Step 1: Analyze the Situation

Health and Commodity Context

The majority of the information in this section is a global-level analysis for purposes of illustration. The country-specific situation analysis should be focused on the local context.

Health Context

Globally, more than eight million of the 136 million women giving birth each year suffer from excessive bleeding after childbirth. This condition—medically referred to as postpartum hemorrhage (PPH)—causes one out of every four maternal deaths that occur annually and accounts for more maternal deaths than any other individual cause (UN Commission Report, 2012). Deaths due to PPH disproportionately affect women in low-resource countries.

Uterotonics are substances that give the uterine muscle tone, causing it to contract and cause labor or reduce hemorrhage. The World Health Organization (WHO) recommends using uterotonics during the third stage of labor to prevent PPH. Oxytocin and misoprostol are both highly effective uterotonics; however randomized controlled trials have shown that misoprostol is less effective than oxytocin and has more side effects, such as high temperature and shivering. Oxytocin is the recommended uterotonic for the prevention and treatment of PPH by the WHO. However, in settings where active management of the third stage of labor, including use of oxytocin, in not possible, WHO recommends 600 micrograms misoprostol orally immediately after the birth of the baby (WHO, 2009)

Approximately 30% of births throughout the world are attended by unskilled attendants (Kaiser, 2012). In sub-Saharan Africa, where nearly half of the world's maternal deaths occur, only 46% of deliveries are assisted by skilled attendants. Poor women and women living in rural areas are far less likely than their urban or wealthier counterparts to receive skilled care during childbirth (UNFPA, 2012). In some countries, as many as 90% of births occur at home.

Commodity Context

Misoprostol is a synthetic prostaglandin—a hormone-like substance—available in an oral tablet form, with tablets containing 25, 100, or 200 micrograms of the drug. Tablets can be stored at room temperature but, because they can be affected by moisture, should be appropriately packaged in double-aluminum blister packs. The cost per tablet from manufacturers is approximately US $0.15. It is available from more than 50 manufacturers globally (at least 35 of which are in developing countries).

In settings where oxytocin is unavailable (due to issues such as stock-out, cost, cold chain issues, or lack of a SBA to administer it), the administration of misprostol (600 micrograms orally) is recommended for the prevention of PPH. WHO recommends the administration of 800 micrograms of misoprostol sublingually as a third line treatment for PPH. Because misoprostol is in tablet form it can be administered by community health workers (CHWs) or even by mothers themselves when skilled birth attendants (SBAs) are not present, however advance community distribution of misoprostol, such as during ANC, remains controversial (WHO, 2010).

Misoprostol can also be used to induce labor, prevent and treat gastric ulcers, treat incomplete abortion and miscarriage, and to cause abortion. Misoprostol's ability to cause abortion is the main reason some countries are reluctant to recommend it.

Audience and Communication Analysis

A recent evidence review found 21 documents related to demand generation for misoprostol, including peer-reviewed articles, grey literature, and program reports, published from 2004 to 2012 (Health Communication Capacity Collaborative, 2013). Nine studies were

from Africa, nine were from Asia, and one literature review spanned low-resource countries. Six additional documents on the use of uterotonics during home births were reviewed, including two from India, one on Sub-Saharan Africa, and one on low-income countries. The following key determinants were found to impact use of misoprostol for preventing PPH or provide insight on potential demand and the need to understand local childbirth practices.

Knowledge and perceptions: Knowledge and attitudes of PPH and misoprostol among women, community members, and providers, including skilled birth attendants as well as traditional birth attendants and CHWs, are an important determinant of misoprostol use. For example, studies on use of uterotonics have found gaps between provider knowledge and practice, substantial incorrect use of uterotonics based on old or faulty knowledge, lack of up-to-date training, and use of outdated guidelines and protocols. Some providers incorrectly believed they could identify women at high risk of PPH, leading to suboptimal use of uterotonics to prevent PPH (POPPHI, 2007).

In Bangladesh, misperceptions, especially around when to take the drug (either before or after delivery), were one of the main reasons for nonuse of misoprostol in one study (EngenderHealth, 2010). Another study in Bangladesh cited lack of knowledge about misoprostol (66%) and belief that it is not necessary (14.4%), among other factors, as reasons why women did not take the drug after delivery (Nasreen et al., 2011). A small percentage of women who did not take the misoprostol they were given said it was due to their male partners' objection to use of the drug [1.6%] (Nasreen et al., 2011) or that their male partner/family would not allow them to take it (Prata el al., 2012a).

Interviews with TBAs in India found that excessive bleeding and other complications appeared not to be recognized as complications and went untreated (Deepak et al., 2013). This and another Indian study (Mirzabagi et al., 2013) found that some medical doctors and auxiliary nurse midwives were aware of and sometimes used misoprostol or oxytocin to prevent PPH. Providers also may be concerned that community-level use of misoprostol for PPH and advance distribution of misoprostol through antenatal care (ANC) clinics might cause harm to women, reduce facility births, or lead to use of the drug for other reasons such as abortion (Oladipo, 2012).

Community mobilization interventions to increase access to misoprostol for PPH prevention have shown some success. For example, in five communities around Zaria in northwestern Nigeria a community mobilization effort reached most women with information about PPH and

misoprostol (88%), resulting in high comprehension of intervention messages (Prata, Ejembi et al., 2012). During postpartum interviews with the 1,875 women enrolled in the study, women said that TBAs, midwives, and health facilities (in that order) were the main sources of information about bleeding after childbirth. These women also said that TBAs, community oriented resource persons, and midwives (in that order) were the primary sources of information about misoprostol.

Evaluation of a pilot study in Ethiopia highlighted the importance of training non-clinical workers to distribute misoprostol as well: In 2007, 128 health extension workers (HEWs), representing 120 health posts in Amhara, Oromiya, SNNP, and Tigray regions were trained on the administration of misoprostol. The introduction of misoprostol into these communities by HEWs increased the community's willingness to seek delivery care from HEWs, increased collaboration between HEWs and TBAs, and increased demand for misoprostol from community members. Although results of the pilot study in Ethiopia confirmed the ability of HEWs to deliver misoprostol safely, the evaluation highlighted the need for sensitization of decision-makers at the district level, community education campaigns to raise awareness, and training TBAs (who already have communities' trust) to distribute misoprostol as well (Venture Strategies Innovations, 2008).

These studies point to the need to ensure that TBAs, CHWs, and other community-based health promoters have accurate information about PPH and misoprostol, and that facility-based providers are reassured about the safety of community-based misoprostol, including any impact on use of SBAs, and updated on PPH prevention and treatment guidelines.

Social/normative: The Ethiopia study referenced above found that while use of HEWs increased misoprostol uptake, most women remained reluctant to seek delivery care from health professionals, including HEWs (VSI, 2008). Other studies have identified that traditional beliefs and practices prevent women from seeking timely modern health care because it would be seen as a sign of weakness - illnesses, including problems during childbirth, are seen as having spiritual causes and thus would not respond to modern medicine - or the cultural "protocol" is to seek health solutions from the ancestors/traditional practitioner first, and modern medicine as a last resort (Ngom, 2003).

Demand: In studies with providers in India (Deepak et al., 2013; Mirzabagi et al., 2013), providers indicated that they used uterotonics

often, if not primarily, because pregnant women and family members (usually mothers-in-law) insisted on it to augment labor. This points to at least the possibility of pregnant women and their families demanding misoprostol to prevent PPH.

Availability: In three studies from Bangladesh (Prata et al., 2012b; EngenderHealth, 2010; Nasreen et al., 2011), community distribution of misoprostol helped increase its use after delivery. One study found CHWs not being present or the drug not being available (17.6%) as a key reason for not using misoprostol (Nasreen et al., 2011). In a Nigerian study, the small proportion (18%) of women who did not take misoprostol to prevent PPH primarily reported that they either were not offered misoprostol (60%), took an injection (12%), forgot to take misoprostol (7%) or, in a few cases (4-5%), could not find the drug, did not think they would need it or their male partner/family would not allow them to take it (Prata el al., 2012a).

Regulatory issues can impact the availability and use of misoprostol for PPH not only at the community level but also in health facilities. For example, misoprostol might only be registered for treating ulcers. Clinicians knowledgeable about misoprostol's effectiveness in preventing PPH can choose to use misoprostol for PPH even though it is only registered for treating ulcers, and some will do so. If, however, misoprostol is also registered for PPH and there are official, widely disseminated clinical guidelines for misoprostol for PPH, demand and use of misoprostol for PPH would likely increase (PATH, UNFPA, USAID, 2012).

Regulatory issues notwithstanding, a review of literature on uterotonic use at home births found oxytocin administered in as few as 1.5% of home births in Bangladesh in 1994 to as many as 69% in India in 2005 (Flandermeyer et al. 2010), suggesting widespread availability at community level in some areas and very little availability in others. Among the intervention studies included in this review, where a uterotonic was administered as part of an intervention, prevention of PPH was the most frequent use of uterotonics at home births. In descriptive studies, that reported qualitative descriptions of uterotonic use at home births, the most common use of injectable oxytocin at home births was to accelerate labor. No studies were found that showed use of misoprostol before delivery of the baby at home births.

Example of Table to Organize Key Information

	Current Behaviors	Primary Barriers to Desired Behavior	Primary Benefits of Desired Behavior
End-user/community members (e.g. pregnant women, caregivers)	Approximately 30% of births worldwide are attended by unskilled attendants. In sub-Saharan Africa, where nearly half of the world's maternal deaths occur, only 46% of deliveries are assisted by skilled attendants. In some countries, as many as 90% of births occur at home. Lack of a skilled birth attendant can mean increased risk of maternal death due to PPH.	Limited access for rural and poor woman to birthing services Women not seeking SBA services Limited misoprostol awareness and promotion Fear of side effects and misperceptions about misoprostol (e.g. a focus on abortifacient properties)	Prevention of PPH Reduction of maternal deaths due to PPH Community-based distribution and use
Providers (incl. public and private, clinic- and community-based)	Misoprostol successfully used by both facility-based and community-based providers in a few countries but not at wide scale in any countries	Low levels of knowledge Lack of up-to-date training and out-of-date protocols Misoprostol not registered for full range of uses (e.g. PPH	Prevention of PPH Reduction of maternal deaths due to PPH No need for cold chain storage

		prevention) Poor perception of misoprostol because it can be used to induce abortions Unclear whether, when, and where misoprostol will be approved for community-based distribution and use	