CHWs to receive visits that reinforce knowledge and skills, help problem-solve, and reaffirm their important roles.

Often trainers offer supportive supervision to health care providers and CHW supervisors. The CHW supervisor should be someone based at the nearest health facility who has also undergone training on the components of the program; this is often an ANC provider. This

supervisor will be responsible for monitoring the distribution of misoprostol tablets first to the CHWs and then to the pregnant women.

Common supportive supervision activities include:

- **Facilitation of monthly or quarterly meetings:** These can be also held with health care providers or CHW supervisors but are essential for CHWs. The meetings are an opportunity for all CHWs in a catchment area to exchange experiences and ideas, and problem-solve together. They also provide the opportunity for mini refresher trainings and/or counseling practice. When practicing, the CHWs can work in small groups observing and coaching each other with the help of job aids. These meetings are also good opportunities for collecting, reviewing, and aggregating data from the CHW registers. Supervisors may also find it useful to complete meeting report forms and/or take notes to track CHW attendance, successes, and common difficulties. Established CHW networks usually have these types of regular meetings into which PPH prevention activities can be integrated.
- **Direct Observation:** This gives those providing supportive supervision the opportunity to provide "live" feedback to those they are supporting. It is also an excellent quality assurance measure to verify the adequacy of counseling, health care provision, training, and/or supportive supervision. For CHW supervisors, this means making supervisory observation visits to watch CHWs counsel women in their homes. The CHW performance checklist (Annex E) can be used as a supportive supervision tool during this visit. Similar tools exist for providing supportive supervision to ANC providers and SBAs.

Those offering supportive supervision should be careful not to be punitive and instead focus on using facilitation and coaching techniques. A recommended format to follow when coaching is:

1. Before the observation session, ask the participants to reflect on their previous performance and what they would like to work on during the current session; review any parts with which they are having difficulty.
2. During the observation, take notes, corresponding to a job aid if applicable, and provide positive reinforcement and suggestions for improvement.
3. After the observation, provide feedback: first ask the participants what they did well and where they could improve; next, referring to notes, tell the participants what you observed them doing well and what could use improvement; finally, work with the participants to establish goals for improvement.

Supportive supervision activities need to be more frequent during the first six to 12 months, usually held weekly or monthly, to address implementation challenges as they arise, and thereafter less frequent activities are usually sufficient. The ability to provide supportive supervision is often limited by the number of trainers available, so factor into training plans how many trainers/supervisors you need based on the time required for supportive supervision. Finally, consider involving MoH officials from various levels in supportive supervision activities to strengthen ownership, motivate staff, and help address any challenges.

Review Guiding Principles

Balance Data Needs with Collection Burden

While a resource-intense data collection system was likely designed to answer the research questions posed in the pilot(s), in most circumstances the burden of such data collection will make it un-scalable. When transitioning to expansion, the purpose of the M&E system shifts from answering research questions to program monitoring and performance improvement. To make data collection both scalable and sustainable, it will need to build on and be integrated with existing government systems. In many countries, such as Afghanistan, it will also mean simplifying forms and tracking procedures.

During program expansion, data collection should inform program performance and help managers in problem solving and improving coverage of the intervention. The overall goal of the program is to increase the coverage of uterotonics during the third stage of labor. For the program to achieve its goals, inputs (such as drugs, the training of health workers and CHWs, and identification and counseling of pregnant women) must result in outputs—such as the number of women reached by the intervention. Fundamentally, every expansion area needs to have a monitoring system in place to answer the following key questions:

- What is the **distribution rate** that is achieved with the intervention? [Proportion of all pregnant women in the catchment area who received misoprostol for the prevention of PPH]
- What is the **coverage rate** of uterotonic for health facility and home births? [Proportion of all women who delivered in the catchment area who ingested or received a uterotonic at the time of birth. May also be disaggregated for facility and home births]

Collect Data to Inform Quality Improvement

Quality improvement mechanisms should become an integral part of the program. The quality of services affects the outcomes and eventually the impact of the intervention. Even when a large percentage of the target population is covered by services, poor quality facility- and community-based health services—those not delivered according to recognized standards—may have sub-optimal or even adverse effects on the health of the women.

Quality of service measurement and management should be an ongoing activity and should be combined with routine monitoring. Some questions to ensure quality service delivery are:

- Have enough health workers and CHWs been trained to ensure almost a 100% distribution rate?
- Do CHWs have adequate knowledge of misoprostol?
- Are key messages provided during counseling of the clients?
- How often are stock-outs of oxytocin and misoprostol experienced at health facilities or by community-level distributors?
- Are drugs properly stored and disposed of prior to their expiration?

Include Measures of Equity

The advance distribution of misoprostol approach addresses inequity because it emphasizes reaching out to women in remote and inaccessible areas and providing prevention against PPH, irrespective of place of delivery. Progress on measures of equity—including access, coverage, and outcomes—should be assessed at each stage of implementation. For example, in the Nepal pilot, household surveys measured increases in uterotonic coverage (oxytocin and misoprostol) by three elements of social disadvantage (wealth, literacy, and remoteness). The implementation team should identify opportunities for strengthening M&E systems to monitor progress toward an equitable program implementation. Possible strengthening measures could include qualitative studies to explore barriers in access for certain populations and data disaggregation and analysis by geographical location, socioeconomic status, vulnerable population, or other characteristics according to context.

Develop an M&E Plan

A unified M&E plan should be prepared at the time of planning for the intervention during Phase II. The plan should be developed in consultation with implementing partners and stakeholders, including national and subnational MoHs. While individual implementing partners may have specific reporting requirements, the unified plan should represent the minimum indicators that will be tracked, tools (data sources) used to track them, and the frequency and method for data aggregation to the central level. Depending on the context,

the responsibility for various M&E activities may be determined centrally (in the unified plan) or by individual implementing agency.

Select Indicators for Program Monitoring and Quality Improvement

Based on the guiding principles outlined above and multi-country experience, MCHIP has developed a set of indicators, listed in **Annex F**, which provide a standard benchmark for measuring results across time and between intervention areas. It is highly recommended that the seven core indicators, highlighted in bold, be considered as a minimum core set that is needed for adequate program monitoring and quality improvement across all implementing partners. It is important that common indicators used by different implementing partners have the same definition and data sources so findings can be aggregated and compared.

An online global misoprostol database has also been developed to capture these indicators. The core indicators measure:

- Distribution, usage, and coverage rates of misoprostol and oxytocin at home and in facilities
- Correct use of misoprostol by women in their homes, adverse events, and satisfaction with taking the drug
- Effects of the program on facility usage rates for deliveries and referrals for complications
- Progress toward meeting training targets and training effectiveness in terms of CHW knowledge regarding the appropriate use of misoprostol
- Frequency of misoprostol and oxytocin stock-outs

Some indicators may or may not be part of existing HMIS systems at the national level, but are crucial to inform program management. It may be necessary to collect project-level data for the initial period, and as country HMIS are revised, efforts should be made to incorporate necessary indicators within the HMIS. For any indicators that are ultimately included, ensure that adequate systems are in place to collect and report high-quality data.

Identify Data Sources

To harmonize reporting with ongoing data collection efforts, it is important to consider all available data collection methods in the country. Suggested data sources for selected indicators can also be found in **Annex F** and in the online toolkit. The data collection schedules should be summarized in a table and included in the M&E plan. Most data should be able to be gathered with small modifications to existing registers and forms in the HMIS.

The following data sources may need to be created or adapted to meet program needs:

- **CHW and/or ANC registers:** The CHW register is the key source of information for distribution rates and the home birth coverage rate. It can also be used to collect data for a number of other indicators. CHWs should keep a Registration and Drug Distribution Register of all pregnant women and deliveries in their catchment areas. At a minimum, the CHW register should include information about the mother's home visits, place of birth, delivery outcome, referrals, and information on misoprostol administration (whether it was offered and taken correctly). Often, CHWs with maternal health responsibilities will have a register for recording most of this information. There is no need for a program-specific register as long as the additional information specific to misoprostol is included/added to existing registers. In some programs where misoprostol is distributed at ANC as well as through CHWs, the ANC registers should record registration and drug distribution.
- **Labor and delivery (L&D) register, hospital admission form, and adverse event reporting form:** If not already included on the L&D register, notation for

administration of a uterotonic during the third stage of labor should be added. It may also be desirable to indicate whether women had been registered and counseled by a CHW or ANC provider. In the case of admissions, whether a woman had ingested misoprostol prior to arrival can be recorded.

Adverse events (such as ruptured uterus, fever more than 40°C, and retained placenta) should be tracked carefully and reported on a regular basis. This information may be added to the CHW register and hospital admission form and/or an independent adverse event form may be created. All CHWs and other facility-based providers who handle misoprostol should be trained on collecting, monitoring, assessing, and evaluating information from health care providers and patients on adverse effects of medication and should be trained on the reporting of any adverse events.

- **Drug management system:** To ensure regular supply and availability of misoprostol and oxytocin, it is essential to maintain a routine record of their receipt and distribution. In some cases, there are exiting stock cards that can be used for this purpose, but if not, it is highly encouraged to design one. This will also be helpful in gathering information on stock-outs. Many programs use monthly misoprostol consumption logbooks for this purpose.
- **Postpartum follow-up survey:** Periodic postpartum follow-up surveys (every six months to a year) are recommended as a quality assurance mechanism. A survey tool example as well as accompanying Access database template can be found online on the PPH toolkit. Data collected should include: delivery information, such as place of birth and type of birth attendant; birth outcome for mother and newborn; questions regarding counseling messages received, whether or not misoprostol was received, and used and who distributed it; if misoprostol was used correctly (timing, dose, and route); perception of blood loss and complications (PPH experience); and any information on referral or additional interventions/treatment at facility, if applicable. Any side effects experienced by the woman after taking misoprostol should also be noted, along with her satisfaction with use of the drug. Data from the survey can be compared against other data sources and used to gather information on the need for refresher training of CHWs in specific areas. It is proposed that these interviews be conducted with a sample of women in their postpartum period. Women can be identified using a small-scale sample methodology called lot quality assurance sampling (LQAS). Implementing partners planning to conduct postpartum follow-up surveys are encouraged to work together to use common tools and sampling methodology to ensure that findings are comparable.
- **Maternal death audits and "near miss" reviews:** Maternal death audits and "near miss" case reviews are an essential part of the overall monitoring system of this program. It has been observed that in many countries maternal death recording and audits are very weak. It is highly recommended to strengthen this aspect of data collection and analysis. It provides valuable information for identifying reasons for maternal death and informs health systems to prepare for corrective action. Carefully monitoring all maternal deaths that take place within misoprostol programs is also of paramount importance as concerns remain concerning its safety in the context of self-administration for PPH prevention. A maternal death audit and "near miss" review format have been provided in the toolkit.

Creating or adapting data sources is best done collectively, led by the MoH with implementing partner involvement. Take advantage of any ongoing efforts to use mobile phones or tablets for data collection to potentially reduce the collection burden. These technologies offer the advantages of reduced human resources needed to transcribe and aggregate data, fewer transcription errors and lost data, and access to real time data analysis. Disadvantages include potential connectivity issues, comfort with data entry, and cost of the devices.

Set Targets

Setting ambitious yet realistic targets for indicators is an important element of the planning process. Good programmatic targets should be linked to a comprehensive and up-to-date

analysis of the situation, including estimates for the number of pregnant women in the intervention area.

When setting targets, the team should consider current and anticipated constraints to scaling up programs. Progress can be hindered by an array of challenges involving lack of skilled human resources, infrastructure, facilities, equipment, and systems that support the provision of services. Measures to overcome these obstacles should be addressed through health systems strengthening activities.

The following steps are recommended for setting targets:

1. Define estimated number of pregnant women in the intervention area: because this is the denominator for measuring program performance, review census data and crude birth rates carefully and make adjustments as needed.

1. Define the current coverage of women receiving ANC and counseling at the community level: current information on CHW coverage may be difficult to find; if so, try to estimate it based on available data and experience.

2. Project the potential for scaling up the delivery of interventions and services for each six months for which targets are to be set, taking into account the following limitations and the parallel efforts to reduce their impact on program performance and scale-up:

    - Constraints, such as limitations in human resource capacity, procurement and supply management, equipment and transport facilities;

    - Environmental obstacles, such as geography and terrain, political situation, physical infrastructure, and climate.

3. Set specific and ambitious annual targets for interventions and services based on the gap analysis (a method to estimate the number of people in need of services that are not yet covered by existing programs) and an understanding of the feasibility for scaling up. Activities aimed at reducing the impact of the identified barriers, constraints and obstacles elaborated below also should have targets.

4. Identify activities and establish targets to reduce the impact of identified barriers, constraints and obstacles.

    - Determine the resources currently available (e.g. human, material, and financial resources).

    - Identify what and how many additional resources will be needed to address the barriers, constraints, and obstacles.

Implement the M&E Plan

Ensure Data Quality and Management; Reinforce/Adapt Training as Necessary

Local counterparts should be responsible for monitoring data collection and identifying both data quality and collection issues early in the program. This will require working closely and collaboratively with the local MoH officials in the district, province, or region. Monitoring should be done on a regular basis and should be aligned with existing quality assurance practices.

Project staff also may provide support to clarify data recording on forms, assist with data entry, and help with data analysis. When reporting and recording are not functioning well, visits can be jointly planned to areas with identified problems, or a larger refresher training can be organized. In addition, the M&E portion of the initial CHW, ANC provider, and SBA trainings should be re-examined to see if the training methodology or content can be strengthened for better results. If data collection methods have changed from the pilot phase, remember to retrain those responsible for M&E in the pilot region(s). Sufficient resources must be budgeted for in anticipation of these possible needs.

The team should ensure that data meet the recommended data quality assessment criteria. Steps to ensure that data meet quality standards include:

- Agree upon definitions and documentation needed for each indicator at the global and country levels.
- Compile and house data and documentation to support results reported in a systematic way.
- Develop data collection forms that are well-designed and conform to M&E best practices.
- Provide adequate training to individuals who record information on data collection forms and build their capacity to aggregate and use this data to inform programs.
- Prepare and distribute standardized M&E guidelines.

Data quality validation procedures should include periodic review of a sample of data from key data sources used at the community and health facility levels.

The M&E plan should outline how data and reports are managed at sub-national and central levels (including data collection, storage, processing, and analysis). Data collected on CHW records, registers, and reports should be stored properly at health facility or district level. Further, a Microsoft Office Access database has been developed for entering and analyzing postpartum follow-up survey data, the template for which can be found in the toolkit.

Routinely Analyze Data and Prepare Reports

The M&E plan should provide details of data analysis and periodicity of analysis. The main analysis should focus on monitoring the number of beneficiaries in each program component on a monthly basis. Other descriptive statistics should include indicators related to the quality of service provision, service utilization, and misoprostol distribution and use.

The analysis plan should include assessment of all three program activities (health education during ANC or BP/CR by CHW, AMTSL/misoprostol at health facility, and misoprostol distribution and administration at home births), using descriptive statistics and initial analysis.

A trend analysis should be conducted on uterotonic data to examine the proportion of women receiving uterotonic as well as the numbers of births at the facility. The misoprostol distribution analysis should include summary statistics of distribution and disaggregation by source of distribution.

Data ideally would flow through MoH data collection systems to the central level. Agreed-upon channels for accessing data or supporting analysis should have been decided in the planning phase. If projects are additionally collecting data, these processes need to be streamlined to provide local MoH officials, project staff, and central level MoH officials access to timely data.

An online database has been created to capture aggregate data on the suggested indicators. The database helps in collecting aggregate data on a monthly and quarterly basis, generates reports for monitoring, and identifies gaps in program implementation.

Hold Regular Meetings with the Stakeholders for Continual Feedback

Regular meetings at all levels will provide opportunities for dialogue and feedback into the program. Review meetings and TAG meetings have been discussed in this section already. Here, the important point is not the number or frequency of scheduled meetings but the openness to feedback and ownership among communities, providers/CHWs and local MoH officials.

Analyse, Share and Use Results

Enter Aggregated Data in Online Global Misoprostol Database

The online global misoprostol database was designed to provide individual implementers as well as countries the ability to easily track core program indicators over time and across intervention areas. It is also intended to inform global guidelines concerning the self-administration of misoprostol by showing correct usage rates and safety information across a broad array of implementation contexts and a large number of users. Program data will not be shared or published without the consent of the organization that entered it. Please see http://data.mchip.net/pph/ for more information and a detailed users' guide.

Use Lessons from the Field, Program Results, and Client Feedback to Improve the Program; Share with Other Implementing Partners and Where Possible in the Region

Data for decision-making at all levels are essential. Measurement should be directed toward quality improvement and corrective action. We should ensure that the data collected are analyzed—to check if we are making progress by enrolling more pregnant women at health facility and community levels, and ensuring they receive the appropriate messages and are satisfied with the program.

Additionally, ongoing program review meetings (suggested every six months) at the appropriate local level can be conducted to facilitate sharing of lessons learned, achievements, and challenges. At these meetings, data aggregated at the project or central level can be shared to demonstrate progress.

Review meetings need to take stock of distribution and coverage rates and help adjust program implementation accordingly. Coverage will not be uniform across an implementation area, so it is important to discuss how best to reach the most vulnerable women in need of PPH prevention.

Documentation is an essential part of this step, and it is suggested that the program identify the types of publications (such as progress reports, human interest stories, final end of project report, journal articles) needed to adequately document and disseminate implementation, lessons learned, and output/outcomes within the country and, if possible, to the larger maternal health community. Budget adequately for the human resources for documentation, printing costs, and dissemination activities (including conference presentations).

Part Three: Lessons from the Field

PROGRAM IMPLEMENTATION CHALLENGES AND SOLUTIONS

In the process of planning and implementing an expanded PPH prevention program, there may be unexpected challenges. This section provides examples of potential challenges with their possible solutions. This section of the guide will be updated as more and more countries scale-up advance distribution programs for misoprostol. Guide users are urged to share their lessons learned with the editors.

ADVOCACY AND POLICY

Challenge: **Previous members of the consensus-building groups change during the planning for scale-up and raise issues previously discussed and resolved.**

Solution: As a working group or TAG, provide frequently asked question (FAQ) sheets to all new members and minutes from previous meetings so they can see and understand the record. Assign someone to orient new members to the history, outcomes, and decisions-making processes of previous implementation in country.

Challenge: **The MoH is supportive of scaling up an initial pilot program but national policies concerning scope of practice and who may distribute and administer misoprostol have not yet been updated. District-level managers, providers, and pharmacists are concerned about liability.**

Solution: Identify key area of concern for local actors and determine what types of assurances from the central government or MoH would be needed for them to feel comfortable participating in the advance distribution of misoprostol. Continue efforts to bring national policy and guidelines into alignment with program design and disseminate up-to-date information relating to policy changes.

CHWs

Challenge: **There is no existing CHW cadre in one of the districts identified for expansion.**

Solution: Depending on resource availability, capacity and previously determined selection criteria determine if selected district should be reconsidered. If moving forward, determine if TBAs are active in the area and consider using them for identifying and counseling pregnant woman and distributing the drug. If not, identify an implementing partner who has experience with developing CHW programs and ask the partner to assist with implementation in that district. See Phase II: Select Local Community Counterparts for additional information. Additional focus may also be placed on antenatal distribution where there is no functional CHW cadre until one can be developed.

Challenge: **CHWs in the pilot project all had basic reading and writing skills but in areas selected for expansion the majority do not.**

Solution: With other implementing partners, collect examples of training materials, job aids, and M&E forms used in other programs with low literacy rates. Examples can be found at http://www.k4health.org/toolkits/postpartumhemorrhage/g-me-tools. Some programs have decided to give literate and non-literate CHWs different roles while others have successfully used only non-literate CHWs or TBAs for full implementation. Adapt the materials as necessary to standardize countrywide. Consider using the materials for non-literate CHWs for everyone, particularly the M&E forms, so that the same data are being collected and can be easily aggregated and compared.

Challenge: **CHWs are unhappy they are not getting paid.**

Solution: Increase the number of CHWs working with the program so that no one volunteer must spend too much time on the program or on the road Identify other changes that may improve their job satisfaction and/or limit the burden of their activities. Identify alternative forms of remuneration or motivation that would be desirable. Facilitate discussions with the community as a whole to evaluate the potential for community-derived remuneration. In some countries, CHWs earn income through selling health-related commodities such as family planning products, latrine kits, etc. Countries with active social marketing programs can consider pilot-testing sales of misoprostol by CHWs. Finally, determine if another cadre of health care providers can oversee the program or if paying volunteers a small stipend is in accordance with government compensation rules. These are a few of many potential solutions; see www.chwcentral.org for more ideas and information.

Challenge: **The formal language of instruction used for health promotion messages is not understood at the village level.**

Solution: To maximize comprehension among village-based pregnant women, counseling must be provided in the local language. During trainings, have the cadre who will be distributing misoprostol practice counseling sessions in the common language of the women they will be serving. Using CHWs as counselors usually alleviates this problem and may partly account for the higher coverage rates seen when distribution is by CHWs as compared to ANC providers.

PREGNANT WOMAN EDUCATION AND MISOPROSTOL DISTRIBUTION

Challenge: **Identified pregnant women do not want to be registered in the program.**

Solution: It is their right not to participate in this program. They should be informed that they may, at any time before they deliver their baby, still be able to participate and to receive the drug after receiving counseling. Counseling messages should still be given.

Challenge: **Pregnant women are unable to remember counseling messages and thus are ineligible to participate in the program.**

Solution: If a pregnant woman is unable to comprehend the key counseling messages, the counselor must first try different approaches of sharing the information, such as using visual cues or role plays. Having women and their families act out the birth will not only help them remember what to do but will show the counselor where there is any confusion or misunderstanding. A support person who will likely be present during the birth (such as the husband, mother, or other relative) should be included in the counseling, and their comprehension of key messages should be checked so that they can help the

woman at the time of birth. If the counselor still feels that the key messages are not well-understood, and she or another provider or trained CHW live nearby, she may plan to have someone qualified to administer the drug, check in on the pregnant woman frequently, and provide the medication after birth.

Challenge: **Pregnant woman shares or gives her medication to someone who has not undergone counseling.**

Solution: During the counseling, all pregnant women need to know that the medication will be tracked, and that it is not safe to provide the medication to women who have not been adequately counseled. Ensuring that the medication is not distributed until pregnant women enter eight months of gestation will also reduce the possibility of sharing and inappropriate use.

Challenge: **Pregnant woman receives two doses of the medication from different service providers.**

Solution: When receiving the drug, pregnant women should be counseled that one dose is sufficient and they should not have two doses. Clear demarcation of catchment areas for CHWs can help prevent overlap, as can inclusion of misoprostol distribution status on ANC cards. The health services system needs to have a tracking system in place so that each prescribed dose is linked to both a pregnant woman and a service provider. In systems where CHWs report to a SBA or other provider, the supervisor is responsible for managing the distribution of the drug.

Challenge: **A woman refused to be registered in the program because she planned to deliver with a midwife. She fails to deliver with the midwife, however, and is being attended by an unskilled provider and she now wishes to take the medication.**

Solution: Counseling messages should stress the concept that advance distribution of misoprostol is for ALL women, regardless of where they plan to deliver. Sometimes unexpected events prevent delivery with a SBA or prevent that SBA from having a uterotonic on hand, in which case the misoprostol can be used. For a woman who has not received counseling, if a trained CHW who has the medication can be found, the CHW may administer the medication. The point of the counseling is to ensure that pregnant women take the medication appropriately if they are alone. If a trained CHW is present, the CHW can ensure appropriate use.

Challenge: **CHWs face resistance from family members during advance distribution of misoprostol tablets.**

Solution: Provide all counseling sessions together with the pregnant woman and her family (including support person) so that everyone receives the same information and has the opportunity to ask questions. Identify and respect their concerns about misoprostol and try to correct any misinformation. Refer them to other women/families in the community who are willing to discuss their experience using misoprostol. Efforts to sensitize the wider community, particularly community leaders and TBAs, to BP/CR and PPH prevention can be helpful in garnering support. If CHWs are facing resistance from many families, consider holding group meetings where concerns can be discussed together. Try to include women/families who have already used misoprostol.

DRUG PROCUREMENT AND LOGISTICS

Challenge: **NGOs are ready to begin expansion into new districts. The MoH is procuring the misoprostol, but because of the tender process, it will be 6–12 months before the drug arrives in country.**

Solution: Advocate for a special one-time importation permit for misoprostol so no delays in programmatic activities occur. Because misoprostol is on the WHO List of Essential Medicines, the in-country UNFPA office may also be able to offer assistance with procurement. Work with the local distributor and contact the manufacturer of the registered product to complete the procurement.

In the future, always factor procurement into the implementation timeline. Do not start trainings until it is known the tablets will be ready for distribution immediately afterward.

Challenge: **More misoprostol was procured than used by the program during the first year of expansion. Current misoprostol stock will expire soon.**

Solution: Plan for a recall and substitution of the expiring stock no later than one month prior to expiration. Inquire and use the country's system for recall of expired drugs.

Determine if births were fewer than expected or if coverage was lower than expected. If coverage was low, determine what gaps or barriers to use are. For example, were enough CHWs trained in the expansion areas? Were IEC/BCC materials effective in demand generation? Did stock-outs occur at distribution points even though adequate supplies were available elsewhere? Review and strengthen forecasting and quantification methodologies for future procurement. When forecasting for program expansion, take into account whether all new districts will start distributing the drug at the same time or if there will be a staggered program rollout.

Challenge: **Drug quality assurance results show that the active ingredient in the tablets is degrading over time, prior to their expiration dates.**

Solution: Brief the MoH and then present this issue to the working group or TAG. Contact the distributor and local drug authority to learn about recall procedures due to quality issues. Proceed as required by the food and drug authority in the country. If imported tablets have come from different batches, test samples from each batch. Ensure that all affected tablets are recalled and destroyed. Encourage the MoH to issue a press release to implementing partners. Find another source of misoprostol tablets for procurement. Strengthen quality assurance procedures.

Challenge: **There is sufficient misoprostol stock in the central medical store, but distribution bottlenecks are resulting in stock-outs at the community or district levels.**

Solution: Create awareness and provide copies of PPH program guidelines that include misoprostol to central medical stores; provide also a copy of PPH program implementation areas/districts. Review the ordering form at district/facility level. Make sure misoprostol is included on the form. Pinpoint which districts or facilities are experiencing stock-outs, identify remaining bottlenecks (such as floods or staff transfer), and explore solutions with district/provincial government officials.

Challenge: **There are stock-outs reported at the community or district levels caused by stock-outs at the central medical stores.**

Solution: Brief the MoH and then present this issue to the working group or TAG. Contact the local distributor, private sector, and NGOs to assess whether they can immediately ship tablets to the districts implementing PPH programming with misoprostol. With the MoH and the working group, review forecasting and quantification; make sure all product procured and

distributed by the public sector meets the national need for all approved indications for misoprostol.

MONITORING AND EVALUATION

Challenge: **There are proportionally fewer funds allocated to monitoring and evaluation activities in the plan for scale-up than were available during the pilot phase. Additionally, there are complaints that the M&E requirements are too burdensome.**

Solution: The M&E requirements of scale-up projects should be fewer than those required during a pilot. With health facility staff, identify where data collection, aggregation, and analysis can be integrated with the existing HMIS and routine health care. Advocacy and sensitization related to the importance and use of M&E information, and sharing of M&E results with those providing the data, may alleviate these challenges. Implementing partners should be careful not to make this a parallel activity but to integrate M&E requirements with other program activities from the beginning.

Challenge: **Different implementing partners are using different methods of data collection so results are difficult to aggregate and compare.**

Solution: Based on multi-country experience, MCHIP has defined core indicators that should form the basis of the M&E framework for this type of program. These indicators are minimally burdensome to collect and can be used to feed into the global database, which will aggregate data across country programs to inform changes to the WHO recommendations for advance distribution of misoprostol. Use the core indicator definitions and recommended data sources to standardize methods of data collection. Overall, it is important to be sure monitoring forms and household surveys define the indicators in the same way.

Challenge: **It is discovered that people are interpreting various M&E data entry fields differently.**

Solution: Finish standardizing M&E forms and reporting requirements prior to rolling out trainings. Make sure all indicators have clear definitions, directions for estimates and source data if needed, and explanations of how they will be used. Ensure that trainers at the top of the training cascade are standardized in their understanding of M&E requirements so that they are disseminating the same information. During trainings, incorporate exercises for participants to practice using the M&E tools relevant to their roles. During implementation, include a session in all review meetings in the districts to present data analysis and any challenges, as well as time for discussion.

TRAINING AND SUPPORTIVE SUPERVISION

Challenge: **Trainers and supervisors do not have enough time to offer supportive supervision to clinicians and CHWs. The quality of the program is compromised.**

Solution: Supportive supervision likely was intensive during the pilot. As this program is integrated into routine maternal health activities and existing supportive supervision (SS) systems, it is important to be sure it remains sufficient, especially in the first 6–12 months. SS is critical for program success. The time is takes to offer SS is often the limiting factor when determining how many trainers and/or supervisors are needed. First, determine what the SS activities will be and a realistic estimate of how much time they will take on a monthly basis. Remember to factor in travel time. Next, find out from the people likely to be trainers and supervisors how much time they can feasibly spend on these activities. This will let you determine how many people they

can supervise. From there you can more accurately determine the number of trainers/ supervisors that need to be developed. Additional strategies include mixing group SS activities with onsite direct observations. For example, bringing CHWs together to practice counseling skills with each other allows the supervisor to observe and coach many people at once.

Challenge: **Those responsible for offering "supportive supervision" are using techniques that shame and intimidate, decreasing morale and motivation.**

Solution: Incorporate descriptions and practice of supportive supervision techniques during trainings for those who will be offering supportive supervision. Have a large group discussion on the effects of shaming and intimidating people versus using coaching techniques. Have participants role play various techniques as both the trainer/supervisor and person being trained. Debrief afterward and discuss how they felt playing each role. Offer ongoing support and supervision in supportive supervision skills to those who need it. Use the coaching skills checklist as a job aid (see toolkit).

FREQUENTLY ASKED QUESTIONS AND ANSWERS

The following questions and answers are intended to help programs get a head start on implementation by already having answers to some commonly asked questions.

General Information about PPH and Misoprostol

Q: **1. Why is prevention of PPH more important than other health interventions?**

A: Severe bleeding after childbirth is the most common cause of maternal mortality, accounting for at least one-quarter of maternal deaths worldwide.

Q: **2. Which women are at risk for experiencing PPH?**

A: All women, without any exception, have the possibility of experiencing PPH, even though they feel that they are healthy and have not experienced PPH in previous deliveries. Some women, however, have a higher risk of experiencing PPH because of certain medical conditions (such as a twin gestation) and others (such as those with anemia) have a higher risk of severe morbidity or mortality should they experience PPH.

Q: **3. What is the current approach to prevention of PPH?**

A: Because it is impossible to predict accurately who will get PPH, all women should be considered at risk. This is why it is recommended that all women who give birth be given a uterotonic immediately after the birth of the baby, before the delivery of the placenta. Oxytocin (10 units) is the preferred drug of choice, but it requires a cold chain and can be given only by injection, therefore requiring a skilled provider, such as a midwife or doctor. Misoprostol (600 mcg orally) is another uterotonic and is recommended for use when oxytocin is unavailable. The pregnant woman can take the medication herself if a skilled provider is unavailable at the time of birth.

Q: **4. What is misoprostol?**

A: Misoprostol is a prostaglandin E1 (PGE1) analogue available in tablet form. It was first developed for treatment of stomach ulcers. It has become an important drug in obstetric practice because of its ability to make the uterus contract and become firm. Its action is similar to oxytocin, but its advantage is that it can be given orally and also by the sublingual, rectal, and vaginal routes. It is also heat stable and has no contraindications for the prevention of PPH.

Q: 5. How is the medication to be taken to prevent PPH?

A: For prevention of PPH, 600 mcg of misoprostol (three tablets of 200 mcg each) should be taken orally immediately after the birth of the baby and before the expulsion of the placenta. The medication should not be taken before the birth of all babies; therefore, check for the presence of a second twin prior to administering. If the placenta comes out prior to taking the misoprostol, the medication should still be taken as soon as possible.

Q: 6. Is the medication safe?

A: Misoprostol has been documented to be very safe since its introduction in the late 1980s. Since then, millions of people have used up to 800 mcg daily for the treatment and prevention of gastric ulcer with no serious side effects, and the few reported cases of extreme overdose recovered rapidly with supportive care (Hemmerling 2006). It is included in the WHO List of Essential Medicines for the indication of PPH prevention and the US Pharmacopeia Expert Advisory Panel (USAP) likewise recommends that prevention of PPH be considered an "accepted" indication in the US Drug Information monograph on misoprostol (Carpenter 2001).

Common side effects associated with misoprostol include nausea, loose stool, shivering, and pyrexia (fever). All side effects are route- and dose-dependent and self-limited, with oral and sublingual routes and higher doses more likely to cause symptoms. Concerns have primarily focused on hyperpyrexia (fever > 40°C), which is most often associated with doses of ≥ 800 mcg. A 2010 study by Durocher et al. examined the characteristics of hyperpyrexia related to misoprostol 800 mcg given for **PPH treatment** and found that high fevers followed a predictable pattern. They were often preceded by moderate to severe shivering within 20 minutes of treatment, peaked one to two hours post-misoprostol, and gradually declined over three hours without resulting in further health complications. No deaths or sequalae have been reported linked to hyperpyrexia related to misoprostol use. A 2013 Cochrane review by Hofmeyr et al. found no statistically significant difference in maternal death or severe morbidity for misoprostol versus other uterotonics for the prevention or treatment of PPH.

The greatest risk with misoprostol is the risk of uterine rupture when the medication is inappropriately taken before the birth of the baby to augment or speed up labor. For this reason, an emphasis is put on the correct timing of administration in both verbal counseling sessions and all pictorial directions, including those packaged with the drug. Although data from current PPH prevention programs have shown extremely low rates of mistimed administration (.06%) and no cases of uterine rupture due to administration prior to birth, it is an outcome that should be carefully monitored and reported.

Q: 7. Will taking misoprostol affect future fertility if a woman wants to get pregnant again?

A: Absolutely not. Misoprostol has been used throughout the world to treat women of reproductive age in the prevention of gastric ulcers. There is no scientific evidence that demonstrates misoprostol has decreased fertility. In addition, where women have used the drug for obstetric purposes, they have gone on to have additional births.

Q: 8. Is misoprostol effective in preventing PPH?

A: Misoprostol is effective in preventing PPH, but slightly less effective than oxytocin. Midwives who assist home births therefore should continue to use oxytocin, unless they are unable to store oxytocin in a cool place or cannot guarantee safe injection.

Misoprostol's ability to prevent PPH has been demonstrated in multiple contexts at the community level. In 2006, Derman et al. found a 50% reduction in PPH and an 80% reduction in severe PPH when comparing misoprostol with a placebo in home births

and at primary care centers. More recently, a randomized placebo-controlled study in Pakistan using trained TBAs showed a 24% reduction in PPH for women giving birth at home who received misoprostol compared to those who received a placebo. Women who received misoprostol were also almost half as likely to have a postpartum drop in hemoglobin > 3g/dl (Mobeen et al. 2011). An older meta-analysis of many studies concluded that 18% of women would have PPH if the placenta was delivered on its own, 2.9% would have PPH if oxytocin was used, and 3.9% would have PPH if misoprostol was used (Prendiville et al. 1988; Villar et al. 2002). For home births, where a SBA is not present, misoprostol is an effective option.

Q: 9. What is WHO's position on using misoprostol for PPH prevention?

A: In the 2012 guidelines for the prevention and treatment of PPH, in settings where SBAs and oxytocin are unavailable, 600 mcg PO misoprostol is recommended.

Q: 10. How many countries are using misoprostol for PPH prevention?

A: Every year, more and more countries are beginning to use misoprostol for PPH prevention. As of May 2013, more than 30 countries were known to have it registered for this indication. A growing number of countries are transitioning from pilots to expansion and national scale-up, including Nepal, Nigeria, Niger, South Sudan, Liberia, Zambia, Afghanistan, and Mozambique.

Q: 11. If misoprostol is such a great drug, why is it not used more in developed countries for prevention of PPH?

A: These countries have access to the storage facilities necessary to store oxytocin, and oxytocin is the most effective drug for the prevention of PPH. It is, however, often used selectively in these countries. For example, women in the United Kingdom may be given misoprostol to avoid having to receive an injection (of oxytocin). In the U.S., it is often used as part of PPH management.

Q: 12. Where can more evidence and advocacy materials be found?

A: Many of these materials can be found under the misoprostol section of the PPH Toolkit on k4health: http://www.k4health.org/toolkits/postpartumhemorrhage. Other online resources include VSI (www.vsiinnovations.org) and www.misoprostol.org.

Program Implementation

Q: 13. How can implementation be integrated with existing service delivery systems as programs transition to scale?

A: There are many ways to avoid vertical programming and integrate the components necessary for successful advance distribution of misoprostol with the existing service delivery system. Working closely with the MoH and other key service delivery stakeholders will help identify existing mechanisms that can be used for implementation. Training will use government in-service training system (trainers, training sites, certification, etc.). Local community health centers will provide the staff to supervise the CHWs. Drug distribution will follow existing national channels and the drug will be stored in public sector warehouses. The information and counseling messages will echo those that are already being used in other safe motherhood interventions. New M&E fields will be added to existing forms (e.g., ANC card, maternal death audit, stock-out cards) and data will be pulled from and feed into the existing HMIS. This may vary if no CHW cadre currently exists, depending on how community-based distribution is designed.

Q: 14. How can high uterotonic coverage be achieved across a country?

A: Coverage will be highest with a combined strategy that addresses the availability of uterotonics for both facility and non-facility deliveries. To reach all women, multiple advance distribution strategies may be used such as using CHWs, existing TBAs, and ANC providers. Enough CHWs need to be recruited so each one serves between 100 and 150 households. Fewer households per CHW is better, so that the CHWs do not feel overly burdened. This of course will vary by population density and geography. The goal is for each CHW to be able to concentrate on the immediate neighborhood and to visit households by foot.

Q: 15. When scaling up, what selection criteria should be used to determine new program boundaries?

A: This will vary country by country based on resources and priorities. Generally, programs should consider equity issues and focus on areas with the highest need. Examine available data detailing: regional rates of maternal mortality; fertility rates; non-facility birth rates; geographic access to facilities; and any areas with particular problems stocking oxytocin. If there are existing community health systems/CHW cadres in some areas and not others, consider if you want to "pick the low hanging fruit" first and focus on those areas with existing structures.

Q: 16. What special drug quality assurance procedures are necessary?

A: Drug quality assurance is an issue that can be addressed across all implementing partners by the MoH and working group. In addition to assuring that quality drugs are being imported, once in the country, drugs must be managed so that expiration dates are not exceeded prior to use. First, work with the drug manufacturer to ensure that drugs have the majority of their "lifespan" left when they arrive in-country. Next, drugs at all levels of the distribution chain should be stored using the "first in, first out" policy. Finally, distributers should be trained to check the expiration date prior to distribution.

If the drug in the country is not from a WHO pre-qualified manufacturer, make sure to have agreements with the local distributor to conduct sample batch testing of the product once distributed to districts and facilities. This will involve collecting a sample of the tablets at six- or eight-month intervals and sending it to a reference laboratory. The analysis requested will help determine the amount of active ingredient in the tablets as well as other agents, if present. This way the program can ensure that the tablets are not degrading over time nor contaminated.

Misoprostol Distribution

Q: 17. Why is it recommended that CHWs or TBAs distribute the drug and not just ANC providers?

A: It has been found that even in countries with high rates of ANC use, both distribution rates (the percentage of pregnant women who receive the drug) and coverage rates (the percentage of pregnant women who actually take the drug) are substantially higher when CHWs or TBAs distribute the drug alone or in addition to ANC providers. This is likely due to a multitude of factors, including: lower rates of ANC use after eight months when the drug is usually distributed; less time available for counseling by ANC providers as compared to CHWs/TBAs; and greater potential for a long-term relationship and trust building with CHW/TBAs as compared to ANC providers. In short, women are more likely to spend more time with a CHW/TBA over more visits and be exposed to more lengthy counseling sessions where their questions are adequately addressed.

Q: 18. Why is it recommended that the woman keep the drug and not the midwife or CHW/TBA?

A: The woman is the only person guaranteed to be at her birth. The advance distribution strategy ensures that women have immediate access to a medication that will help prevent PPH regardless when and where they deliver. A midwife, CHW, or TBA is sometime not available when needed.

Q: 19. Why is it recommended to distribute the drug to someone who plans to deliver with a skilled provider?

A: Many things can disrupt plans to deliver with a skilled provider. Sometimes babies are born quickly before the mother can reach a skilled provider and are born at home or during transport; transportation cannot be found or is not working at the time of labor; roads are impassable due to weather or security; the skilled provider cannot be found or is not available; or the provider is out of uterotonic. In Indonesia, for example, we know that in 25% of planned midwife births, the midwife was not able to get to the woman in time. It is best to deliver with a skilled provider, but in the event that is not possible, having this medication on hand will provide women with an option to prevent PPH.

Q: 20. Does advance distribution of misoprostol encourage women to use TBAs instead of SBAs, or to deliver at home instead of in a facility?

A: Up until now, there is no evidence that access to advance distribution of misoprostol serves as an incentive to use TBAs due to the perception that it makes it safer to deliver with a TBA. The overall message of the counseling in the program is that all women should plan to have a SBA. Patients are informed that SBAs can provide care for additional complications that may occur in pregnancy and childbirth. Advance distribution of misoprostol is aimed at helping those women who still choose not to have a SBA or cannot access one, whether because of economic, cultural, or physical reasons. It is reassuring to note that from the program experience in Indonesia, the proportion of births occurring at the midwife's house actually increased 12% as a result of the counseling provided by community health volunteers in the program. Other programs studying this outcome have also found modest increases in facility birth rates.

Q: 21. How do you prevent unauthorized distribution channels for the drug?

A: Preventing unauthorized distribution of misoprostol is done in the same ways as for other drugs. There are many different strategies depending on the exact program design. Having a clear accounting system that shows the chain of custody for the drug is one, periodic audits can then be done to reconcile numbers along the distribution chain. Ensuring that staff at each distribution point know who can procure the drug for further distribution and who cannot is another. Only CHWs/TBAs who have been trained and who are carrying out program activities under a supervisor can be given the drug for distribution.

It also is important that pregnant women as beneficiaries know who are the authorized health workers who distribute misoprostol. Women should be informed, and be discouraged from getting misoprostol from unauthorized sources. A good IEC/BCC campaign should among other things create awareness about distribution channels.

Q: 22. What guidelines are needed related to distribution?

A: Clear guidelines should be written and disseminated that outline who may distribute the drug, to whom, and under what circumstances. They also should consider restocking guidelines, strategies to avoid double distribution to the same pregnant woman, and what to do in the case that a dose is reported lost or missing.

Use of Misoprostol

Q: 23. How can you ensure that the intervention medication will not be misused?

A: First, carefully develop appropriate over-branding and IEC/BCC materials that indicate the drug's purpose for PPH prevention and correct use. Second, distribute the drug only to pregnant women who have been counseled on the safe use of misoprostol and who can repeat key counseling messages. Counseling must emphasize that the medication should be used only after birth of the baby, should not be shared with anyone else, and should be returned if not used. Monitoring distribution channels adds further safeguards.

On a broad level, misoprostol is available in many pharmacies for the treatment of stomach ulcers. Pharmacists need to be educated not to provide misoprostol to patients without a valid prescription and appropriate counseling about PPH prevention and the safe use of the medication. Drug regulatory bodies should continue to regulate and re-educate the pharmaceutical sales industry.

Q: 24. Should midwives and other SBAs switch to using misoprostol if they are already allowed to use oxytocin?

A: Misoprostol is effective in preventing PPH, but has been shown to be slightly less effective than oxytocin. Therefore, all SBAs able to should continue to use oxytocin as the drug of choice. When it is unavailable, unable to be stored in a cool place, or safe injection cannot be guaranteed, misoprostol can substitute oxytocin for the prevention of PPH. Midwives and other SBAs should also have misoprostol available for the treatment of PPH when prevention fails.

Q: 25. Can oxytocin be used in conjunction with misoprostol?

A: Yes, there are no medical contraindications from using the two drugs together, but there is no need to use both.

Q: 26. How is misoprostol used in the case of multiple births?

A: Misoprostol should be administered after the birth of the last baby. After the birth of each baby, check for the presence of another baby before administering. The same dose is always used, regardless of the number of babies.

Q: 27. If a woman forgets to take the pill immediately after giving birth, is there a time limit to when she can take it?

A: The clinical recommendation is that a pregnant woman should take the pill right after the baby is delivered or at least within 10 minutes of giving birth and before the placenta is delivered, to provide the maximum uterotonic effect. If she forgets, it is still reasonable to take the pill within two hours of giving birth to prevent PPH. If after two hours, but within 24 hours, there is some bleeding, she may still take the medication but should also be referred immediately to a SBA or health facility.

Q: 28. What symptoms would indicate that the pill has not been effective in preventing PPH?

A: There are three reasons to refer a woman to a SBA or health facility. These are:

- If more than two sarongs (or other local measure used to "guestimate" blood loss greater than 500 cc) are used to absorb the blood flow.
- If a woman complains of feeling dizzy, faint, and weak. If a woman is anemic, she could have difficulty in tolerating even small amounts of blood loss.
- If blood loss continues for longer than one hour, although not in great amounts, as this could indicate the bleeding is from a laceration and the woman will need suturing to stop the bleeding.

Q: 29. What happens if misoprostol is inadvertently taken before the birth of the baby, and how are programs designed to prevent this?

A: Misoprostol has been used to induce labor and does this successfully with doses of 25–100 mcg. The 600 mcg (three tablets of 200 mcg) dose should never be taken before the birth of the baby, because there is a risk of rupture of the uterus, which can be deadly for both the mother and fetus. In the Maternal and Neonatal Health (MNH) Program/Indonesia PPH demonstration project, women were counseled by midwives and community volunteers on the correct time to take the medication, which is immediately after the birth of the baby. Patients and their support persons received this information on two occasions during their pregnancy from midwives and community volunteers who were specially trained for this purpose. Patients were asked to correctly recount the information before being given the medication. Women were given a sealed misoprostol medication packet with a permanently attached safety information leaflet at approximately the eighth month of pregnancy to ensure no accidental misuse in early pregnancy. Trained field supervisors supervised the counseling. As a result of these measures, no women took the medication before the birth of the baby. Other programs have had similar results, with only seven (.06%) of 12,615 women taking the medication prior to birth (Smith et al. 2013).

Q: 30. With what fluids can the drug be taken?

A: The woman should take the drug with water, warm tea, or fruit juice.

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Annex A: Additional Resources

These resources can be found in the Postpartum Hemorrhage: Prevention and Management toolkit at http://www.k4health.org/toolkits/postpartumhemorrhage under the section *Advance Distribution of Misoprostol Program Resources*. This list will be updated online, as more countries gain experience in scaling up misoprostol programming as part of their comprehensive PPH prevention strategies. Please contact the authors if you have materials to share.

Resources
A. Implementation Guides, Plans, Budgets, and Job Descriptions
▪ This implementation guide plus individual files for associated annexes and the checklist for program expansion
▪ *Prevention of Postpartum Hemorrhage at Home Birth: A Program Implementation Guide.* Jhpiego (2009)
▪ *Nine Steps to Developing a Scaling-Up Strategy* (2010). WHO ExpandNet. (English, French, and Spanish)
▪ *International Drug Price Indicator Guide.* MSH (2012)
▪ *Quantification of Health Commodities A Guide to Forecasting and Supply Planning for Procurement.* JSI (2009)
▪ *Forecasting Misoprostol Tablets for Postpartum Hemorrhage (PPH) Prevention and Treatment in Liberia. VSI (*2013)
B. **Program Study Briefs and Case Studies**
▪ Misoprostol for Postpartum Hemorrhage, Reaching Women Wherever they Give Birth: Stories of Success in Bangladesh, Nepal, and Zambia. FCI (2012). (English and French)
▪ Availability Case Study: Misoprostol in Tanzania. VSI (2012)
▪ Case Study: Somaliland. Prevention and Treatment of PPH in Somaliland: Navigating a Complex Course to Greater Impact. PSI
▪ Prevention of Postpartum Hemorrhage Study: West Java, Indonesia. Jhpiego (2004)
▪ 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. Jhpiego (2010)
▪ Technical Brief #11: Community-Based Postpartum Hemorrhage Prevention in Nepal, Nepal Family Health Program (2010)
C. Clinical Guidelines and Protocols
▪ Prevention of Post-partum Haemorrhage with Misoprostol: FIGO Guideline, Annotated Version. International Federation of Gynecology and Obstetrics (2012)
▪ Treatment of Post-partum Haemorrhage with Misoprostol: FIGO Guideline, Annotated Version. International Federation of Gynecology and Obstetrics (2012)
▪ WHO Recommendations for the Prevention and Treatment of Postpartum Haemorrhage. World Health Organization (2012)
▪ WHO Recommendations for the Prevention and Treatment of Postpartum Haemorrhage: Evidence Base. World Health Organization (2012)
▪ Managing Complications in Pregnancy and Childbirth: A Guide for Midwives and Doctors. World Health Organization (2000)
▪ Country Example - Clinical Guidelines for the Prevention and Management of Postpartum Haemorrhage in South Sudan. MoH, Government of the Republic of South Sudan (2013)
D. Advocacy Materials and References
▪ Global Misoprostol Registration by Indication (map and detailed spreadsheet). VSI (May 2013)
▪ www.misoprostol.org ▪ This site is dedicated to providing information on the use of misoprostol in obstetrics and gynecology. It links to many additional resources and includes an extensive bibliography of over 1,500 misoprostol references.
▪ Policy Brief: Scaling up Misoprostol for Postpartum Hemorrhage: Moving from Evidence to Action. FCI (2012) (English and French)
▪ Preventing Postpartum Hemorrhage at the Community Level: A Compendium of Operations Research. VSI (2013)

Resources
▪ Oladapo OT. Misoprostol for preventing and treating postpartum hemorrhage in the community: A closer look at the evidence. *Int J Gynaecol Obstet* 2012; 119: 105–110
▪ Smith J et al. Misoprostol for postpartum hemorrhage prevention at home birth: An integrative review of global implementation experience to date. *BMC Pregnancy and Childbirth* 2013; 13: 44
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▪ *Misoprostol for Maternal Health*. Caucus on New and Underused Reproductive Health Technologies, Reproductive Health Supplies Coalition (2012)
▪ Durocher J et al. High fever following postpartum administration of sublingual misoprostol. *BJOG* 2010; 117: 842–852
▪ Hemmerling A. The safety of misoprostol. *Int J Gynaecol Obstet* 2006; 94 (Supplement 2):S149–S150
E. Training Materials, Job Aids, and Supportive Supervision Tools
Facility-based
▪ South Sudan Trainer Handbook – Training of Health Facility Staff: Clean and Safe Delivery and Management of Postpartum Haemorrhage (2013)
▪ South Sudan Participant Handbook – Training of Health Facility Staff: Clean and Safe Delivery and Management of Postpartum Haemorrhage (2013)
▪ South Sudan AMTSL job aid
▪ Madagascar Trainer Handbook – Curriculum de Formation des Agents de Santé: Prévention des Hemorragies du Postpartum (French only)
▪ Madagascar Participant Handbook – Formation des Agents de Santé: Prévention des Hemorragies du Postpartum
CHWs
▪ South Sudan Trainer Handbook --Training of Home Health Promoters: Prevention of Postpartum Haemorrhage at the Community Level (2013)
▪ Afghan Trainer's Manual – Training of CHWs: Expansion of Prevention of Postpartum Haemorrhage Program in Afghanistan
▪ Prevention of Postpartum Hemorrhage: Learning Resource Package for Community Health Workers, Ministry of Health and Population, Nepal (2005)
F. IEC/BCC Materials
▪ Misoprostol Information, Education and Communication: Examples from the Field. VSI (2013)
Counseling materials for women
▪ Flip charts: Birth Preparedness and Complication Readiness; PPH (include text on the CHW side), Afghanistan
▪ Flip cards: Birth Preparedness and Complication Readiness; PPH (illustrations only, designed for non-literate CHWs), South Sudan
Examples of drug branding, packaging, and instructions for use
▪ External packaging: Rwanda (local language)
▪ Packaging inserts/instructions for use: Madagascar, Zambia, Liberia, South Sudan
G. M&E Tools
MCHIP Database for Prevention of PPH Misoprostol Programming: Core Indicators
▪ Description of the Recommended Core Indicators and Data Sources (Annex F)
▪ MCHIP Core Indicator Database User Guide
▪ Database report sample
M&E tools
▪ CHW register or pictorial forms: South Sudan (Annex G)
▪ Provider/CHW Survey

Resources
▪ AMTSL Observation Checklist
▪ Education Session Observation Checklist (Annex E)
▪ Monthly Misoprostol and Oxytocin Consumption logbooks: Facility-based distribution monthly stock report
▪ Misoprostol Postpartum Questionnaire
▪ Hospital admission form/Adverse event reporting form
▪ Maternal Death Audit form
▪ Monitoring and Supervision tool for facility-based distribution of misoprostol
Country M&E plans
▪ Field manuals and data collection plans outlining M&E procedures and responsibilities

Annex B: Course Overview—PPH Prevention and Management for Facility-Based Providers

This five-day training is designed to prepare the skilled health care workers who are based at health facilities and are primarily responsible for providing ANC, labor and delivery, and care after childbirth to women and their newborns, to prevent PPH and manage PPH at the facilities and thereby reduce maternal deaths in their country. Specifically, the course will prepare the health facility staff to:

- Counsel women attending ANC clinic on making birth preparedness and complication readiness (BP/CR) plans and preventing PPH using misoprostol during home births; and
- Provide safe and clean birth including prevention and management PPH cases at the health facility and refer cases to higher levels as appropriate.

This training course is based on the principles of competency-based training and learning. Competency-based learning is learning by doing—learning that emphasizes how the participant performs (i.e., a combination of knowledge, attitudes, and, most important, skills). The trainer assesses participants' skill competency by evaluating their overall performance.

The use of competency-based checklists to measure clinical skills or other observable behaviors in comparison to a predetermined standard is an integral part of learning new skills. A checklist contains the individual steps or tasks in sequence (if necessary) required performing a skill or activity in a standard way. If opportunities allow, the participants will also practice skills with patients.

Learning to perform a skill occurs in three stages:

- ***Skill acquisition:*** The participant knows the steps and their sequence (if necessary) to perform the required skill or activity but needs assistance.
- ***Skill competency:*** The participant knows the steps and their sequence (if necessary) and can perform the required skill or activity.
- ***Skill proficiency:*** The participant knows the steps and their sequence (if necessary) and efficiently performs the required skill or activity.

CORE COMPETENCIES

Participants are expected to develop the following competencies to successfully prevent and manage PPH:

1. Assist pregnant women and their family members to develop a birth preparedness and complication readiness (BP/CR) plan using BP/CR counseling flip charts.
2. Using PPH prevention flip charts, counsel pregnant women on the use of misoprostol, and provide misoprostol for the prevention of PPH.
3. Demonstrate clean and safe childbirth, including AMTSL and immediate essential newborn care.
4. Provide essential newborn interventions, including those for warmth, cord care and eye care, and newborn resuscitation; recognize danger signs; and promote early and exclusive breastfeeding.
5. Identify the presenting symptoms and signs of shock.
6. Perform adult resuscitation and management of shock.
7. Identify the presenting symptoms and signs, determine the probable diagnosis, and use simplified management protocols for vaginal bleeding after childbirth.

COURSE GOAL

To provide the participants with essential knowledge, skills, and attitudes in prevention of PPH at community and facility levels and manage cases of PPH at health facilities.

PARTICIPANT LEARNING OBJECTIVES

By the end of this training, the participants will be able to:

- Describe the current status of maternal and newborn health and mortality in their country.
- Identify interventions for making pregnancy safer.
- Define maternal death.
- Use interpersonal and communication skills to counsel a pregnant woman.
- Describe the components of BP/CR plans.
- Perform the steps of clean and safe delivery including AMTSL and immediate essential newborn care.
- Manage the cases of PPH at the health facility using the PPH management protocol and refer in a timely manner when needed.
- Provide supportive supervision to the CHWs/TBAs attached to their health facility.

PARTICIPANT LEARNING ACTIVITIES

To achieve the learning objectives, participants will carry out following activities:

- Complete the pre- and post-course knowledge assessment.
- Practice skills including clean and safe birth with AMTSL and immediate newborn care, manage shock, and perform bimanual uterine compression and manual removal of placenta on anatomical models.

TRAINING/LEARNING METHODS

- Interactive presentations
- Large group discussion
- Small group work
- Case studies
- Practice in role play setting
- Clinical simulations

TRAINING MATERIALS

- PPH prevention and BP/CR flip chart or cards
- Recordkeeping forms
- Government clinical guidelines on prevention and management of PPH
- Participant reference materials
- Anatomical models (MamaNatalie and NeoNatalie)
- Instruments and equipment for conducting normal labor, management of PPH, manual removal of placenta, uterine balloon tamponade (UBT), and newborn resuscitation
- Infection prevention supplies
- Videos

PARTICIPANT SELECTION CRITERIA

Participants for this course are:

- SBAs[7] who have recently been/are conducting deliveries;
- Released for the training by their supervisors and have the support of their supervisors to implement new skills; and
- Interested in updating their skills and knowledge to prevent and manage PPH.

METHOD OF EVALUATION

Participants: A pre-test will be completed on Day 1 and a post-test on Day 4. However, the main focus is participants' ability to prevent and manage PPH. The evaluation includes:

- Pre-course knowledge assessment
- Post-course knowledge assessment
- Evaluation of skills on anatomical models

Although the training is short, the goal is that ALL participants will be COMPETENT on a model in "assisting a normal birth with AMTSL and essential newborn care." As the clinical trainer(s), you will observe and rate the participant's performance on each step of this skill on the checklist. The participant must be rated "Satisfactory" for each skill/activity group covered in the checklist in order to be evaluated as qualified.

COURSE DURATION

Five days

SUGGESTED COURSE COMPOSITION

16 participants, four trainers

[7] In some cases, non-SBAs who provide delivery care such as maternal and child health workers (MCHWs) may also participate. The training will need to be modified according to their skills level.

TRAINING ON CLEAN AND SAFE BIRTH AND PREVENTING/MANAGING POSTPARTUM HEMORRHAGE (PPH)				
DAY 1	**DAY 2**	**DAY 3**	**DAY 4**	**DAY 5**
AM (4 hours) ▪ Welcome and opening ▪ Participant introductions ▪ Overview of the workshop: Course expectations; training goals and objectives; schedule; training materials and training approach; group norms ▪ Pre-test ***Tea break*** ▪ Overview of maternal health situation in country and PPH prevention program ▪ Group work around 3 delays (includes referral process) ▪ Review BP/CR and PPH prevention flip cards	**AM (4 hours)** ▪ Agenda and warm-up ▪ **Video:** Assisting a normal birth ▪ Conducting clean and safe delivery – **Trainer demonstration** Clean and safe delivery including AMTSL and immediate routine care of mother and newborn ***Tea break*** ▪ **Skills practice in clean and safe delivery, AMTSL, immediate routine care of mother and her newborn**	**AM (4 hours)** ▪ Agenda and warm-up ▪ **Trainer demonstration**: Management of shock linked to PPH ▪ **Skills practice in teams:** Management of shock linked to PPH ***Tea break*** ▪ **Case study 1:** Management of PPH ▪ **Trainer demonstration** – Bimanual uterine compression – Uterine balloon tamponade (UBT) – Aortic compression ▪ **Skills practice** – Bimanual uterine compression – UBT	**AM (4 hours)** ▪ Agenda and warm-up ▪ Post-test ▪ **Clinical simulation:** Management of PPH ▪ **Trainer demonstration:** Episiotomy and perineal repair ***Tea break*** ▪ **Skills practice:** Episiotomy and perineal repair and others ▪ **Skills practice**: all skills in classroom/clinical area and checkout	**AM (4 hours)** ▪ Agenda and warm-up ▪ Introduction/orientation to record keeping and reporting: – Health facility admission form – CHW register or pictorial forms – Monthly Misoprostol & Oxytocin Consumption Log Books – Delivery registers ***Tea break*** ▪ Skills practice in classroom/clinical area and checkout
LUNCH	**LUNCH**	**LUNCH**	**LUNCH**	**LUNCH**
PM (3 hours) ▪ Warm-up ▪ **Pre-test results and discussion** ▪ **Role play 1: Communicating with pregnant women** ***Tea break*** ▪ **Update on infection prevention** – Handwashing activity – Personal protective equipment – Decontamination – Instrument processing ▪ **Summary** of **the day**	**PM (3 hours)** ▪ Warm-up ▪ **Overview of birth asphyxia** ▪ **Newborn resuscitation demonstration** ▪ **Newborn resuscitation practical session** ▪ **Practice continues** ***Tea break* (during practice)** ▪ **Overview of postpartum and newborn care and discussion** ▪ Trainer presentation: Management of PPH protocol ▪ **Summary of the day**	**PM (3 hours)** ▪ Warm-up ▪ **Misoprostol quiz** ▪ **Trainer demonstration:** ▪ **Manual removal of placenta** ▪ **Skills practice** – Manual removal of placenta ▪ **Ensuring supply and safe storage of oxytocin** ▪ Skills practice in classroom as time allows ▪ **Summary of the day**	**PM (3 hours)** ▪ Warm-up ▪ **Groupwork:** Strengthening the referral process ▪ **Trainer demonstration**: Counseling a woman and her family using PPH prevention flip charts ▪ **Skills practice:** Counseling women on prevention of PPH ▪ Introduction to supportive supervision ▪ **Role Play 2**: Supportive supervision ▪ Skills practice continues and checkout when able ▪ **Summary of the day**	**PM (2 hours)** ▪ Warm-up ▪ Action plans for implementing new skills in health facilities ***Tea break*** ▪ Training evaluation ▪ **Summary and closing**
Assignments: Review normal birth checklist and PPH guidelines	**Assignments:** Review PPH guidelines and checklists	**Assignments:** Review all materials, checklists, and flip cards	**Assignments:** Begin completing action plans (completed on Day 5)	

Annex C: Course Overview: PPH Prevention for CHWs/TBAs

This four-day training is designed to prepare the health care workers who are providing ANC information and/or services at the community level to implement PPH interventions in the community they serve. These workers are often called CHWs or may be TBAs. More specifically, the course will prepare the participants to:

- Educate the community on PPH prevention interventions and counsel pregnant women and their family members on BP/CR planning; and
- Distribute misoprostol tablets to women before they give birth, thereby preventing PPH during home births.

This training course is conducted in consideration of the educational background and work experience of participants and, thus, relies heavily on the use of simple job aids and IEC/BCC materials. This course encourages hands-on training by using interactive and participatory approaches—a key to competency-based training.

CORE COMPETENCIES

The participants are expected to develop the following competencies to successfully implement PPH prevention interventions at the community level:

- Use counseling flip charts to counsel pregnant woman on developing a BP/CR plan.
- Counsel pregnant woman on the use of misoprostol for prevention of PPH during home births.
- Complete essential recordkeeping and reporting forms for effective monitoring and evaluation of community-based programs for prevention of PPH.

COURSE GOAL

The goal of this course is to provide participants with the knowledge, skills, and attitudes needed to counsel pregnant women, their support persons, families, and other community members about the importance of taking misoprostol tablets for the prevention of PPH and what actions to perform when PPH occurs.

PARTICIPANT LEARNING OBJECTIVES

By the end of this course, the participants will be able to:

- Describe the current status of maternal health and mortality in their country
- Identify interventions for making pregnancy safer.
- Explain maternal death and the three delays linked to maternal deaths.
- Describe the importance of the essential components of the BP/CR plan.
- Use interpersonal and communication skills to counsel pregnant women.
- Use BP/CR counseling flip charts while counseling pregnant women on the BP/CR plan.
- Using PPH prevention flip charts, counsel pregnant women on the use of misoprostol, and provide misoprostol for the prevention of PPH.
- Complete the essential forms and registers for recordkeeping and reporting.
- Describe the roles and responsibilities of CHWs/TBAs in implementing PPH prevention interventions at the community level.

PARTICIPANT LEARNING ACTIVITIES

To achieve the learning objectives, participants will perform the following activities:

- Complete the pre and post-tests.
- Actively participate in discussions during the presentations.
- Complete the group work assignments.
- Use BP/CR and PPH prevention flip charts during classroom practice.
- Use BP/CR and PPH prevention flip charts during supervised practice in the community.
- Complete the recordkeeping and reporting forms using a case study.

TRAINING/LEARNING METHODS

The following training/learning methods will be used during this training:

- Interactive trainer presentations
- Large group discussions
- Small group work
- Practice in role play settings
- Individual assignments

TRAINING MATERIALS

You will need the following materials during this training:

- BP/CR flip charts
- PPH prevention flip charts
- Recordkeeping forms
- CHW/TBA Trainer Handbook

PARTICIPANT SELECTION CRITERIA

Participants for this course are the CHWs/TBAs who:

- Are selected and approved by the community according to government guidelines on CHWs/TBAs;
- Stay and work in the community;
- Are preferably women and involved in providing some maternal and child health services in the community;
- Are prepared to volunteer 10–15 hours per week of their time; and
- Have completed the initial training of CHWs/TBAs according to government guidelines, if applicable.

METHOD OF EVALUATION

Participants: Given the literacy level of the participants, the evaluation is not rigorous. The main focus is the participants' ability to counsel pregnant women and their families and provide correct information. Participants will be evaluated using the following methods:

- Pre-course knowledge assessment
- Post-course knowledge assessment
- Skills evaluation during community practice

TRAINING COURSE

The participants will evaluate the course by answering four or five questions about the arrangements for learning, the content, and the training methods used by the trainer. Another suggestion is to draw on a flip chart a "happy face" ☺, "sad face," ☹ and "neutral face" 😐 and ask participants to choose one face to indicate how they feel for each area you are evaluating.

COURSE DURATION

This training course is four days long. A typical training day includes four hours of classroom time before lunch, a one-hour lunch break, and three hours of classroom time after lunch. The agenda for this training follows.

Three days are based in the classroom, and one day is based in the community setting.

SUGGESTED COURSE COMPOSITION

Six to 10 participants, two or three trainers

PREVENTION OF PPH TRAINING FOR COMMUNITY-BASED HEALTH WORKERS: 4 DAYS, 8 SESSIONS			
DAY 1	**DAY 2**	**DAY 3**	**DAY 4**
A.M. (4 hours) ▪ Welcome and opening ▪ Participants' introduction ▪ Overview of PPH prevention program ▪ Overview of workshop: Course goals and objectives; agenda; training materials; group norms and expectations; training approach ▪ Pre-course assessment ▪ Tea break ▪ Maternal death: definition; direct and indirect causes; making pregnancy and childbirth safe ▪ Postpartum hemorrhage: Definitions; causes; prevention of PPH in community; introduction to PPH prevention flip charts	**A.M. (4 hours)** ▪ Agenda and warm-up ▪ **Classroom practice** counseling women and their family members using BP/CR flip charts ▪ Follow-up discussion on practice ▪ Tea break ▪ **Trainer demonstration**: Counseling a woman and her family using PPH prevention flip charts ▪ **Classroom practice:** Counseling women on prevention of PPH ▪ **Activity:** Calculating eighth month of pregnancy	**A.M. (4 hours)** ▪ Agenda and warm-up ▪ Recordkeeping and reporting ▪ Introduction to recordkeeping and reporting of prevention of PPH project ▪ **Group work:** Complete recordkeeping and reporting forms ▪ Tea break ▪ **Practice counseling:** Approaching pregnant women and their families, counseling on BP/CR, counseling on PPH prevention, providing postpartum visits	**A.M. (4 hours)** ▪ Agenda and warm-up ▪ **Practice** PPH prevention competencies in community
LUNCH	**LUNCH**	**LUNCH**	**LUNCH**
P.M. (3 hours) ▪ Warm-up: Misoprostol quiz ▪ Tips for being an effective counselor ▪ Tea break ▪ Introduction to BP/CR flip charts and trainer demonstration on use of BP/CR flip charts ▪ Summary of the day and closing	**P.M. (3 hours)** ▪ Warm-up ▪ Identify pregnant women in community; discussion and brainstorming ▪ **Discussion**: Approaching pregnant women and their families for the first time–how to be culturally responsive? ▪ Tea break ▪ Managing pregnant women from registration until after childbirth ▪ **Summary of the day and closing**	**P.M. (3 hours)** ▪ Warm-up ▪ Identify the roles and responsibilities of CHWs/TBAs for PPH prevention ▪ Post-course assessment ▪ **Classroom practice and assessment**: Approaching pregnant women and their families, counseling on BP/CR, counseling on PPH prevention, providing postpartum visits ▪ Review preparation for supervised practice in community ▪ **Summary of the day and closing**	**P.M. (2 hours)** ▪ Discussion and feedback from community-based practice ▪ Course evaluation ▪ Summary of the course ▪ Closing ▪ Tea break
Assignments: Review BP/CR and PPH prevention flip charts	Assignments: Review and practice BP/CR and PPH prevention flip charts	Assignments: Review and practice BP/CR and PPH prevention flip charts	

Annex D: Key Counseling Messages for Pregnant Women and Their Support Persons

A CHW, TBA, and/or ANC provider may be designated as the appropriate health worker to counsel pregnant women on the following topics. They include the messages necessary to plan for a safe delivery and to act when a complication occurs. The precise messaging may change depending on the context of implementation. Interactive methods should be used to convey the key messages: ask what the pregnant woman knows/believes; discuss what the CHW has learned; use visual aids; use role plays and/or demonstrations; and ask the woman to repeat back key messages to check for understanding. There should be a job aid, such as a flip chart, to help CHWs/TBAs and ANC providers to convey the key messages.

ANTENATAL CARE (ANC)

- Ask the woman if she has attended a clinic or skilled provider for ANC.
  - If she has, encourage her to continue to attend ANC.
  - If the woman has not, encourage her to visit a clinic or skilled provider for ANC as soon as she can.
- All women should attend ANC, even if they plan to give birth at home because complications for the woman or her baby can occur even in a normal pregnancy.
- If a woman is having any problems with her pregnancy, she should seek ANC immediately.

BIRTH PREPAREDNESS AND COMPLICATION READINESS (BP/CR)

The woman and her family should prepare for childbirth by doing the following:

- Identify a skilled provider and a support person to be present at birth.
- Attend ANC, either at the clinic or by visiting a skilled provider.
- Gather items needed for a clean and safe birth, including soap, clean bed clothes, clean and unused razor blade, and clean strips of cloth to tie the cord.
- Have funds available to pay for care during a normal birth and for emergency transportation and referral if there is a problem.
- Have a plan for transportation to the nearest clinic or hospital.
- Know the danger signs of pregnancy. If any of the following are present, the woman should seek skilled care immediately:
  - Vaginal bleeding
  - Difficulty breathing
  - Fever
  - Severe abdominal pain
  - Severe headache/blurred vision
  - Seizures, loss of consciousness
  - Foul-smelling discharge from the birth canal
  - Decreased or absent fetal movements
  - Leaking of green- or brown-colored fluid from the birth canal

What is PPH?

- PPH is too much bleeding after the baby is born. It is the main reason why so many women die in childbirth. It is not possible to know ahead of time whether a woman will have PPH.
- Some bleeding after childbirth is normal.
- It is often hard to know when this normal bleeding becomes too much bleeding because it may happen over a long period of time instead of all at once.
- If a woman gives birth at home and has too much bleeding, she could die. Her family should immediately take her to the nearest health center for treatment or for transfer to a hospital.

KEY MESSAGE

Danger Signs for Postpartum Hemorrhage

- Bleeding after childbirth that soaks one cloth or pad in less than five minutes, or more than two cloths within 30 minutes of the birth.
- Woman is pale and feels faint and weak.
- Woman has abdominal pain.

If any of these signs are present, the woman and her family should go to the local health center immediately. Do not wait—delay can mean death for the woman.

What Causes PPH?

- The woman's womb remains soft and large after the baby is born.
- The afterbirth does not come out completely.
- There are cuts on the opening of the woman's womb (cervix) or her birth canal (vagina).
- The womb tears open (ruptures).

How to Prevent PPH

- The best way to prevent PPH is to give birth with a skilled provider. The skilled provider gives the woman an injection of a drug called oxytocin, delivers the afterbirth and rubs her womb to help it contract. Sometimes PPH will still happen. A skilled provider can do other things to stop the bleeding and save the woman's life.
- If a woman plans to give birth at home without a skilled provider, there is a drug called misoprostol that she can take as soon as the baby is born but before the placenta comes out. Misoprostol will help her womb get smaller and prevent too much bleeding. Misoprostol has been tested in many countries around the world and is safe for the woman and baby.

How to Use Misoprostol (Use the brand name in country)

- The woman should store misoprostol in a safe, locked place in the woman's home. She should be sure that her support persons know where the misoprostol is stored and how to unlock the storage place.
- The woman should take all three pills as soon as the baby is born, but before the placenta comes out. If the placenta comes out with the baby, she should still take three tablets.
- If the woman is giving birth at the clinic or hospital, she should take the misoprostol with her and tell the skilled provider that she has the pills. The skilled provider will decide whether to use misoprostol. Or, if the woman arrives at the clinic or hospital and the skilled provider is not in attendance, the women should take the misoprostol as directed.

KEY SAFETY MESSAGES
• The woman should not take misoprostol before the baby is born because it will harm the mother and baby. • If the bleeding does not stop after she takes misoprostol, the woman should immediately go to the nearest clinic or hospital.

Side Effects of Misoprostol

After childbirth, it is normal for a woman to have some shivering. After taking misoprostol, the woman may have shivering for about 30 minutes. If she is uncomfortable, she should drink a cup of warm, sweet tea.

These side effects do not happen often but if they do, will last only two to three hours:

- Vomiting
- Diarrhea/watery stool
- Low fever

Annex E: CHW Performance Checklist

Household Monitoring Visit and Education Session Observation Checklist
Prevention of PPH Project

CHW/TBA Name: _____ Health Facility Name: _____

District Name: _____ Supervisor Name: _____

S.NO	AREAS OF SUPERVISION	YES	NO
Observe the CHW/TBA meeting with the pregnant woman and her family members. Does he/she:			
1	Greet the family and then introduce himself/herself		
2	Explain the purpose of meeting		
3	Mention the length of time the meeting might take		
4	Listen to them when they talk or ask questions		
5	Use the flip chart while providing education		
6	Place the flip chart in the appropriate way so the pictures are directed toward the pregnant women and the text to him/her		
7	First ask the woman "what do you see in the picture?" at the start of every message/page?		
8	Answer the woman's questions		
9	Ask questions in a manner to encourage interaction (two-way communication)		
10	Ask questions at the end of each message to know if the woman has understood it		
11	Use easy-to-understand and local language		
12	Ask the woman to repeat the messages conveyed to her and help her to repeat the messages		
13	Thank the pregnant woman and family members		
14	Fix the time of the next appointment		
15	Say good bye to the woman and family members		
Observe the interaction of the CHW/TBA with the pregnant woman and support person and note if he/she provides necessary information about:			
17	Antenatal care		
18	Danger signs of pregnancy and what to do if they appear		
19	Importance of nutrition for pregnant woman		
20	Importance of delivering at a health facility		
21	Collecting money for emergency incidents		
22	Importance of identifying blood donor, determining blood groups and HIV status		
23	Provide the messages according to the flip charts		
Observe the interaction of the CHW/TBA with the pregnant woman and support person and note if he/she provides necessary information about:			
24	PPH and why is it dangerous		
25	Different ways of PPH prevention		
26	Three tablets of misoprostol and how it reduces the chance of PPH		
27	Misoprostol could be dangerous if it is taken before the delivery of the baby		
28	Correct time of taking the tablets when a woman has twins		

S.NO	AREAS OF SUPERVISION	YES	NO
29	Not taking the drug for antepartum hemorrhage		
30	A woman should take all three tablets immediately after the delivery of the baby and before the delivery of placenta but it can be taken even after delivery of the placenta		
31	Side effects of the medicine and how to cope with them		
32	Types of PPH that need to be referred		
33	Causes of PPH and what to do if a woman is still bleeding after she took Misoprostol		
34	Ask the pregnant woman if she is having twins and advise accordingly		
35	Give misoprostol tablets to the woman, and instruct her to keep them in a safe place where they will be available at the time of delivery		
36	Ask the woman to repeat the messages conveyed to her and help her to repeat the messages		
Check the monitoring form. Interview or observe the CHW/TBA to see if he/she can fill the correct information in the appropriate box of the required field:			
	FIRST VISIT		
37	Write the name of the pregnant woman and her husband		
38	Use the appropriate row for the first visit in the form		
39	Ask the woman for the number of months she has had no menstrual bleeding and mark appropriate number of crescents		
40	Mark the appropriate box after she finishes education		
	SECOND VISIT (8th month of gestation)		
41	Use the appropriate row for the second visit in the form		
42	Ask the woman if she has a single pregnancy or twins and mark the appropriate box		
43	Mark the appropriate box after she finishes education and gives the drug package		
	THIRD VISIT (Postpartum)		
44	Use the appropriate row for the third visit on the form		
45	Ask the woman if she delivered at a health facility and mark the appropriate box		
46	Ask the woman if she delivered at home		
47	Ask the woman if she had postpartum hemorrhage and was referred to a health facility and mark the appropriate box		
48	Ask the woman if she took, all (three), two, one, or none of the tablets given to her and mark the appropriate box		
49	Ask the woman to return the tablets if not taken		
50	Ask the woman if she had a fever after delivery or after taking the drug and mark the appropriate box		
51	Ask the woman if she had chills after delivery or after taking the drug and mark the appropriate box		
52	Ask the woman if she had vomiting after delivery or after taking the drug and mark the appropriate box		
53	Ask the woman if she had diarrhea after delivery or after taking the drug and mark the appropriate box		

Comments and Suggestions:

Annex F: Recommended Core Indicators for PPH Prevention Program Monitoring and Evaluation

*Indicators in **bold** have been identified as Core Indicators: A1, A2, A3, A4, A5, C10, and D13. Others indicators are suggested for monitoring, and programs may decide on including them within their M&E systems*

#	INDICATORS	PURPOSE	NUMERATOR (N)/ DENOMINATOR (D)	DATA SOURCE	COMPUTATION AND CRITERIA
A	**OUTPUT INDICATORS**				
A1	**Distribution Rate: Percentage of pregnant women who received misoprostol**	1) Compare against program targets to measure success in reaching pregnant women. 2) Use to calculate the usage rate (A2).	N: Number of pregnant women who received misoprostol in the study area during the specified timeframe	CHW and/or ANC registers (depending on program distribution channels)	The indicator should be disaggregated by source of counseling and misoprostol i.e., health care providers and CHWs/TBAs.
			D: Total estimated number of pregnant women in the study area during the specified timeframe	Census	
A2	**Misoprostol Coverage Rate Community Level:** **Percentage of women with home births who receive and ingest misoprostol**	Monitor uterotonic protection of all home births and compare against program targets.	N: Number of women with home births who received and ingested misoprostol D: Total estimated number of home births in the study area during the specified timeframe	CHW registers Misoprostol postpartum questionnaire	*The misoprostol coverage rate can be combined with the facility coverage rate to calculate the total uterotonic coverage rate of all births.
A3	**Of those with home births who ingested misoprostol, the percentage of women who ingested it at the correct time**	Monitor **correct** use of misoprostol.	N: Number of women with home births who ingested misoprostol at the correct time D: Total number of women with home births who ingested misoprostol	Misoprostol postpartum questionnaire	Correct Use is: 1. 600 mg of misoprostol 2. Taken immediately after delivery and before delivery of the placenta 3. Not taken before delivery of second baby, if twins Disaggregated by source of counseling: health care providers vs. CHWs/TBAs.
A4	**Percentage of deliveries at study health facilities**	Monitor if health facility deliveries are increasing or decreasing in conjunction with the intervention.	N: Number of deliveries occurring at health facilities included in the study area D: Total number of estimated deliveries in the study area	Labor and Delivery register	

#	INDICATORS	PURPOSE	NUMERATOR (N)/ DENOMINATOR (D)	DATA SOURCE	COMPUTATION AND CRITERIA
A5	**Uterotonic Coverage Rate Health Facility Level:** **Percentage of women who delivered at a health facility and were given a uterotonic immediately after birth**	Monitor uterotonic use for health facility deliveries; use to make program decisions related to facility based activities.	N: Number of women who delivered at facility, and received a uterotonic D: Number of women who delivered at study health facilities	Labor and Delivery register	
#	**INDICATORS**	**PURPOSE**	**NUMERATOR / DENOMINATOR**	**DATA SOURCE**	**COMPUTATION AND CRITERIA**
B	**TRAINING**				
B6	Percentage of CHWs/TBAs trained on misoprostol distribution package*	Monitor progress against training targets. Useful to compare ratio of number of women reached for distribution with number of health workers and CHWs trained and make decisions on training more CHWs. This will also be useful in scaling-up implementation as we can learn from previous experience of coverage with number trained.	N: Number of CHWs and TBAs trained on misoprostol distribution package* D: Number of target CHWs to be trained	Training report	Target number can be derived by = estimated pregnant women/estimated number of pregnant women per CHW.
B7	Percentage of ANC providers trained on misoprostol distribution package*	Monitor training progress against targets.	N: Number of ANC providers trained on misoprostol distribution package* D: Number of eligible ANC providers at baseline	Training report	
B8	Percentage of SBAs trained in AMTSL	Monitor training progress against targets.	N: Number of SBAs trained in AMTSL D: Number of eligible SBAs at baseline	Training report	
B9	Percentage of CHWs and TBAs who know the correct administration of misoprostol	Measure quality of training of CHWs and TBAs and can be used as a proxy quality assurance measure of correct counseling to pregnant women concerning drug administration.	N: Number of CHWs and TBAs who know the correct administration of misoprostol D: Total number of CHWs and TBAs interviewed	Supportive Supervision or interview	Correct administration defined by accurately listing ALL three: 1. Timing of drug 2. Dosage of drug (Number of pills) 3. Not to be taken before delivery of second baby, if twins

#	INDICATORS	PURPOSE	NUMERATOR (N)/ DENOMINATOR (D)	DATA SOURCE	COMPUTATION AND CRITERIA
C	**DRUG STOCK-OUTS**				
C10	**Percentage of misoprostol distribution points (Health Facility and CHWs/TBAs) experiencing NO stock-out during the reporting period**	Monitor availability of misoprostol at distribution points. Information can then be used to decrease the number of stock-outs and to assist in interpreting distribution and coverage data.	**For a single month**: Number of misoprostol distribution points reporting zero stock-outs (MSO) during the month **Average across multiple months**: $MSO_1+MSO_2+MSO_3$.... **For a single month**: Total number misoprostol distribution points (MDP) **Average across multiple months**: $MDP_1+MDP_2+MDP_3$...	Misoprostol consumption log; Stock-out reports	Distribution points include health facilities and CHWs/TBAs if they are involved in distribution of misoprostol to woman. If misoprostol is being distributed from the health facility, the health facility will be considered as a distribution point. If misoprostol is being distributed by an individual health worker during outreach or a CHW/TBA at the community level, this individual will be considered as a distribution point. Higher-level health facilities or regional drug storage centers are not considered drug distribution points. This is only for "end-user distribution."
C11	Percentage of oxytocin administration points (health facilities) experiencing NO stock-out during the reporting period	Monitor availability of oxytocin at distribution points. Information can then be used to decrease the number of stock-outs and to assist in interpreting distribution and coverage data.	**For a single month**: Number of oxytocin distribution points reporting zero stock-outs (OSO) during the month **Average across multiple months**: $OSO_1+OSO_2+OSO_3$.... **For a single month**: Total number oxytocin distribution points (ODP) **Average across multiple months**: $ODP_1+ODP_2+ODP_3$...	Oxytocin consumption log: Stock-out reports	Distribution points include health facilities providing oxytocin directly to women. Regional drug storage centers are not considered drug distribution points. This is only for "end-user distribution."
D	**ADVERSE EVENTS & COMPLICATIONS**				
D12	Percentage of women with home births who ingested misoprostol and experienced an adverse event	Monitor drug safety to address remaining concerns over the use of misoprostol at home.	N: Number of women with home births who ingested misoprostol and experienced an adverse event D: Total number of women with home births who ingested misoprostol	Adverse event reporting form; hospital admission form; CHW register Misoprostol postpartum questionnaire Maternal death or near miss audits	Adverse events include: 1. Uterine rupture, 2. High fever (> 40 °C), and 3. Retained placenta Any woman experiencing one of these adverse events should be included in the numerator regardless of outcome. If a woman died but did not experience one of these three adverse events she should not be included. (see D15) If using multiple data sources, take care not to double count cases.

#	INDICATORS	PURPOSE	NUMERATOR (N)/ DENOMINATOR (D)	DATA SOURCE	COMPUTATION AND CRITERIA
D13	**Percentage of women who used misoprostol at a home birth, experienced PPH and were referred to a health facility**	Track referral of women to health facilities to see if BP/CR counseling given by ANC providers and/or CHWs is increasing danger recognition and referral rates and to ensure the use of misoprostol isn't providing a false sense of security and decreasing care-seeking behavior.	N: Number of women with home births who took misoprostol, experienced PPH and went to a health facility D: Total number of women with home births who ingested misoprostol and experienced PPH	Misoprostol postpartum questionnaire	PPH as self-reported during postpartum interview. Care-seeking for PPH at any health facility (self-referral).
D14	Total number of maternal deaths		Maternal deaths in the catchment area	Death register Maternal death audit	When maternal deaths are identified, perform a maternal death audit to provide information concerning the cause of death.
E	**WOMEN SATISFACTION**				
E15	Percentage of women who are satisfied with the use of misoprostol	Measure acceptability and desire for misoprostol among women who had a home birth and took misoprostol.	N: Number of women interviewed who had a home birth, took misoprostol and are satisfied with misoprostol D: Total number of women interviewed who had a home birth, received and ingested misoprostol	Misoprostol postpartum questionnaire	Satisfaction defined by answering yes to ANY: 1. Ready to ingest misoprostol for next delivery 2. Recommend misoprostol to friend or relative 3. Ready to pay a minimal charge for misoprostol

*Misoprostol Distribution Package includes counseling on BP/CR and PPH prevention and the administration of misoprostol.

Annex G: Pictorial CHW Form from South Sudan

Prevention of PPH at Home Births in South Sudan

Home Health Promoter Pictorial Form

1. HHP's Name	2. Village/Health Centre/Unit	3. County
4. Name of the Pregnant Woman	**5. Name of the Husband**	**6. Drug Serial #**
 	 	

1 ANC	7. HHP Visiting Homes	8. Woman has No Menstrual Cycle	9. Months that She Had No Menstrual Cycle	10. Education On BP &CR and PPH given	11. Participants ID Card Issued
					Prevention of Postpartum Haemorrhage ID CARD
	☐	☐		☐	

2 ANC	12. HHP Visiting Home	13. Woman is 8 Months Pregnant	14. Single	15. Twins	16. Education on BP & CR and PPH Given	17. Drug Given by HHP
						
	☐	☐	☐	☐	☐	☐