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PREVENTING POSTPARTUM HEMORRHAGE AT THE COMMUNITY LEVEL IN SENEGAL WITH MISOPROSTOL

December 2010

This publication was produced for review by the United States Agency for International Development. It was prepared by Christine Ortiz, Amadou Sylla, Mohamed Diadhou, Thierno Dieng, Ibrahima Mall, and Nancy L. Sloan for the Health Systems 20/20 Project.

HEALTH SYSTEMS 20/20

Mission

The Health Systems 20/20 **cooperative agreement,** funded by the U.S. Agency for International Development (USAID) for the period 2006-2011, helps USAID-supported countries address health system barriers to the use of life-saving priority health services. Health Systems 20/20 works to strengthen health systems through integrated approaches to improving financing, governance, and operations, and building sustainable capacity of local institutions.

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PREVENTING POSTPARTUM HEMORRHAGE AT THE COMMUNITY LEVEL IN SENEGAL WITH MISOPROSTOL

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ACRONYMS

CEFOREP	*Centre en Formation et Recherche en Santé de la Reproduction* (Center for Training and Research on Reproductive Health)
DHS	Demographic and Health Survey
EOC	Emergency Obstetric Care
FCFA	*Franc Communauté Financière d'Afrique* (West African currency)
ICP	*Infirmiers Chefs de Postes* (Head nurses at health posts)
MDG	Millennium Development Goals
MoH	Ministry of Health (Senegal)
PAC	Post-abortion Care
PPH	Postpartum Hemorrhage
SD	Standard Deviation
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
WHO	World Health Organization

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COLLABORATORING HEALTH DISTRICTS AND MATERNITY HUTS

Medical Region	District	Maternity Hut
KAOLACK	KASNACK	Bouthie
		Keur Diene
		Ndiakhate
	NDOFANNE	Sikatroum
	NIORO DU RIP	Velingara Walo
		Ndiago Ii
		Keur Mandongo
		Ndiague Walo
		Keur Madi Yacine
THIES	POPENGUINE	Bentagnier
		Bouthou
		Kignabour I
	POUT	Khodoba
	THIADIAYE	Kiniabour Ii
		Yabo Yabo
	THIES	Keur Thiene
		Dioungne
		Keur Mor Ndiaye
	TIVAOUANE	Ndiaye Bopp
		Beyti Bocar

EXECUTIVE SUMMARY

Senegal has a maternal mortality ratio of 401 maternal deaths per 100,000 live births; only 33 percent of deliveries in the country are assisted by skilled attendants qualified to prevent or treat obstetric complications (Ndiaye and Ayad 2006). Twelve percent of deliveries in Senegal occur in hospitals or in private clinics, the highest-level providers of maternity care; 22 percent occur in health centers with essential obstetric care (EOC) capacity; 24 percent in health posts that refer to the health centers or higher level hospitals; and 1-2 percent at maternity huts. Thirty-eight percent of women deliver at their own or another's home. Most births and nearly all maternal deaths occur in rural areas where home deliveries are common, birth attendants are scarce or inadequately prepared to prevent and manage postpartum hemorrhage (PPH), and reaching institutional care is difficult (World Health Organization et al. 2005). Hemorrhage is the single leading cause of maternal mortality in Senegal, as in Africa and Asia, accounting for over 29 percent of maternal deaths (Khan et al. 2006, UNFPA 2000).

Millennium Development Goal (MDG) 5 aims to reduce maternal mortality by 75 percent from 1990 levels by the year 2015. This goal is receiving increasing political attention as 2015 approaches, as shown by the African Union's 15th Summit on maternal and child deaths and the pre-summit on gender which also focused on maternal deaths. To reach MDG 5, public health policymakers in Senegal are working to improve maternal health outcomes by promoting institutional births. Until most women deliver institutionally, improving quality of care for the women who are still giving birth at the community level merits attention. Preventing PPH by giving misoprostol in areas where oxytocin is not available is being considered as a concomitant approach.

This study was originally designed to investigate whether auxiliary midwives (known locally as *matronnes*) under the supervision of a certified midwife could safely give misoprostol to women giving birth at maternity huts. Matronnes are the medical professionals at the community level in Senegal. Twenty auxiliary midwives were trained from 20 different communities in two districts, 11 in Thiès and nine in Kaolack. All auxiliary midwives and their supervisors attended a six-day training session at their area health center or health post. Approximately five days were spent on refresher EOC training. Approximately one day of training plus a practicum of up to 10 supervised deliveries was dedicated to instruction on the safe and correct administration of misoprostol. Each auxiliary midwife conducted from three to 14 deliveries, in addition to the 10 deliveries per auxiliary midwife that were to be conducted during the health center training period. One hundred and fifty-four eligible pregnant women were identified in Thiès (113 during the training period and 41 whose deliveries occurred in the maternity huts) and were assisted by the participating auxiliary midwives. In Kaolack, auxiliary midwives assisted 82 deliveries in the health center or health post during the training period and nine deliveries in the community maternity huts.

Due to the local requirement that all administration of misoprostol by auxiliary midwives be supervised, and the fact that full survey data were collected on only about women who received misoprostol, the study is currently unable to evaluate the unsupervised administration of misoprostol for PPH prevention and can only estimate the proportion of women delivering in the community maternity huts who received misoprostol.[1] However, all 245 study participants whose deliveries were assisted by trained auxiliary midwives received 100 percent correct, safe administration of misoprostol for PPH prevention.

[1] A separate study monitoring report estimated that only 18 percent of maternity hut deliveries in Thiès and 4 percent of maternity hut deliveries in Kaolack were administered misoprostol during the study period.

The study results indicate that only limited training is required to effectively teach auxiliary midwives to provide misoprostol for PPH prevention. Most women, particularly those delivering in the village maternity huts, were also willing to pay for some or all of the costs of misoprostol for PPH prevention.

It is the official policy of the Ministry of Health in Senegal to promote institutional births. This is a laudable long-term goal for all women in Senegal. However, community-level births will undoubtedly continue to occur in the short and medium term, for a variety of reasons including cultural norms, education levels, limited transport networks, and the cost of facility-based care. It is therefore realistic and appropriate to consider community-level approaches for preventing PPH. This study indicates that the provision of misoprostol by trained auxiliary midwives at the community level (in this study, with supervision as required by the Senegalese ethics committee) is a safe approach to preventing PPH. However, consistent supervision of all community-level deliveries by nurse midwives is unfeasible outside of a study setting. The availability of skilled attendants at delivery also negates the need for administering misoprostol to prevent PPH, as certified midwives can administer injectable oxytocin for PPH prevention.

1. INTRODUCTION

In September 2000, world leaders met and ratified their intention to meet the eight Millennium Development Goals (MDGs) by 2015 in an unprecedented effort to improve the life of the world's neediest populations. Three of these goals relate to health issues, and MDG 5 is specifically devoted to maternal health, with one of the targets being to reduce maternal mortality ratios by 75 percent by 2015. With less than five years to go, it is becoming clear that many countries are struggling to meet this goal. While efficient and effective interventions have been identified and constitute the underpinning of the fight to reduce maternal mortality in developing nations, most of these are difficult to deliver at community level, especially where health systems are weak and cultural habits dissuade women from accessing modern medical care at childbirth.

Most births and nearly all maternal deaths occur in rural areas of developing countries where home deliveries are common, birth attendants are scarce or inadequately prepared to prevent and manage postpartum hemorrhage (PPH), and reaching institutional care is difficult. Hemorrhage is the single leading cause of maternal mortality, accounting for over 30 percent of maternal deaths in Africa and Asia (World Health Organization et al. 2005). MDG 5 cannot be reached without successful prevention and timely treatment of PPH.

While oxytocin is the first drug of choice for the prevention and treatment of PPH, it requires refrigeration and must be administered via injection. As an alternative in low-resource contexts, prophylactic misoprostol is a highly effective and cost-effective intervention to avert PPH, particularly severe PPH (Bradley et al. 2007, Derman et al. 2006, Walraven et al. 2005). The drug, which does not require refrigeration and is administered orally, has been shown to be a simple, safe, affordable mechanism to prevent and manage PPH. It is particularly useful in rural areas of developing countries where many births occur at home, far from health care institutions offering essential obstetric care. However, because of concerns that the drug could also be misused at the community level, some policymakers have been slow to promote community-level administration of misoprostol. Some have also argued against promoting misoprostol for fear that it would encourage women to continue delivering at home, rather than at health facilities.

To contribute to the evidence base on this topic, the United States Agency for International Development (USAID) funded a study in Senegal in 2009 to assess the feasibility of administering misoprostol at the community level. The study was implemented in two districts by the Abt Associates-led Health Systems 20/20 project and the Senegalese research institution CEFOREP (*Centre en Formation et Recherche en Santé de la Reproduction*, or Center for Training and Research on Reproductive Health). It was designed to investigate whether auxiliary midwives (known locally as *matronnes*) under the supervision of a certified midwife could safely give misoprostol to women giving birth at maternity huts. The remainder of this report provides more background on the Senegalese context, describes the methods used for the study, presents study findings, and discusses their policy implications.

2. BACKGROUND AND CONTEXT

Senegal is divided into 14 regions, with a total of 45 departments. The population was estimated at 12 million by the 2005 Demographic and Health Survey (DHS), of which 50 percent live in rural areas. Population growth is quite rapid (2.6 percent average growth rate between 2005 and 2010[2]) and contraceptive prevalence rates have declined in comparison to the 1992 DHS. Maternal mortality is estimated at 401 maternal deaths per 100,000 live births (Ndiaye and Ayad 2006). In 2007, the Gross National Product was US$11 billion according to International Monetary Fund data, and per capita income $820, with an unemployment rate estimated at 48 percent. Despite the fact that overall quality of life has improved in Senegal since the devaluation of the currency (FCFA) in 1994, much of the Senegalese population is still living in poverty (34 percent live on less than $1.25 a day) (UNICEF 2009).

The public health system is organized in a classical health pyramid structure, with 20 national and regional hospitals at the top, supported by 76 health centers, 1,173 health posts, and 2,200 health/maternity huts (Mbengue et al. 2009). At the maternity hut level, auxiliary midwives (matronnes) are the primary maternal health care providers. Matronnes generally receive some formal training, are registered with the Ministry of Health (MoH), and frequently have substantial practical experience. However, the MoH does not consider matronnes sufficiently qualified to dispense medication or provide injections (such as oxytocin) or maternity huts sufficiently well equipped to provide "institutionalized" delivery care.

In January 2005, the government of Senegal instituted a policy of providing free access to institutional childbirth services as part of its commitment to improving maternal outcomes and reaching the MDGs. Although recent evaluations of this policy disagree about its success, the recent UNFPA evaluation of this policy shows limited impact thus far on the rate of institutional births, especially for rural populations (UNFPA 2008). The lack of impact may be due to remaining nonfinancial barriers, such as lack of transportation, poor quality of facility-based care, cultural norms, or lack of information. Senegalese policymakers and international donors have thus been interested in investigating other strategies for providing safe motherhood services to those women who deliver at home or at the maternity hut level. The study of community-level administration of misoprostol is part of this effort.

At the time of this study, misoprostol was not on the list of registered pharmaceuticals in Senegal, except for use in treating gastric ulcers. Because misoprostol can be used to induce labor and can also cause miscarriage, some obstetricians and gynecologists were concerned that the drug could be misused by lower-level or inadequately trained practitioners. This project was designed to evaluate whether a training protocol could ensure safe and correct administration of misoprostol for prevention of PPH at the community level. Upon approval of the study, Venture Strategies donated the necessary supply of misoprostol to USAID, which provided the supplies required to CEFOREP for conduct of the study.

[2] http://www.unfpa.org/swp/2009/en/pdf/EN_SOWP09_DemSocialEcon.pdf

3. METHODOLOGY

3.1 STUDY OBJECTIVES

The study's original goal was to contribute to the prevention of PPH at the community level in Senegal. Specific objectives included:

1. Demonstrating that auxiliary midwives are capable of using misoprostol during childbirth at both the health center and maternity hut level, while guaranteeing its safe (correct) administration for the prevention of PPH and,

2. Evaluate whether ≥70 percent of all maternity hut births could be provided with misoprostol in the selected sites during the study period, based on the established protocol.

3.2 STUDY POPULATION AND SUBJECTS

At the study's inception in 2006, a technical review committee was established including participation by the MoH, USAID, Abt Associates representatives in Senegal, the World Bank, CEFOREP, the Christian Children's Fund, IntraHealth, and Groupe ISSA Senegal. Participants also included medical professionals, statisticians, community workers, and public health program managers (please see Annex A for full list of technical committee members). The technical review committee reviewed and finalized the study protocol. The study was originally planned to be conducted at health posts as the MoH had made a concerted effort over the previous years to discourage home and maternity hut births and to encourage institutional delivery. The technical committee, however, felt that it was critical to implement the study at the most basic community level possible, i.e., the maternity huts, to inform decision making to overcome inequities, improve obstetric services, and save more women's lives.

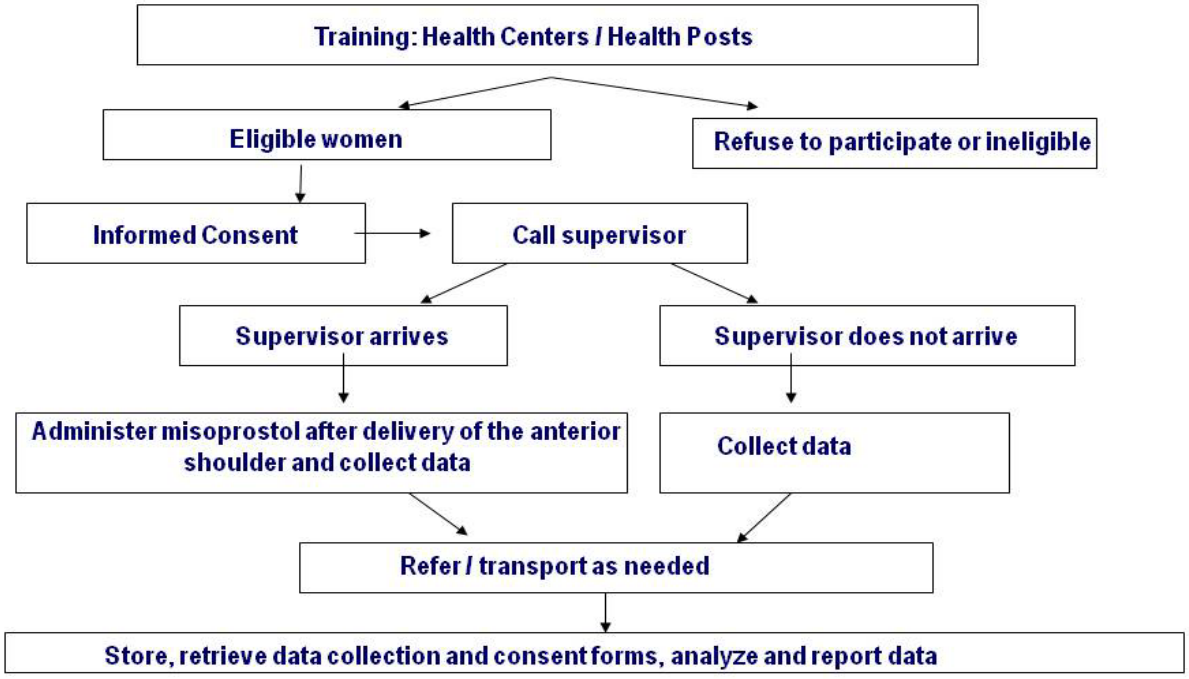
The technical committee concluded that the study could demonstrate safe and correct administration of misoprostol by training eight matronnes and their supervisors in each of two regions. Each matronne would be required to attend a six-day training session at a regional health center, including attending and providing 600 mg (three 200-mg tablets) of oral misoprostol to 10 women delivering at the health center. If the matronne demonstrated that she could correctly provide misoprostol by the end of the training period, she would then be permitted to go back to her village and provide misoprostol to three to five women delivering in her maternity hut. This implied that the study would enroll approximately 240 pregnant women to participate in the study (8 matronnes * 2 districts * 15 deliveries per matronne).

The project was designed to be conducted in two socio-demographically distinct areas where rates of institutional delivery and skilled attendance were poor and that had also participated in the earlier PSSC safe motherhood project that provided essential obstetric care (EOC) training. The three medical districts considered to best meet these criteria were Thiès, Louga, and Kaolack. Of these, Thiès and Kaolack were most different and thus selected for this study. Thiès is the third-largest city in Senegal with a population officially estimated at 320,000 in 2005, located approximately 60 km east of Dakar. Kaolack, with a population estimated at 180,000, located approximately 150 km southeast of Dakar, is much more rural and less densely populated. According to the 2005 DHS in Senegal, 21 percent of women in Thiès and 50 percent of women in Kaolack delivered at home, with 25-30 percent of women

delivering at health posts and approximately 8-9 percent of women delivering with auxiliary midwives. The study intended to enroll 120 pregnant women in Thiès and 120 in Kaolack.

The Senegalese ethics review committee required that the misoprostol be stored and maintained at each area's health post and did not give permission to store misoprostol at the maternity hut level, or for matronnes to dispense misoprostol without a supervisor present. The ethics review committee also required that matronnes be supervised by a more senior practitioner when administering misoprostol. The project therefore developed a protocol by which the matronnes working in the community-level maternity huts would call the supervising certified midwife or ICP (*Infirmier Chef de Poste,* the head nurse at the health posts) when a woman eligible for inclusion in the study had presented for delivery. The project provided cell phones to all participating matronnes to facilitate mobilization of their supervisors. When called, the supervisors were to immediately arrange transportation (the health post ambulance or bush taxi) and personally take the misoprostol to the village maternity hut, where they would supervise the matronne administering the drug. Figure 1 illustrates the protocol.

FIGURE 1: STUDY PROTOCOL



The study established criteria to select maternity huts, and thus sample areas, that would best ensure supervision and provision of misoprostol for the deliveries occurring in the village maternity huts (Table 1). It was not possible to identify eight matronnes and maternity huts meeting all of these criteria, thus 20 auxiliary midwives who best met these criteria (11 in Thiès and nine in Kaolack) were selected to achieve the sample of 240. The sample is sufficient to test correct administration of misoprostol with a margin of error of +/- 5 percentage points, assuming 80 percent power, 5 percent probability of a Type I error, and a two-tailed test.

TABLE 1: SELECTION CRITERIA FOR MATRONNES

Criteria for matronnes
Auxiliary midwife is educated/literate
Auxiliary midwife has proven experience in delivering babies
Auxiliary midwife received training/participated in the PSSC safe motherhood intervention activities
Auxiliary midwife works in a functional maternity hut (with a supervising ICP/midwife, a community health agent, a local operational health committee) where the package of basic services of the Community Health Program is available
Auxiliary midwife works in a maternity hut located no more than 15 km from the health post
Auxiliary midwife works in a maternity hut where there is an average of 20 deliveries or more per year
Auxiliary midwife works in a maternity hut where the population seems engaged in health activities/care

3.3 INCLUSION AND EXCLUSION CRITERIA

Pregnant women were eligible for study participation if they were at least 15 years old, presented at the maternity hut in the first stage of labor, provided cognizant informed consent, were pregnant with singletons (multiple gestation was excluded), and had no known allergies to prostaglandins (Table 2).

TABLE 2: INCLUSION CRITERIA FOR STUDY PARTICIPANTS

Criteria for delivering women
Age ≥ 15 years
Admitted to maternity hut during first stage of labor
Demonstrating no morbidity factors or danger signs which might require intervention by more qualified health personnel
Monofetal pregnancy
No known allergies to prostoglandins
Willing to participate in the study (formal informed consent agreement)

3.4 TRAINING

All auxiliary midwives and their supervisors attended a six-day training session at their area health center (or health post in one area where the health center was unavailable). Approximately five days were spent in refresher EOC training. Approximately one day of training plus a practicum of at least 10 supervised deliveries was dedicated to instruction on the safe and correct administration of misoprostol, including identifying and excluding multiple gestation, and provision of three 200-mg tablets of oral misoprostol with water to women after the delivery of the baby's anterior shoulder. One day was dedicated to training the auxiliary midwives and their supervisors in data collection.

The training included training of trainers (the supervisors as well as district medical officers from the two regions involved). For this purpose a training manual was developed for supervisors as was a guide for the matronnes.

3.5 DATA COLLECTION AND ANALYSIS

The Health Systems 20/20 team adapted, translated and back-translated (into French and Wolof) questionnaires that were adapted from similar studies (Walraven et al. 2005). The in-country study team led by CEFOREP pretested the series of eight questionnaires in Thiès and modified them accordingly. Data were collected between July and December 2009. According to the original study design, information was to have been collected on all eligible women presenting for delivery at the maternity hut level (Figure 1). However, because the data collection forms were pre-packaged together with the misoprostol, data were only collected from the subset of women with supervised deliveries who actually received misoprostol. Upon completion, all data forms were stored in a locked file separately from informed consent forms, and held by the supervisor until retrieval by the study team. Delivering women's names were not recorded, and only the data collector signed the informed consent form. Upon retrieval, the data collection forms were maintained in a similarly secure manner at CEFOREP, where they were entered into an EpiData version 6.0 database. The data were then analyzed in SPSS version 17. Chi-squared and t-tests were used to test differences in categorical and continuous variables, respectively, between Thiès and Kaolack.

3.6 ETHICAL REVIEW AND INFORMED CONSENT

The study was conducted in accordance with the Declaration of Helsinki. The protocol was approved by the Senegal ethics review committee and by the Institutional Review Board (IRB) of Abt Associates Inc. The consent script was translated from French into Wolof and tested prior to use (see Annex B for the French version).

4. FINDINGS AND DISCUSSION

4.1 RESULTS

Each of the trained matronnes conducted between three and 15 deliveries. These included up to 10 deliveries during the health center training period. In Thiès, most auxiliary midwives assisted 10 deliveries during the training period in the health center or health post, whereas matronnes in Kaolack attended nine deliveries on average during the training period. The study design aimed for each matronne to attend at least three supervised deliveries in the maternity huts, but not all matronnes were able to do so during the study period because the study was conducted in rural areas, and relatively few deliveries occur at the community maternity huts (Ndiaye and Ayad 2006) (most community-level births take place in people's homes). Overall, 154 eligible women in labor were identified in Thiès (113 during the training period and 41 in the maternity huts). In Kaolack, auxiliary midwives assisted 82 deliveries in the health center or health post during the training period and nine deliveries at the community maternity huts.

Because the data collection forms were packaged with the misoprostol and kept by the supervisors at the health posts, data were not collected on women for whom a supervisor did not arrive in time to supervise the delivery. A separate study monitoring report estimated that only 18 percent of maternity hut deliveries in Thiès and 4 percent of maternity hut deliveries in Kaolack were administered misoprostol. All eligible women with supervised deliveries from whom data were collected consented to participation in the study (Table 3).

TABLE 3: ENROLLMENT OF PREGNANT WOMEN

	Thiès		Kaolack		
	Health Centers	**Maternity Huts**	**Health Centers**	**Health Posts**	**Maternity Huts**
Eligible women	113	41	74	8	9
Consenting women	100%	100%	100%	100%	100%

As expected, some socio-demographic differences in study participants were observed between Thiès and Kaolack (Table 4). Significantly more women were of Wolof ethnicity and were working as housewives in Kaolack than in Thiès, while significantly more women in Thiès had formal schooling and more had monogamous marriages. Women in Thiès had significantly more antenatal consultations, yet a similar proportion in both districts received iron-folate supplementation. Most women received some type of antimalarial medication during pregnancy. However, significantly more women in Kaolack received antimalarial *prophylaxis* during pregnancy, while significantly more women in Thiès received antimalarial *treatment*. As expected, significantly more women had experienced five or more births in Kaolack.

TABLE 4: SOCIO-DEMOGRAPHIC CHARACTERISTICS OF PREGNANT WOMEN

	Thiès (N=154)	Kaolack (N=91)	P-value	Total (N=245)
Mean age in years [SD]	26.8 [5.7]	25.7 [5.3]		26.4 [5.5]
Ethnic group				
Wolof	35.3%	57.1%	≤0.001	43.6%
Pular	17.3%	19.8%		18.3%
Sérère	40.0%	17.6%		31.5%
Mandingue	5.3%	5.5%		5.4%
Other	2.0%	0.0%		1.2%
Gravidity [SD]	3.5 [2.0]	4.1 [3.0]		3.7 [2.4]
Parity [SD]	2.8 [1.9]	3.2 [2.6]		2.9 [2.2]
Primiparous	9.1%	9.9%		9.4%
Parity ≥5	18.2%	29.7%	≤0.05	22.4%
Number of living children [SD]	2.6 [1.7]	2.9 [3.6]		2.7 [2.6]
Principle occupation			≤0.01	
Housewife	80.3%	90.1%		84.0%
Farmer	0.7%	5.5%		2.5%
Business/Trader	9.2%	1.1%		6.2%
Professional	1.3%	0.0%		0.8%
Other	8.6%	3.3%		6.6%
Highest level of education			≤0.001	
None	47.1%	36.3%		43.0%
Primary	20.9%	13.2%		18.0%
Secondary	13.1%	4.4%		9.8%
Technical training	0.7%	0.0%		0.4%
University	0%	0%	0%	0%
Other	17.6%	46.2%		28.3%
Don't Know	0.7%	0.0%		0.4%
Marital status				
Monogamous marriage	65.6%	53.8%		61.2%
Polygamous marriage	30.5%	40.7%		34.3%
Widowed/Divorced	.6%	2.2%		1.2%
Other	3.2%	3.3%		3.3%
Number of antenatal care visits [SD]	3.4 [0.9]	2.7 [1.1]	≤0.001	3.1 [1.1]
Gestational medications				
Iron folate	96.1%	96.7%		96.3%
Antimalarials	87.7%	94.5%		90.2%
Medications to prevent malaria	80.9%	93.4%	≤0.01	85.6%
Medications to treat malaria	14.9%	3.3%	≤0.01	10.6%

Table 5 summarizes the administration of misoprostol by trained matronnes as well as active management of the third stage of labor (delivery of the placenta). Correct administration of misoprostol (three tablets of 200 mg misoprostol, with water, promptly after delivery of the baby's anterior shoulder) was observed for 100 percent of study participants – at the health center, health post, and maternity hut levels. These data indicate that minimal training is sufficient to teach matronnes to correctly and safely provide misoprostol; most of the six-day training of the auxiliary midwives focused on EOC review, with only one day dedicated to misoprostol training.

TABLE 5: MISOPROSTOL ADMINISTRATION AND ACTIVE MANAGEMENT OF THE THIRD STAGE OF LABOR TO PARTICIPANTS IN HEALTH CENTERS, HEALTH POSTS, AND MATERNITY HUTS

	Thiès		Kaolack			Total	
	Health Centers (n=113)	Maternity Huts (n=41)	Health Centers (n=74)	Health Posts (n=8)	Maternity Huts (n=9)	Health Centers (n=187)	Maternity Huts (n=50)
Misoprostol correctly administered (3 tablets, with water, after delivery of anterior shoulder)	100%	100%	100%	100%	100%	100%	100%
Uterine massage	24.8%	2.4% ≤0.001*a*	25.7%	0%	77.8% ≤0.001	25.1%	16.0%
Controlled cord traction	27.4%	19.5%	13.5%	0%	75.0% ≤0.001	21.9%	28.6%

Because evidence regarding benefit or harm of controlled cord traction and uterine massage is sparse, particularly when administered by matronnes in community settings, the training purposefully recommended avoiding either intervention in the deliveries conducted in the maternity huts. Nonetheless, controlled cord traction was carried out for some women delivering in the maternity huts, and uterine massage was also commonly conducted in these deliveries in Kaolack.

As observed in the literature, women reported few side effects from the misoprostol. Some women reported chills (approximately 30 percent of women in the health centers and health posts during the training and about 40 percent in women delivering in the maternity huts) or fever (about 4 percent in both the health centers/posts and maternity huts) (Table 6). All side effects were transient, and only one woman who delivered in the health center in Thiès found the chills she experienced to be intolerable. All other women experiencing side effects found them to be tolerable or neutral.

TABLE 6: SIDE EFFECTS AS OBSERVED BY THE ATTENDING AUXILIARY MIDWIFE AND SUPERVISOR

	Thiès		Kaolack			Total	
	Health Centers (n=113)	Maternity Huts (n=41)	Health Centers (n=74)	Health Posts (n=8)	Maternity Huts (n=9)	Health Centers (n=187)	Maternity Huts (n=50)
Side effects in the hour following delivery							
Nausea	0	0	0	0	1≤0.01	0	1
Vomiting	0	0	0	0	1≤0.01	0	1
Diarrhea	0	1	0	2≤0.05	0	0	3
Chills	27 (23.9%)	17 (41.5%)*	28 (37.8%)	3 (37.5%)	4 (44.4%)*	55	21
Loss of consciousness	0	0	0	0	0	0	0
Fever	0	2 (4.9%)*	7 (9.5%)	0	0	7	2
Fatigue	0	3	1	0	1	1	4
Headache	1	0	1	0	1	2	1
Other	0	0	0	0	0	0	0
Referred to a higher level of care	0	0	0	0	0	0	0

*p<0.05 (comparing across health facility types within each district)

Women participating in the study were asked whether they would be willing to pay something for misoprostol to prevent PPH. All women delivering in the maternity huts (where oxytocin is not available as an alternative uterotonic) reported being willing to pay for the misoprostol to prevent PPH, with 28 percent willing to pay the local price (about 1,000 FCFA) and 56 percent willing to pay between 500 and 1,000 FCFA (Table 7). Slightly fewer women (86 percent) delivering in the health center were willing to pay for misoprostol to prevent PPH, with 21 percent willing to pay ≥1,000 FCFA and 48 percent willing to pay between 500 and 1,000 FCFA.

TABLE 7: PATIENT WILLINGNESS TO PAY FOR MISOPROSTOL FOR PPH PREVENTION

	Thiès		Kaolack			Total	
	Health Centers (n=113)	Maternity Huts (n=41)	Health Centers (n=74)	Health Posts (n=8)	Maternity Huts (n=9)	Health Centers (n=187)	Maternity Huts (n=50)
Willing to pay for 3 misoprostol tablets (%)							
Yes	82.3	100 (≤0.05)	90.5	100	100	85.6	100
No	7.1	0	4.1	0	0	5.9	0
Depends on how much	10.6	0	4.1	0	0	8.0	0
Don't know/no response	0	0	1.4	0	0	0.5	0
How much willing to pay (FCFA)							
Nothing	8.8	0	8.1	12.5	0	8.6	0
<500	7.1	9.8	13.5	12.5	0	9.6	8.0
500 to 1000	51.3	48.8	41.9	62.5	88.9	47.6	56.0
≥1000	19.5	31.7	24.3	12.5	11.1	21.4	28.0
Don't know	13.3	9.8	12.2	0	0	12.8	8.0

4.2 DISCUSSION

This study evaluated whether auxiliary midwives (matronnes) in Senegal, under the supervision of a certified midwife, can be trained to correctly and safely administer misoprostol for the prevention of PPH during childbirth at both the health center and community maternity hut level. We found that this is indeed possible: all study participants whose deliveries were assisted by the trained matronnes received correct, safe administration of misoprostol for PPH prevention. Moreover, the study results indicate that limited didactic training (one day) in combination with a short practicum was sufficient to effectively teach matronnes to provide misoprostol for PPH prevention.

Because the Senegalese ethics review committee required that all administration of misoprostol by auxiliary midwives be supervised by certified midwives for this study, we are unable to draw conclusions about whether auxiliary midwives without supervision could correctly and safely administer the drug. However, the protocol for administering the drug is extremely simple. The fact that the matronnes performed the intervention perfectly in all instances leads us to surmise that they would indeed be capable of correct, safe administration without supervision.

Because data collection forms and misoprostol were kept by the supervisors at the health center level, we are also unable to provide a precise estimate of the proportion of women delivering in the community maternity huts who received misoprostol. However, a separate data sweep of the maternity huts estimated that 18 percent of maternity hut deliveries in Thiès and 4 percent of maternity hut deliveries in Kaolack were administered misoprostol.

We found that most women were willing to pay for some or all of the costs of misoprostol for PPH prevention (based on current market prices). Over 80 percent of women in our study were willing to pay at least 500 FCFA for this preventive treatment. This leads us to believe that Senegalese women would be open to receiving this care option if it were offered to them, even if they were expected to cover the cost of pharmaceuticals. It is interesting to note that all the women who stated they were unwilling to pay delivered at the health center level, where oxytocin is available as an alternative uterotonic; those delivering in the village maternity huts, where alternative drugs for PPH prevention are not available, were most likely to be willing to pay for misoprostol. Stated willingness to pay is pertinent because the free access to childbirth care and cesareans instituted in 2005 by Senegal's MoH only covers the cost of the service itself, not any related drugs. It is probable that any costs of providing misoprostol at the community level in the future would be covered by direct charges to the woman (or her family). Currently, 62 percent of all expenditure for health in Senegal is out-of-pocket spending and only 20 percent of the population is covered by some sort of risk sharing (Mbengue et al. 2009). The national norm regarding mark-ups for generic pharmaceuticals at health post or lower levels is 50 percent, which would bring the cost per preventive treatment to 1,500 FCFA (~ $3) at prices currently available in pharmacies. However, it should be noted that if the drug were obtained from a nonprofit source in generic form (similar to the tablets provided by Venture Strategies), the cost would drop to approx 167 FCFA (~ $0.33).

Because misoprostol can be used to induce labor and can also cause miscarriage, some obstetricians and gynecologists in Senegal remain hesitant about unsupervised matronnes providing misoprostol to women to avert the consequences of PPH, including maternal death. However, requiring certified midwives to supervise all provision of misoprostol for PPH prevention is not replicable on a broad scale. Such a restriction would result in limited coverage of misoprostol for PPH prevention, especially in areas where transportation between health posts and maternity huts and round-the-clock availability of supervisors is challenging (such as in Kaolack). The availability of skilled attendants at delivery also negates the need for alternative mechanisms to prevent PPH, as certified midwives can administer injectable oxytocin for PPH prevention. Furthermore, the recent Health Systems Assessment for Senegal (Mbengu et al. 2009) shows that human resources for health are stretched thin, especially in rural areas. These are exactly the areas where the drug's potential to save lives is greatest.

Concern was also expressed during the technical committee team meetings that misoprostol could find its way into parallel markets and be sold for use as an abortative during the first trimester of pregnancy. Parallel markets for drugs and seepage from the public sector is a documented reality in Senegal (Mbengue et al. 2009). While misoprostol is available in Senegal for use in the treatment of gastric ulcers, it has not yet been approved for gynecological use. The gynecological uses of the drug are not limited to PPH, as misoprostol can also be used for post-abortion care (PAC). While abortion is illegal in Senegal except in cases where the mother's health is at risk, 13,719 women were hospitalized in Senegal in 2007 following unsafe abortions.[3] This demonstrated need for adequate PAC as well as the opinions voiced by gynecologists at the regional Gynuity conference held in Dakar in May 2009 regarding the need for misoprostol to be made available for PAC, compounded by the drop in contraceptive prevalence rates over the last 10 years, show that the demand for (illegal/unsafe) abortion exists. These concerns should therefore not be dismissed, and must be adequately addressed before the MoH will feel comfortable putting misoprostol on the list of registered drugs, let alone adding it to the essential medicines list for gynecological uses.

A possible way to mitigate the existing concern about misuse of misoprostol would be to promote it for treatment rather than prevention of PPH. Evidence has accumulated in recent years from several

[3] http://www.unfpa.org/webdav/site/global/shared/documents/events/2010/pac/faye_051310.pdf

developing country trials indicating that misoprostol is efficacious for treatment of PPH as well as prevention (Winikoff et al. 2010). Policymakers in Senegal might consider training matronnes to provide misoprostol for PPH treatment and to immediately arrange transportation and referral to the nearest health center where additional oxytocics (and in some cases transfusion and hysterectomy) are available for secondary treatment. Since under the "treatment" policy, only those women actually experiencing a PPH would receive the drug, fewer doses would need to be in circulation. The prevalence of simple PPH (defined as loss of ≥500 ml of blood) is estimated to be 10.5 percent, while severe PPH (loss of ≥1000 ml) is 1.9 percent in studies of measured blood loss. Thus, even using simple PPH as an indicator for treatment would only require stocks of misoprostol for approximately 10 percent of pregnant women, rather than the stocks of misoprostol for 100 percent of women required for a PPH "prevention" policy (Carroli et al. 2008). Allowing matronnes to maintain small amounts of misoprostol sufficient for treatment of one or two women every few months would limit potential leakage while ensuring sufficient access to save women's lives. For this to be made possible, existing legislation on dispensing medications would have to be modified, as currently medicines are not dispensed at the maternity hut level.

It was often expressed to the study team that the general view of the medical establishment in Senegal is that the best method of achieving MDG 5 is for all women to have institutional births. There is concern that any intervention which might encourage women to continue delivering at home, rather than in a health facility, slows Senegal's progress toward reduced maternal mortality. There is additional concern in promoting the use of misoprostol since oxytocin is the drug of choice to prevent PPH, despite the fact that oxytocin cannot be used at the maternity hut level due to lack of refrigeration and matronnes not being authorized to administer injections. Clearly, promoting access to good-quality and affordable institutional delivery care is of paramount importance, both in Senegal and worldwide.

Nonetheless, it seems unlikely that institutional births will be accessible for all women in Senegal by 2015. Although the rate of institutional births increased from 47 to 52 percent between the Demographic and Health Surveys in 1992 and 2005 – accompanied by a substantial decrease in maternal mortality, from 510 to 401 per 100,000 live births – these rates of change will not allow Senegal to reach MDG 5 by 2015. The government's "free" childbirth and cesarean policy instituted in 2005 will likely accelerate the trend to institutional births. A recent evaluation of that policy showed a 20 percent increase in births attended by qualified personnel in 2005 alone, probably attributable to these policies. However, the evaluation also noted that the majority of the increase was attributable to areas close to hospital-level providers, in part because rural populations were not as informed as their urban counterparts about the free delivery policy. Substantial financial barriers to care still exist for the poorest (UNFPA 2008) for whom transport and medication costs continue to be barriers to accessing care. Difficult geographical access to health posts and irregular availability of care at those facilities also pose challenges; 33 percent of the Senegalese population is further than five kilometers from a health facility (not including maternity huts). Qualified human resources for health gravitate to urban locations, so lower-level facilities in rural areas are chronically understaffed and qualified personnel are not always available to provide care (Mbengue 2009). Furthermore, there is a clear preference for births to be assisted by traditional midwives or matronnes in many rural communities, partially because husbands do not want their wives to be attended by a male nurse or even a male gynecologist (UNFPA 2008).

Thus, while the MoH continues to promote institutional births as the optimum approach, that strategy could be paired with providing misoprostol to treat PPH at the community level. This would make childbirth safer for women in rural areas where access to institutional delivery care is likely to be limited for many years to come. This study adds to the evidence base in favor of such an approach by confirming that community-level practitioners are capable of correctly and safely administering misoprostol after receiving minimal training.

5. RECOMMENDATIONS AND NEXT STEPS

MDG 5, to reduce 75 percent of maternal mortality by 2015, cannot be reached without successful prevention and timely treatment of PPH (United Nations 2008). The World Health Organization has recommended that oxytocin or misoprostol be offered by a health worker trained in its use for deliveries that otherwise occur in the absence of active management of the third stage of labor (World Health Organization 2007). Misoprostol is an orally administered, safe, affordable mechanism to prevent and/or treat PPH; it can be particularly useful in rural areas of developing countries where many births occur at home, far from health care institutions offering essential obstetric care. It can be administered more feasibly than oxytocin by community-level practitioners, because it does not require injection or refrigeration. The results of this study suggest that auxiliary midwives at the community level, under supervision of a certified practitioner, can deliver misoprostol for prevention of PPH safely and do so in a consistent fashion, after a short period of didactic training combined with a practicum.

A second phase of this study was originally planned using a larger sample size. However, since the original study protocol was developed, other studies have indicated that the use of misoprostol for treatment of PPH is efficacious (Winikoff 2010). In the context of the concerns raised in Senegal about possible leakages of misoprostol into parallel markets and use of the drug to terminate pregnancy rather than prevent PPH, it may be more acceptable to advance community-based PPH treatment and referral. Unfortunately, we are concerned that the results of the current study are still insufficient to convince decision makers in Senegal to authorize misoprostol for prevention of PPH at community level (see draft notes from USAID Senegal workshop May 2010).

Possible actions to increase the political feasibility of providing access to misoprostol at the community level might include:

- Supporting advocacy activities, such as an informational campaign addressing concerns about misoprostol
- Providing technical assistance to strengthen pharmaceutical management and oversight in Senegal, which would address concerns related to leakage
- Facilitating study tours for politicians and decision makers to other countries that have approved misoprostol for use (e.g. Egypt, Nigeria, Brazil). This could be done as a regional effort including delegations from Ethiopia, the Democratic Republic of Congo, and Tanzania, countries that are also considering rolling out misoprostol for PPH at community level
- Using a champion to promote safer births at the community level. This has been a successful behavior change communication method for promoting reproductive health/family planning in South Asia that has the potential of being adapted for other issues.

ANNEX A: LIST OF TECHNICAL COMMITTEE MEMBERS

Name	Institution
Dr Bocar M. DAFF	MoH Reproductive Health Division
Dr El Hadj Ousseynou Faye	MoH Reproductive Health Division
Khady SY	MoH Reproductive Health Division
Mr Doulo Der	MoH Studies and Research Division
Dr Matar Camara	USAID Senegal
Dr Mame Cour N'dour	Groupe ISSA/Sub contract to Abt bilateral "Health Care Financing and Policy Program"
Mme Mariamme Fall	Childfund
Dr Fatou Ndiaye	Intrahealth
Dr Mohamed Diadhiou	CEFOREP
M Thierno Dieng	CEFOREP
M Amadou Sylla	CEFOREP

ANNEX B: INFORMED CONSENT FORM

Formulaire de consentement informé

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Nous conduisons une évaluation afin d'assurer qu'on vous donne correctement un médicament qui protège contre les hémorragies du post-partum (après l'accouchement). En général, on n'administre pas d'ocytocine par injection aux femmes qui accouchent sans l'assistance d'une sage-femme ou d'un médecin pour la prévention des hémorragies du post-partum. Le misoprostol, sous forme de cachet administré par voie orale immédiatement après l'accouchement, a montré son efficacité dans la réduction des hémorragies du post-partum dans de nombreux pays et son utilisation a récemment été recommandée pour toutes les femmes qui ne reçoivent pas d'ocytocine. Jusqu'à maintenant, le misoprosotol n'a pas été utilisé au Sénégal pour la prévention des hémorragies du post-partum.

Si vous décidez de participer à l'évaluation, la matronne va vous donner trois comprimés de misoprostol à prendre avec de l'eau presque immédiatement après l'accouchement de votre ou vos enfants (dans le cas où vous accouchez de jumeaux). Après avoir pris ces trois comprimés, vous aurez peut-être des nausées, des frissons et de la fièvre, des crampes abdominales, des saignements, des vomissements ou de la diarrhée. Mais ces effets vont normalement se dissiper après une courte période de temps.

Avant votre accouchement, on va vous poser des questions sur vos antécédents médicaux. Et avant de retourner chez vous, on va vous poser des questions sur votre âge, votre niveau d'instruction, votre occupation (ou métier) et autres informations similaires. Si, pour une quelconque raison, vous n'êtes pas éligible pour cette étude, ou si vous décidez de ne pas participer, vous recevrez quand même les soins standards de traitement avant, pendant et après votre accouchement.

Toute information que vous fournirez durant l'étude sera confidentielle et rangée dans un endroit sous clé. On ne pourra pas vous identifier dans les résultats et la présentation des données. Des informations vont être collectées sur environ 270 femmes et vont être agrégées. Votre nom n'apparaîtra sur aucun document, excepté la page sur laquelle vous acceptez de participer à l'étude. Seules les personnes faisant l'étude vont avoir accès à l'information que vous donnez.

L'évaluation va montrer les bonnes procédures à suivre pour que vous et d'autres femmes receviez correctement un médicament qui permet de protéger contre les hémorragies après l'accouchement. Ceci est dans le but de permettre que le misoprostol soit donné dans tout le Sénégal aux femmes ne recevant pas d'ocytocine après l'accouchement et pour réduire les hémorragies du post-partum et les complications qui lui sont associées.

Avez-vous des questions à propos de cette étude ?

Si vous souhaitez recevoir plus d'information concernant l'étude et ce qui précède, vous pouvez joindre Mr Thierno Dieng au numéro de téléphone suivant : 33 823 37 64.

Voulez-vous y participer ?

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J'ai été informée par la matronne qu'une évaluation était en cours pour assurer qu'on me donnait correctement un médicament qui permettra de me protéger contre les hémorragies après l'accouchement. En général, on n'administre pas d'ocytocine par injection aux femmes qui accouchent sans l'assistance d'une sage-femme ou d'un médecin pour la prévention des hémorragies du post-partum. Le misoprostol, sous forme de cachet administré par voie orale immédiatement après l'accouchement, a montré son efficacité dans la réduction des hémorragies du post-partum dans de nombreux pays et son utilisation a récemment été recommandée pour toutes les femmes qui ne reçoivent pas d'ocytocine. Jusqu'à maintenant, le misoprosotol n'a pas été utilisé au Sénégal pour la prévention des hémorragies du post-partum. La matronne a expliqué que le misoprostol va être donné à 90 femmes consentantes qui vont se présenter pour un accouchement à ce centre de santé, 90 femmes consentantes dans un autre centre de santé et 90 femmes consentantes dans diverses cases de santé.

Je comprends que cette étude ne présente aucun risque pour moi autre que la possibilité d'avoir des nausées, des frissons et de la fièvre, des crampes abdominales, des saignements, des vomissements ou de la diarrhée qui vont se dissiper après une courte période de temps. Cette évaluation va démontrer les procédures qui vont assurer que moi et d'autres femmes vont recevoir ce médicament correctement pour me protéger contre les hémorragies après l'accouchement. Ceci est dans le but de permettre que le misoprostol soit donné dans tout le Sénégal aux femmes ne recevant pas d'ocytocine après l'accouchement et pour réduire les hémorragies du post-partum et les complications qui lui sont associées.

J'accepte de faire partie de cette étude. Je comprends que ma participation est volontaire, que je peux refuser de participer ou de répondre à certaines questions et que je peux retirer mon consentement de participer à tout moment sans pénalité ou représailles quant aux soins que je vais recevoir. On m'a assuré que toutes les informations collectées sur moi vont être traitées de manière confidentielle, vont être sous clé et qu'on ne pourra m'identifier personnellement lorsque les résultats seront présentés. Des informations seront collectées sur environ 225 femmes et seront présentées de manière agrégée.

Je comprends que je peux poser des questions sur l'étude à ce moment. Si j'ai d'autres questions sur cette étude, je peux contacter (inscrire nom de la personne à contacter) au (inscrire adresse ou numéro de téléphone) _____

Je donne mon consentement volontaire pour participer à cette étude.

_____ _____

Signature ou marque de la patiente Signature de la matronne

_____

Nom du sujet (femme enceinte) en lettre majuscule :

Date : |___|___|/|___|___|/|___|___|___|___|

Numéro d'identification de la patiente à l'étude |___|___|___|___|___|

ANNEX C: REFERENCES

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