

**Review of Policy and
Procedures on Use of
Uterotonics for
Active Management
of the Third Stage of
Labor and
Prevention of
Postpartum
Hemorrhage in Four
African Countries**

***Benin,
Burkina Faso,
Cameroon,
and Mali***

Management Sciences for Health
is a nonprofit organization
strengthening health programs worldwide.



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Review of Policy and Procedures on Use of Uterotonics for Active Management of the Third Stage of Labor and Prevention of Postpartum Hemorrhage in Four African Countries: Benin, Burkina Faso, Cameroon, and Mali

Rational Pharmaceutical Management Plus Program

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About RPM Plus

RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen medicine and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

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The opinions and interpretations expressed in this report are the author's alone and do not necessarily reflect the points of view of the countries or Management Sciences for Health.

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ACRONYMS

AMTSL	active management of the third stage of labor
CAME	Centrale d'Achat de Médicaments Essentiels (Central Medical Stores, Benin)
CAMEG	Centrale d'Achat de Médicaments Essentiels Génériques (Central Medical Stores, Burkina Faso)
CENAME	Centrale Nationale d'Approvisionnement en Médicaments Essentiels (Central Purchasing Agency for Essential Medicines, Cameroon)
CMS	Central Medical Stores
DHS	Demographic and Health Survey
DPM	Pharmacy Directorate
DSF	Directorate of Family Health
FCFA	franc of the African Financial Community
FIGO	International Federation of Gynecology and Obstetrics
ICM	International Confederation of Midwives
NEML	National Essential Medicines List
MoH	Ministry of Health
PATH	Program for Appropriate Technology in Health
POPPHI	Prevention of Postpartum Hemorrhage Initiative
PPH	postpartum hemorrhage
PPM	Pharmacie Populaire de Mali (Central Medical Stores)
PPPH	prevention of postpartum hemorrhage
RPM Plus	Rational Pharmaceutical Management Plus [Program]
STG	standard treatment guidelines
USAID	U.S. Agency for International Development
WHO	World Health Organization

INTRODUCTION

Background

In 2004, the U.S. Agency for International Development (USAID) awarded a three-year project called the Prevention of Postpartum Hemorrhage Initiative (POPPHI) to a consortium formed by the Program for Appropriate Technology in Health (PATH), RTI International, EngenderHealth, the International Confederation of Midwives (ICM), and the International Federation of Gynecology and Obstetrics (FIGO).

Management Sciences for Health's Rational Pharmaceutical Management (RPM) Plus Program is a partner supporting this initiative; other collaborators in the POPPHI project include HealthTech and Access to Clinical and Community Maternal, Neonatal and Women's Health Services (ACCESS). The POPPHI project is part of USAID's special initiative to reduce postpartum hemorrhage (PPH), the leading cause of maternal deaths worldwide, by increasing use of active management of the third stage of labor (AMTSL).

Though several countries around the world are in the process of adopting AMTSL, to date little is known about the progress and success of implementation of these programs. Understanding that certain steps need to be taken at the central level to provide for successful scale-up and implementation at the facility level, RPM Plus selected four countries in West Africa—Benin, Burkina Faso, Cameroon, and Mali—all at various stages of implementing and expanding AMTSL, to assess whether these conditions had indeed been put into place.

Active Management of the Third Stage of Labor

AMTSL is an intervention that reduces the incidence of PPH by 60 percent. According to the 2003 Joint Statement of the ICM and FIGO and 2000 World Health Organization (WHO) guidelines, AMTSL consists of interventions designed to facilitate the delivery of the placenta by increasing uterine contractions and to stop PPH by averting uterine atony.

To effectively reduce the number of PPH cases, AMTSL should be provided systematically to all women after giving birth, when attended by a qualified health care provider.

The principal components of AMTSL include—

- Administration of a uterotonic (preferably oxytocin) within one minute of delivery
- Controlled traction of the umbilical cord
- Uterine massage after delivery of the placenta, as appropriate

Availability and Management of Uterotonics

The availability of uterotonics is a key component of any AMTSL intervention. Even well-trained health care providers would be unable to provide quality care without the assured availability of effective uterotonics.

Managing medicines effectively requires the prudent selection of products, procurement, storage, distribution, and use—all supported by a regulatory policy and environment that promotes the widespread supply of high-quality products.

Objectives

The goal of this study was to identify issues at the central level that might negatively affect the quality of services at the facility level, looking specifically at—

- Factors affecting the widespread availability of uterotonics in health facilities
- Training initiatives to ensure that staff are well trained in AMTSL and the storage requirements for uterotonics
- Systems to ensure quality products, maintained through a secure distribution chain

As part of this study, RPM Plus conducted a series of structured interviews and meetings to investigate the supply, storage conditions, and distribution procedures for uterotonics at the central level. Standard treatment guidelines (STGs) and essential medicines lists in support of AMTSL were reviewed. Areas for possible harmonization of AMTSL training as well as the supply and storage procedures for uterotonics to support the adoption and scale-up of AMTSL in several countries were also identified.

The specific objectives of the study were to—

- Collect the existing STGs, the national drug formularies, and national essential medicines lists (NEMLS) from the selected countries
- Compare these STGs to the reference treatment protocols (treatment protocols according to the WHO)
- Identify the elements of the regulatory documents that must be strengthened on the national and regional levels
- Propose recommendations to improve the implementation of AMTSL and explore opportunities for regional harmonization of treatment protocols and training for AMTSL

On the basis of data collected and analysis of policies governing the registration and importation of uterotonics as well as the practices regarding their supply and management, this report summarizes the conclusions, proposes recommendations, and identifies the strategies that, in collaboration with the decision makers, allow implementation of the activities identified.

This study should also facilitate, at a later stage, harmonization of policies and protocols so that countries in the region will be able to work together to support national efforts to scale up and adopt AMTSL practices. Training and technical assistance from other countries, and the development of pharmaceutical management tools that can be used in several countries would make sharing technical assistance resources possible and increase the likelihood of adoption of AMTSL in increasing numbers of countries.

Methodology of the Study

The study consisted of a review of STGs, essential medicines lists, and other regulatory documents from the following countries: Benin, Burkina Faso, Cameroon, and Mali. The objective of the review was to identify the differences, strengths, and similarities of the national protocols for AMTSL as compared to the WHO reference standard.

The study included interviews with several key contacts within the Ministry of Health (MoH), including the Division of Family Health (Direction de la Santé familiale, or DSF); the division regulating drug policy (Direction de la Pharmacie et du Médicament, or DPM); and the central medical stores (CMS), the national procurement agency for essential medicines. In addition, reproductive and maternal health educators and other health professionals who play a key role in improving the availability and use of uterotonics for AMTSL were consulted in order to complete the questionnaire for each country. Interviews were completed by telephone, as needed, because of the limited availability of certain resource people. The people interviewed were not informed in advance of the team's arrival, and they demonstrated a willingness that evidenced their motivation and support for the prevention of postpartum hemorrhage (PPPH) initiative.

The study also included visits to the national CMS, through which all essential medicines are financed, procured, stored, and distributed to public health facilities. In some countries, the CMS also sells medicines and supplies to the private sector. Questions related to procurement, availability of uterotonics, inventory management, and means of storage. Other questions sought to identify weaknesses in the cold chain and temperature monitoring (recording) from the time products arrived at the CMS to the time they were distributed to the peripheral level. In addition, the means of distribution, the volume of the inventory, the frequency of stock-outs, the type of uterotonics on hand, and product pricing were discussed.

SUMMARY OF FINDINGS AND PROBLEMS IDENTIFIED

Texts on the Drugs and the AMTSL Protocol

The national policy documents, in particular the STGs and formularies, have not been updated to include AMTSL and as a result do not reflect the policies and practices of the reproductive health program as defined in documents such as Emergency Obstetric Care and Emergency Obstetric and Neonatal Care guidelines. In addition, certain medicines, most often misoprostol, are not on the NEML but may be available in the CMS for the reproductive health programs.

The use of posters as “jobs aids” describing proper conservation of oxytocin and the practice of AMTSL is not yet widespread in labor and delivery rooms except in Mali and Benin.

Training on the Practice of AMTSL

For some countries, such as Benin and Mali, training in AMTSL started under the PRIME II project (2001–2004). Under that activity, training was conducted as part of in-service continuing education.

With the exception of Burkina Faso, training modules dedicated to AMTSL have not yet been incorporated into the core education curricula for physicians, nurses, and midwives, even where management of PPH is addressed. AMTSL training is sometimes provided by obstetricians/gynecologists, but more often by midwives who have already been trained in the practice.

With the exception of Mali and of Benin, CMS personnel had not been trained specifically on the risks of degradation of uterotonics when the cold chain is interrupted.

Though health facility visits were not included as part of this study, some information regarding clinical practice was collected through informant interviews, including the following—

- Staff members accustomed to using uterotonics for induction of labor were unaware of “prevention of PPH” being an indication for oxytocin and ergometrine.
- AMTSL is practiced by *matrones* or other lesser-qualified personnel in certain countries because of lack of personnel.
- Midwives are using oxytocin, sometimes clandestinely, for induction of labor, which effectively reduces stocks available for AMTSL.
- Unfavorable bias against the generic medicines pertaining to their effectiveness and quality persist, consequently causing midwives to prefer and select branded products for their patients.

Discussions with health professionals who were less familiar with AMTSL and working in reproductive health programs or inventory management show a persistent confusion between

the injection of oxytocin to induce/assist in physiological labor and the injection of oxytocin after delivery as recommended in AMTSL to facilitate the delivery of the placenta and prevent PPH.

Management of Supplies and Inventory

Interviews with personnel from the CMS reveal that stock-outs of uterotonics do occur at the central level and most likely are a result of several factors, including (a) the absence of needs estimates provided by peripheral health centers; (b) the irregularity of tender schedules and long procurement lead times; (c) the use of uterotonics for indications other than PPPH, such as induction of labor; and (d) the degradation of medicines caused by interruption of cold chain during distribution to regional and peripheral health centers.

In forecasting needs and eventually ensuring availability of uterotonics, the use of these products not only for PPPH, but also for other gynecological indications needs to be considered, in particular for the induction of labor, which is the more traditional indication for oxytocin. Taking into account a new and expanding program such as AMTSL is also important. As a country expands its AMTSL program, the demand for oxytocin in particular will greatly increase and clearly affect stock available for other uses. It is unclear from this study whether this increased demand from scale-up has been accounted for in procurements. Subsequent country visits by RPM Plus will investigate this point to ensure availability of uterotonics as the programs expand.

In addition, it was evident that the CMS sells products to facilities outside the public health system, such as private pharmacies and missionary hospitals. It was unclear from this study whether this demand had been considered in forecasting required quantities of medicines. The difficulty in ensuring availability is generally intensified by the frequency between scheduled tenders, which varies from one country to another, ranging from one to three years, and procurement lead times, which can reach three to six months. The suppliers come from many countries of origin, which in itself contributes to the varied lead times.

In terms of inventory management, products were often stored in cold rooms on pallets in the CMS, though sometimes on the floor, with no clear order for selecting and identifying products according to the batches, suppliers, or both. Without a clear system for identifying and organizing products based on date of expiry, the possibility exists that products will expire in the warehouse before they can be distributed and used. With the exception of Burkina Faso and Benin, where cold storage rooms have a device for monitoring the temperature, temperatures are rarely recorded. Maintenance programs were also seldom in place for cold storage rooms.

Whereas programs to support HIV/AIDS and WHO's Expanded Programme on Immunization have provided training to logistics personnel on the vital importance of availability of medicines and the security of the cold chain, these same personnel have rarely been sensitized on the importance of these factors to the PPPH initiative. Maintaining the cold chain during the distribution of uterotonics to the regional stores and in the health centers is not included in written and disseminated procedures nor is follow-up documented.

In addition, the following observations were made during the study visits—

- Central Medical Stores are not sharing information about suppliers and the quality of their products with each other, even though they are all members of the Association of Central Medical Stores (Association des Centrales d'Achat de Médicaments Essentiels, ACAME).
- No real written procedure exists for assuring quality of uterotonics from the point of the supplier to the labor and delivery room.
- Products used for PPPH that are not included on the NEML and not registered with the DPM are available in CMS.

The study shows also the importance of reinforcing supply management principles in the CMS, including standard practices for inventory control, maintenance of the cold chain, and methods for ensuring product quality from the CMS to the delivery room.

COUNTRY FINDINGS

Benin

In Benin, the 2001 Demographic and Health Survey (DHS) reveals an estimated maternal mortality rate of 498 maternal deaths per 100,000 live births. In a country where postpartum hemorrhage is among the four principal causes of maternal deaths, the introduction of a proven and low-cost intervention to prevent PPH is an invaluable tool for saving lives.

With the assistance of the PRIME II project, in 2003 the MoH Division of Family Health started AMTSL training in seven pilot sites. Health care providers were so convinced of its effectiveness that the MoH decided to adopt AMTSL as policy for the country, and AMTSL is now part of the national strategy to reduce maternal and neonatal mortality.

Information for this study came from interviews with officials from the Ministry of Health: Division of Family Health, National Health Laboratory, Division of Pharmacies and Laboratories. The CMS, Centrale d'Achat de Médicaments Essentiels (CAME), was also visited.

Regulatory Texts and STGs

The national essential medicines list (NEML January 2003) includes oxytocin 10 IU/ml and 5 IU/ml, and ergometrine tab/cap 0.2 mg, injectable: 0.2 mg/ml and 0.5 mg/ml, under the oxytocic heading. The NEML is revised every two years. The most recent version of the National Formulary for Essential Medicines (1993) available does not describe the use of oxytocin for PPPH or AMTSL.

The National Strategy for the Reduction of Maternal and Neonatal Mortality was published in March 2006 and specifically identifies AMTSL as an intervention to reduce postpartum hemorrhage.

Training of Health Care Providers

According to the Director of Reproductive Health, AMTSL is not included as part of initial training for doctors, nurses, or midwives. Plans exist, however, to integrate AMTSL training when curricula are revised. Complications during pregnancy and measures to be taken to treat PPH are taught. A pool of regional trainers is carrying out a program of continuing in-service AMTSL training; they have managed to cover more than 50 percent of the departments of Benin. The MoH is hoping to reach more than 80 percent coverage before the end of 2007. AMTSL training was even being organized for doctors practicing in the private sector.

Job aids have been developed and distributed with guidance on the components of AMTSL practice according to WHO guidelines and maintaining the cold chain. Training in proper storage of uterotonics (namely oxytocin) had been given to stock managers working in the facilities. Analysis of information collected shows that although people are receiving information regarding the importance of respecting the cold chain during in-service training, the need to record the temperature of the cold room was not communicated.

On the same note, the management of the cold chain and proper storage of uterotonics for the PPPH initiative are not included in the preservice training for pharmacists and pharmacy managers.

Inventory Management

The procurement and the purchase of uterotonics are included as part of an open international tender process, completed every two years in accordance with the NEML. The orders are then prioritized according to the needs and the monies available for purchasing. Misoprostol, restricted for use only by gynecologists, was in stock at the CAME even though it is not included on the essential medicines list and is not registered with the drug regulatory body (DPM). Suppliers are disqualified by the CAME if they do not respect the conditions of the tender, if they fail to meet delivery deadlines especially when it results in a stock-out for the CAME, and if products are delivered with less than two-thirds of shelf life remaining.

Stock cards are used to manage inventory with electronic backup. Pharmaceuticals are stocked according to good practices of inventory control (first-expiry, first-out, or FEFO). Frequent stock-outs still occur, however, because of the long times for deliveries and the fact that quantification for procurement is not based on needs expressed by health facilities. A defined set of stock dedicated for PPPH was not found; oxytocin is still largely used by the midwives to induce labor at the time of the childbirth.

Prejudices about the quality and effectiveness of generic drugs have resulted in a reticence to use generic uterotonics, and the suppliers of uterotonics are numerous and of various origins. These prejudices find their origin in the midwives, who believe the branded uterotonics preserve their potency and their effectiveness even in the event of interruption in the cold chain, whereas the generic products are more likely to lose some potency and effectiveness even after a short time outside the cold chain. In practice, this belief often translates to the use of two ampoules rather than one to get the intended effect when using generics.

The CAME has a cold room that ensures a temperature between +2°C and +8°C. At the time of the visit, the posted temperature was 7°C, compatible with the storage conditions recommended by the supplier. In the cold room, products are stored on pallets. Uterotonics are not grouped together, which makes facilitation of the first-in, first-out (FIFO) inventory practice difficult and increases the risk of products expiring. A system of recording the temperature is still needed even if personnel monitor the temperature. The director of CAME did not have a maintenance program for the cold room.

Uterotonics are distributed from CAME to the regional or district stores through a “pull” or requisition-based system, respecting the cold chain with the use of refrigerators. This means that the health facilities are responsible for determining the quantity of products they wish to purchase and for delivery of their orders to their facilities. According to the CAME manager, an uninterrupted cold chain is not specifically monitored after delivery to the regional stores, yet CAME refuses to deliver the uterotonics health centers that do not have refrigerators.

Quality control measures include the determination and level of the active ingredient of the product when it is received but seldom after distribution to health centers. A documented follow-up of the stability of uterotonics in stock has not been completed for more than a year.

No formal procedure of quality control exists for the uterotonics in the health facilities, and DPM supervisory visits to peripheral health centers do not specifically take into account the storage conditions for uterotonics.

Burkina Faso

In Burkina Faso, the 2001 Demographic and Health Survey reveals an estimated maternal mortality rate of 484 maternal deaths per 100,000 live births. In a country where postpartum hemorrhage is among the four principal causes of maternal death, the introduction of a proven and low-cost intervention to prevent PPH is an invaluable tool for saving lives.

To date, health care providers at health facilities in 6 of 13 provinces have been trained, providing over 40 percent program coverage.

Information for Burkina Faso was collected from interviews with officials from the Ministry of Health: Division of Family Health and the Pharmacy Regulatory Authority. The CMS, Centrale d'Achat de Médicaments Essentiels Génériques (CAMEG), was also visited.

Texts and Guidelines for AMTSL

Burkina Faso reviews its NEML every two years. In this document, ergometrine and oxytocin are both included as oxytocics. Misoprostol is included on the NEML and was found to be present in the central medical stores, apparently at the request of the program. At the time of the visit, no validated document described the practice of AMTSL specifically. The national therapeutic guide or formulary is an old edition and does not describe AMTSL or the prevention of PPH as an indication for uterotonics. The guidance document on Emergency Obstetric Care detailing PPH was not available because it was being revised. However, the MoH did present job aids on the methods of application and practice of AMTSL in accordance with WHO guidelines.

Training of Health Care Providers

The practice of AMTSL is included in preservice training for midwives and nurses after the second year and is required before they can perform these skills in the labor and delivery room. Students must complete six hours of training and perform AMTSL for three deliveries. Preservice training for doctors is not documented, but the MoH has extended AMTSL training to doctors working in the private sector.

Challenges in expanding AMTSL to reach 100 percent coverage relate to the structure of the health system. AMTSL cannot be practiced in health centers because midwives are not present and uterotonics are not authorized at this level.

In-service training for stock managers at the facility level is not organized. Job aids providing guidance on the proper storage of uterotonics and maintenance of cold chain were not available.

Inventory Management and Storage Conditions

Uterotonics are procured as part of a restricted tender (open to prequalified suppliers) for medicines included in the NEML and registered with the DPM. Quantification of needs is based on past consumption rather than quantitative feedback (estimations) from the health facilities.

CAMEG has three large regional depots that are supplied through a “push” mechanism (quantities are determined at the central level). Health centers purchase medicines directly from the regional depot through a “pull” system (quantities determined by the health facilities): 40 FCFA/ampoule of 10 IU/ml for oxytocin and about 58 FCFA/ampoule for the ergometrine. CAMEG does not monitor the cold chain after medicines have left the stores.

During the study, CAMEG presented the best example of all four countries for conditions of storage. The posted temperatures of the cold room are recorded on A4 paper. The products are well arranged on the racks and the uterotonics were clearly identified.

A quality assurance system operates from the time when orders are received until they are supplied to the regional stores/depots. Quality checks are carried out on samples sent to Laboratory S.G.S.-SIMON in Belgium and locally by the National Laboratory of Health when orders are received. In spite of their particular conservation requirements, routine controls and monitoring of the stability of uterotonics are not documented by CAMEG or the National Quality Control Laboratory.

No formal procedure of quality control exists to monitor the stability of uterotonics. Supervisory visits to the pharmacy sector by the MoH do not include monitoring of the storage conditions of uterotonics.

Cameroon

The situation in Cameroon is characterized by a mortality rate of 669 per 100,000 live births in 2004, an increase from an estimated 484 maternal deaths per 100,000 live births in 1998. In a country where postpartum hemorrhage is among the four principal causes of maternal death, the introduction of a proven and low-cost intervention to prevent PPH is an invaluable tool for saving lives.

Cameroon is just starting to integrate AMTSL into its reproductive health program. The first cycle of in-service training for AMTSL took place in 2005 with the support of AWARE (Action for West Africa Region).

Information for Cameroon was collected from interviews with officials from the Ministry of Health: Directorate of Family Health and Pharmacy Regulatory Authority. The CMS, the Centrale Nationale d'Approvisionnement en Médicaments Essentiels (CENAME), was also visited.

Texts and Guidelines for AMTSL

The NEML was available, but the standard treatment guidelines were being revised at the time of the visit. Ergometrine and oxytocin are included under the oxytocic and tocolytic headings. The 2003 document on Emergency Obstetric Care was available but does not specifically describe the use of oxytocin and ergometrine for the prevention of PPH and the practice of AMTSL. It describes the use of uterotonics for complications of childbirth. The Director of Family Health plans to include AMTSL in an updated version of Emergency Obstetric Care guidelines.

Training of Health Care Providers

Prevention of PPH is not included in preservice training for physicians, nurses, or midwives, even when modules addressing PPH are taught. Job aids providing guidance in the practice of AMTSL were not available in delivery rooms.

Inventory Management and Storage Conditions

Uterotonics are included in national procurements, which are completed every three years. CENAME supplies regional centers by a “push” system where the central level determines the quantities to be supplied. The regional stores, in turn, supply the peripheral health centers by a “pull” system or based on quantities specified by the facility.

The quantities of products procured by CENAME are based on estimates made at the central level. Stock-outs of uterotonics are frequent; both oxytocin and ergometrine were out of stock at the time of visit and had been unavailable for the last two months. Stock-outs seem to be a result of insufficient resources and underestimates of the needs; these products are still largely used in Cameroon to induce labor at the time of childbirth.

At CENAME, the cold room does not have system of recording the temperature and the products are stored on pallets on the floor. The maintenance and upkeep of the cold room are not documented. Job aids providing guidance in management of pharmaceuticals, proper storage conditions, and the like were not observed.

A system of quality assurance begins from the time orders arrive in the country until medicines are delivered to the regional stores of CENAME. Quality checks are carried out for some medications at Lanspex Laboratory in Niger because locally, the national laboratory does not provide for the analysis for dry pharmaceutical formulations. Routine checks and ongoing monitoring of stability of uterotonics, in spite of their particular requirements of conservation, are not documented. Supervisory visits by the DPM do not include monitoring the management of the cold chain or the quality of uterotonics.

Mali

In Mali, the health situation is characterized by a mortality rate of 582 deaths per 100,000 live births (DHS 2001). In a country where postpartum hemorrhage is among the four principal causes of maternal death, the introduction of a proven and low-cost intervention to prevent PPH is an invaluable tool for saving lives.

The AMTSL program began with the training of 97 health care providers in the eight pilot sites in April 2003. AMTSL training is currently ongoing, and by 2007, the MoH plans to reach a rate of 90 percent coverage in Bamako and 50–60 percent in other regions of the country.

Information for Mali was collected from interviews with officials from the Ministry of Health: Division of Reproductive Health; Country Director for IntraHealth, Mali; National Public Health Laboratory and the Pharmacy Regulatory Authority. The CMS, Pharmacie Populaire de Mali (PPM), was also visited.

Results of the Interviews and Assessments

The MoH emphasized that in spite of difficulties with implementation, strong support existed for AMTSL among the trained staff, in particular midwives, as a result of the positive outcomes observed when the strategy was used. In fact, during meetings and interviews, midwives declared that AMTSL had enormously reduced the stress they had before attending a birth. They realized in their practices the potential for AMTSL to considerably reduce the incidence of PPH and maternal and infant mortalities. Difficulties in implementation have been related to the availability of medicines and supplies (tensiometers, ice boxes, and refrigerators) to ensure the cold chain.

Regulatory Texts and Guidelines for AMTSL

The NEML includes as uterotonics oxytocin 10 IU/ml and ergometrine 0.25 mg/ml and 0.2 mg/ml injection. Misoprostol has been included on the 2006 NEML and was present in the CMS at the time of visit. In the National Therapeutic Formulary, oxytocin is indicated both for the induction of labor and for obstetric hemorrhage and postpartum uterine atony. The newest version, yet to be validated and released, will include prevention of PPH as an indication for oxytocin. Ergometrine is described for use in controlling hemorrhage and postpartum uterine atony. The guidelines for AMTSL exist in the *Facilitator's Handbook* and *User's Guide* and MoH Reproductive Health guidance document for Emergency Obstetric and Neonatal Care. Job aids for AMTSL exist and are available.

Training of Health Care Providers

AMTSL training is not yet included as part of preservice training for physicians, midwives, or nurses, even when PPH is addressed. Regional pools of trainers have been formed to expand in-service training. Program directors presented several cycles of continuing education for health care providers. This training was started in 2004 with the support of the PRIME II project, targeting physicians, pharmacists, and midwives who have since carried out the training for new professionals to continue the extension of AMTSL. The current rate of program coverage is more than 70 percent of the districts of Bamako and 40 percent for departments in the interior of the country.

Inventory Management and Storage Conditions

The PPM procures uterotonics as part of its annual open tender based on the NEML. The health centers receive medicines and supplies from the central level by direct cash purchase: 60 FCFA/ampoule for oxytocin and of 70 FCFA/ampoule for the ergometrine. The resale prices for patients are 65 FCFA and 75 FCFA, respectively. In the private sector, one

10 IU/ml ampoule of branded oxytocin (Syntocinon) is 410 FCFA. Branded ergometrine (Méthergin) sells for 465 FCFA while the generic sells for 155 FCFA.

The procurement manager explained that the distribution of pharmaceuticals to the multiple regions of the country represents a significant challenge. Climatic conditions and the vast geographical layout of Mali have forced the PPM to supply remote facilities by air. Supplies are also delivered from border countries with a maritime port.

Stock-outs at the PPM have been reduced since the launch of the PPPH initiative. However, they persist because uterotonics are included as part of caesarean kits free of charge. Because no reliable quantitative feedback is available from the health centers, needs are assessed on the central level by the DPM and the PPM based on previous consumption.

Informal management of storage conditions occurs, although the health centers use the refrigerators of the Expanded Programme on Immunization, whose temperatures are recorded daily. Means of transport for uterotonics outside the PPM network are not controlled: equipment making it possible to ensure transport and the storage of the products at necessary temperatures in health centers is not always available.

The system of quality assurance exists and quality checks are carried out locally by the National Laboratory of Health when orders are received in the country. The absence of a quality control procedure to monitor the quality of uterotonics in precarious storage conditions predisposes them to early deterioration of the active ingredients. Supervisory visits do not take into account the storage conditions for uterotonics.

CONCLUSIONS AND RECOMMENDATIONS

The analysis of the country situations on the adoption of AMTSL and the management of uterotonics reveals strong support for the PPPH initiative from health workers and the countries that benefited from the support of partners to integrate PPPH into their health programs.

The national policy documents, in particular the STGs and formularies, have not been updated to include AMTSL and as a result do not reflect the policies and practices of the reproductive health program as defined in documents such as guidelines for Emergency Obstetric Care and Emergency Obstetric and Neonatal Care. In addition, certain medicines, most often misoprostol, are not included on the NEML but are available in the CMS for the reproductive health programs.

In the course of adopting and scaling up AMTSL, the MoH divisions of reproductive health need to communicate program objectives to national formulary committees so that national policy documents include the prevention of PPH as an indication for oxytocin and ergometrine. This information will allow national planning and procurement to take account of all policies adopted at the program level. If the program advocates for the use of misoprostol in the prevention and treatment of PPH, the drug must be registered and included on the NEML and also in national policy documents.

The study revealed that AMTSL was not included in the curricula for student physicians, nurses, and midwives, even in lessons regarding complications of PPH. In most countries AMTSL was taught as part of in-service training. Stock managers did not always receive the necessary training about the importance of maintaining the cold chain for oxytocin and ergometrine.

Reproductive health programs need to advocate for the support of the partners to introduce AMTSL modules into various health education programs (doctors, midwives, and nurses) as soon as possible. Training should also include information on the proper storage conditions required, the importance of maintaining the cold chain, and the importance of using generic products where available.

In regard to inventory management, the study shows that stock-outs at the central level persist and most likely are a result of several factors, including (a) the absence of needs estimates provided by peripheral health centers; (b) the irregularity of tender schedules and long procurement lead times; (c) the use of uterotonics for indications other than PPPH, such as induction of labor; and (d) the degradation of medicines caused by interruption of cold chain during distribution to regional and peripheral health centers.

Personnel responsible for the management of medicines should be trained in inventory control and the good management practices of including maintenance of logistics system. Written procedures for maintaining the cold chain need to be established.

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ANNEX 1. SUMMARY OF FINDINGS

	BENIN	BURKINA FASO	CAMEROON	MALI
National Policies and Guidelines				
Which uterotonics are included on the NEML?	Oxytocin Ergometrine	Oxytocin Ergometrine Misoprostol	Oxytocin Ergometrine	Oxytocin Ergometrine Misoprostol (2006)
Are these medicines registered?	Yes	Yes	Yes	Yes
When was AMTSL program introduced?	2003	2004	2005	2003
Are uterotonics indicated for PPPH (AMTSL) in <i>national</i> therapeutic guidelines?	No	No	No	No
Is AMTSL included in treatment guidelines for reproductive health?	Yes	Yes	No	Yes
Is 10 IU/ml oxytocin recommended as drug of choice for AMTSL?	Yes	Yes	Not applicable	Yes
Do guidelines include controlled cord traction?	Yes	Not applicable	Not applicable	Yes
Do guidelines include uterine massage?	Yes	Not applicable	Not applicable	Yes
Training in AMTSL				
Is AMTSL included in core curricula for doctors, nurses, and midwives?	No	Yes	No	No
Is AMTSL training provided as continuing education?	Yes	Yes	Yes	Yes
Is there training for facility-level supply managers in proper storage of uterotonics?	No	No	No	Yes
Are job aids for AMTSL practice available?	Yes	Yes	No	Yes
Are job aids for storage of uterotonics available?	No	No	No	No
Current coverage of AMTSL training?	>50% program coverage in 2006	60% program coverage in 2006	Not applicable	40% program coverage in 2006
Inventory Management				
Opportunity to select new supplier through tender	Every 2 years	Every 2 years	Every 3 years	> 1 year, variable
Date of last call for bids	December 2005	April 2005	March 2004	December 2004
Method for quantifying needs	Past consumption	Past consumption	Past consumption	Past consumption
What is buffer stock for medicines at CMS?	3 months	9 months	6 months	6 months
Maximum duration of stock-out for uterotonics	< 1 month	2 months	2 months	<1 month

	BENIN	BURKINA FASO	CAMEROON	MALI
Reasons given for stock-outs	<ul style="list-style-type: none"> • Late delivery • Consumption greater than forecast 	<ul style="list-style-type: none"> • Late delivery • Consumption greater than forecast 	<ul style="list-style-type: none"> • Late delivery • Consumption greater than forecast 	<ul style="list-style-type: none"> • Late delivery • Consumption greater than forecast
Does CMS supply facilities outside the public sector?	Yes	Yes	Yes	Yes
Are uterotonics stored in cold rooms at CMS?	Yes	Yes	Yes	Yes
Are systems in place to maintain uninterrupted cold chain during delivery to regional stores?	Yes	Yes	Yes	Yes
By what mechanism are uterotonics delivered to the regional stores?	Pull	Push	Push	Push
Does a system exist for quality control checks of storage conditions for uterotonics after distribution to the facilities?	No	No	No	No

ANNEX 2. DATA COLLECTION TOOL

ACTIVE MANAGEMENT OF THE THIRD STAGE OF LABOR INFORMATION NECESSARY ON THE NATIONAL LEVEL

This questionnaire gathers information on the documentary review (Essential Medicines List, treatment standards, guide, initial training and continuing education on the management of the third stage of labor), a visit to the warehouse where pharmaceutical products are stored, and an interview of the persons responsible for the national level supply and storage of uterotonic medicines.

Complete the questions below based, if necessary, on administrative documents in effect on the national level. In some cases, interviewing professionals in the sector will be necessary.

Q#	QUESTION	RESPONSES	SKIP TO
101	Name of the person completing the questionnaire:		
102	Country:		
103	Facility and position:		
104	Date of the visit:		
LIST OF ESSENTIAL MEDICINES			
105	Does the country have a list of essential medicines?	YES.....1 NO.....2	112
106	Are uterotonic medicines on the national list of essential medicines?	YES.....1 NO.....2	112
107	If yes, which ones? Circle the responses: * on the new list adopted on January 2, 2006, not yet published, Misoprostol 25µg vaginally	OXYTOCIN.....1 ERGOMETRINE.....2 MISOPROSTOL.....3 OTHER PROSTAGLANDINS 4	
108	Which uterotonic medicines on the list of essential medicines are registered? Circle all applicable. Several oxytocin generics from various Indian laboratories are registered.	OXYTOCIN.....1 ERGOMETRINE.....2 MISOPROSTOL.....3 OTHER PROSTAGLANDINS.....4	

Q#	QUESTION	RESPONSES	SKIP TO												
109 *109b	Is the supply of medicines for AMTSL limited to those on the list of essential medicines? <i>Please explain.</i>	YES.....1 NO.....2 Magnesium sulfate for eclampsia													
110	Where did you find the answer?	SPECIFY: Reproductive Health Directorate and Pharmacie Populaire du Mali (PPM)													
111	What indication is specified on the NEML for each uterotonic medicine? OXYTOCIN _____ ERGOMETRINE _____ MISOPROSTOL _____ OTHER PROSTAGLANDINS _____														
111b	<i>What uterotonic medicines are registered in the country?</i> <i>Circle the products concerned,</i>	OXYTOCIN.....1 ERGOMETRINE.....2 MISOPROSTOL.....3 OTHER PROSTAGLANDINS...4													
TREATMENT STANDARDS AND GUIDELINES															
112	Is there a standard national treatment guide for mothers and reproductive health in the country?	YES.....1 NO.....2 Standards and Procedures Policy (PNP)	124												
113	What type of document describes the standard national treatment guide for mothers and reproductive health?	DOCUMENT:													
114	What is the publication date of the document that describes the national guide on treatment standards?	<table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td style="width: 20px; height: 20px;"></td> </tr> <tr> <td style="text-align: center;">D</td> <td style="text-align: center;">D</td> <td style="text-align: center;">M</td> <td style="text-align: center;">M</td> <td style="text-align: center;">Y</td> <td style="text-align: center;">Y</td> </tr> </table>							D	D	M	M	Y	Y	
D	D	M	M	Y	Y										
115	Is the practice of AMTSL specifically promoted in the standard national treatment guide?	YES.....1 NO.....2													
116	What component of AMTSL is described in the standard national treatment guide?		118												
117a	If yes, what first-line type, means of delivery, and dose? 1st LINE TYPE _____ 1st LINE MEANS OF DELIVERY _____ 1st LINE DOSE _____														

Annex 2. Data Collection Tool: Active Management of Third Stage of Labor

Q#	QUESTION	RESPONSES	SKIP TO
117b	If yes, what second-line type, means of delivery, and dose? 2nd LINE TYPE _____ 2nd LINE MEANS OF DELIVERY _____ 2nd LINE DOSE _____		
118	Control and traction of the cord (uterine massage)?	YES.....1 NO.....2	
119	Uterine massage after expulsion of the placenta?	YES.....1 NO.....2	
120	Other actions recommended in the practice of AMTSL?	SPECIFY:	
121	Do you have a copy of the section of the national treatment standards guide relative to AMTSL? If yes, attach a copy to the questionnaire.	YES.....1 NO.....2	
122	Are there texts in the national treatment standards guide on restrictions to the practice of AMTSL?	YES.....1 NO.....2	
123	If yes, what are these texts? Restrictions by level of care? Restrictions by level of competency?		

Q#	QUESTION	RESPONSES	SKIP TO
INITIAL TRAINING AND CONTINUING EDUCATION IN THE SERVICE			
124	Is AMTSL currently included in the training program for midwives, nurses, and physicians in the public education institutions? Midwives YES NO (to 126) Nurses YES NO (to 126) Physicians YES NO (to 126)		
125	If yes, can you obtain a copy of the pages describing the AMTSL procedure as it is taught? (If yes, send these copies with the questionnaire: to be determined) For midwives YES NO NA For nurses YES NO NA For physicians YES NO NA		
126	If no, what person informed you that AMTSL is not included in the training programs for midwives, nurses and physicians in public education institutions?	Specify:	
127	Do you have proof that the continuing education programs in the department on AMTSL were held in the public sector health centers in preceding years? For midwives YES NO For nurses YES NO For physicians YES NO		
128	Who spoke to you about the continuing education program in the department? SPECIFY:		
129	Is the definition of AMTSL used in the continuing education in the department comparable to the definition of AMTSL received during the initial training?	YES.....1 NO.....2	
130	If yes, what elements are different? Specify:		
131	The staff is trained on the side effects and specifics of the supply, transport, and administration of oxytocins:		

Annex 2. Data Collection Tool: Active Management of Third Stage of Labor

Q#	QUESTION	RESPONSES	SKIP TO
132	Is there a training program for pharmacists and managers of uterotonics for the supply and storage? - basic program YES NO - continuing education YES NO - at the time of hire YES NO		
133	Mode of transport of the products for deliveries outside of health centers guaranteeing quality:		
134	Qualification of the person conducting the training:		

The information in this table must be collected in interviews and visits to the central stores and storage facilities for pharmaceutical products.

	Oxytocin	Ergometrine	Combination Oxy-Ergo	Misoprostol	Other Prostaglandins	Others: specify
201: Unit, form, dosage of the medicine (example: 5 IU or 1ml vial)						
202: Are there supply sources for the program other than the PPM?						
203: Address of the vendor?						
204: Storage conditions recommended by the manufacturer -cold chain -temperature -away from light -room temperature						
205: Is there a quality assurance system? -Controls carried out upon receipt of the products? -Routine control? If yes, what ones?	YES NO	YES NO	YES NO	YES NO	YES NO	YES NO
206: Describe the storage conditions for each medicine -cold chamber? -central warehouse?						
207: Describe the methods for quantifying orders?						

3. Evaluation of the Management of the Medicines and Quality of the Data

Q#	QUESTION	RESPONSES
3.1	Frequency of the orders -monthly, quarterly, annual	
3.2	Reasons for stock-outs	
3.3	Maximum duration of stock-outs For oxytocics (months)	
3.4	Average shelf life of the medicines	
3.5	Do you keep inventory records or cards for all medicines, including oxytocics?	
3.6	How frequently are these cards usually updated?	

4. Warehousing and Storage Conditions

Q#	QUESTION	YES = 1 NO = 0
4.1	Products are arranged so that identification labels and expiration or manufacture dates are visible.	
4.2	Products are stored and organized according to first-expiry/first-out procedures.	
4.3	The boxes and products are in good condition.	
4.4	The boxes and products are protected from water and moisture.	
4.5	Products are protected from direct sunlight at all times.	
4.6	The boxes and products are protected on palletes or shelves above the ground.	
4.7	The storage/stockpiling has no visible insects or vermin.	
4.8	The storage/stockpiling location is secured with a lock and key, accessible during work hours and limited to authorized personnel.	
4.9	The roof is well maintained to prevent sunlight and water from entering.	
4.10	Damaged or expired products are placed away from the good products and are not in the inventory.	
4.11	How is the cold chain maintained during the receipt of products from vendors of the PPM?	
4.12	Does the central store supply facilities other than those in the public sector?	
4.13	If yes, how is the cold chain maintained during the distribution? <i>(Describe the procedures.)</i>	
4.14	How are damaged or expired products positioned? <i>(Describe the procedure.):</i>	
	Frequency of the medicine inventories	

5. Procurement and Quantification

Q#	QUESTION	RESPONSES	SKIP TO
5.1	What is the PCA system or mechanism for procuring medicines in the public sector? (Example: International or national call for bids? What are the roles of the various government departments?)		
5.2	What was the date of the last PCA call for bids for pharmaceuticals? - Prices: - Quantities ordered? -Who are the vendors?		
5.3	Is the call for bids in the public sector limited to medicines on the NEML?		
5.4	Is there a system to monitor the performance of the vendors? (Y/N) If yes, describe it.		
5.6	What is the average delivery period (of orders upon delivery in the country)?		
5.7	What quantities of medicines are planned on the national level for the AMTSL?		
5.8	Is the quantification decentralized? (Y/N) If yes, on what level are medicines quantified for the AMTSL?		If no, to 10

6. Storage, Distribution, Transport, Cold Chain, Inventory of Supplies

Q#	QUESTION	RESPONSES	SKIP TO
6.1	Is there a buffer inventory for medicines for AMTSL on the central level? If yes, what percentage of the inventory does it represent?		
6.2	Is there a buffer inventory for medicines from the PCA on the regional level? If yes, what percentage of the inventory does it represent?		
6.3	What is the frequency of the orders made on the regional level?		
6.5	What record system is used in the health centers to control the inventories and distribution of PPH medicines and supplies?		