Pilot use of oxytocin in a Uniject™ device for AMTSL in Mali

Evaluation of the safety and feasibility of a new delivery technology

December 2008

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INTRAHEALTH INTERNATIONAL

Keneya Iwara

PROGRAMME SANTE USAID
ATN

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Prevention of Postpartum Hemorrhage Initiative (POPPHI)

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Acknowledgments

Authors

- Ms. Susheela Engelbrecht, Senior Program Officer, PATH/POPPHI project
- Dr. Vivien Tsu, Associate Director, PATH Reproductive Health Global Program; Deputy Director, PATH Japanese Encephalitis Immunization Solutions Global Program
- Mr. Steve Brooke, Commercialization Advisor, PATH Technology Solutions Global Program
- Ms. Deborah Armbruster, Director, POPPHI project
- Dr. Yuxiao Tang, Program Officer, PATH Reproductive Health Global Program

Technical reviewers

- Dr. Keïta Binta, Director, Division for Reproductive Health, Mali
- Dr. Cheick Touré, Country Director, IntraHealth International, Inc./Mali
- Ms. Sara Stratton, Program Manager, IntraHealth International, Inc.
- Mme. Lisa Nichols, Chief of Party, USAID/Assistance Technique Nationale
- Dr. Sangaré Madina Ba, Reproductive Health Advisor, USAID/Projet Keneya Ciwara
- Ms Catharine Taylor, Director, Maternal and Newborn Health and Nutrition, PATH

Proofreader: Ms Mary Lou Austin, PATH

Editor: Mr John Ballenot, PATH

Demonstration project team in Mali

- Dr. Keïta Binta, Director, Division for Reproductive Health, Mali
- Mme. Diallo Haoua, Division for Reproductive Health, Mali
- Mme. Coulibaly Fanta, Medical Assistant, Division for Reproductive Health, Mali
- Mme. Cissé Aminata Bâ, Midwife, Division for Reproductive Health, Mali
- Dr. Guindo Seybou, Regional Medical Director, Koulikoro
- Dr. Klenon Traoré, Regional Medical Director, Gao
- Staff from the following facilities in Bamako: Communes 1, 4, 5, and 6
- Staff from the matrone demonstration sites in Koulikoro. CSComs: Sirakorola, Koula, Koulikoroba, Kenekoum, Kolebougou; CSRéf for Koulikoro district
- Staff from the matrone demonstration sites in Gao. CSComs: Aljanabadjia, Chateau, Gadeye, Boulgoundje; Regional Hospital in Gao; CSRéf for Gao district
- Dr. Christine Sow, HPN Officer, USAID/Mali
- Dr. Cheick Oumar Touré, Director, IntraHealth International, Inc./Mali
- Ms. Susheela Engelbrecht, Senior Program Officer, PATH/POPPHI project
- Mme. Lisa Nichols, Chief of Party, USAID/Assistance Technique Nationale (ATN)
- Dr. Doucouré Arkia Diallo, Reproductive Health Advisor, USAID/ATN

- Dr. Sangaré Madina Ba, Reproductive Health Advisor, USAID/Projet Keneya Ciwara
- Mme. Konaté Ramata Fomba, Project coordinator/Matrone demonstration pilot, Projet Keneya Ciwara/POPPHI in Mali
- Mme. Touré Aminata Dagnoko, Clinical Training Advisor, USAID/Projet Keneya Ciwara

Research team in Mali

- Mr. Touré Idrissa, Statistician Consultant
- Data collection
    - Dr. Coulibaly Hamma
    - Dr. Diallo Binta
    - Dr. Doucouré Arkia
    - Mme. Konaté Haby
    - Mme. Konaté Ramata
    - Mme. Sanogo Astan
    - Mme. Sanogo Bintou
    - Mme. Sanogo Fatoumata
    - Dr. Tangara Bakary
    - Mme. Touré Aminata
    - Dr. Traoré Demba
    - Mme. Traore Safiatou
- Data entry
    - Mr. Bylla Baba Dicko
    - Mme. Harama Assetou
    - Dr. Modibo Kanté
    - Mr. Moussa Kouyaté

Acronyms

AD	autodisable syringe
AMTSL	active management of the third stage of labor
ATN	Assistance Technique Nationale (USAID bilateral/Mali)
BIOL	Instituto Biologico Argentino SAIC
CSCom	community health center
CSRéf	district reference health center with operative capacity
DNS	Department of Health
DPM	Department of Pharmaceuticals and Medications
DSR	Reproductive Health Division
EDL	essential drug list
IU	international unit
MOH	Ministry of Health
PKC	Projet Keneya Ciwara (USAID project led by CARE International/Mali)
POPPHI	Prevention of Postpartum Hemorrhage Initiative
PMTSL	physiologic management of the third stage of labor
PPH	postpartum hemorrhage
TTI	time-temperature indicator
USAID	United States Agency for International Development
WHO	World Health Organization

Executive summary

This report describes use of the BD Uniject™ device[1] prefilled with 10 international units (IU) of oxytocin for actively managing the third stage of labor in selected health centers in Mali. Although this single-dose, autodisable injection device has previously been used for tetanus toxoid vaccination in Mali, the Ministry of Health lacked documentation of the safety and feasibility of using the device to deliver oxytocin for active management of the third stage of labor (AMTSL).

With assistance from USAID projects (HealthTech, POPPHI, Capacity, Assistance Technique Nationale, and Keneya Ciwara), PATH, and IntraHealth International, the Malian Department of Health (DNS) evaluated use of oxytocin in the Uniject device with a time-temperature indicator (TTI) (hereafter known as the oxytocin-Uniject device) to show whether the drug had been exposed to prolonged high temperatures that would decrease its effectiveness. The pilot test was conducted in 33 sites in Bamako, as well as 12 sites in Gao and Koulikoro that were participating in a study of the safety of training *matrones* (midwifery assistants, also translated as auxiliary midwives) to apply AMTSL.

The study team used interviews and reporting forms to evaluate the use of the Uniject device with the TTI in several areas: coverage of AMTSL; feasibility, safety, and acceptability of the oxytocin-Uniject device with TTI in the Malian context; and experience with the TTI in the desert heat of Mali. Results showed that:

- Coverage of AMTSL was high when the oxytocin-Uniject device with TTI was introduced and did not increase significantly after its introduction.
- The TTI allowed providers to immediately evaluate whether oxytocin had been exposed to high temperatures over a period of time that would decrease its effectiveness.
- Providers quickly learned how to use the Uniject device and interpret the TTI through formal or informal training.
- Providers preferred the oxytocin-Uniject device with TTI to a standard or autodisable syringe.
- Rates of retained placenta and postpartum hemorrhage (PPH) were not significantly different when oxytocin in ampoules or oxytocin in the Uniject device was used.
- Rates of retained placenta and PPH were significantly lower when AMTSL was applied using the oxytocin-Uniject device with TTI than with vaginal births without AMTSL.
- Rates of uterine rupture remained constant and were reported to occur only in women who had been referred from peripheral facilities to the district reference health center and appear not to have been associated with introduction of the oxytocin-Uniject device with TTI.
- A case of uterine inversion was reported by a reference health center in Bamako in a woman who had given birth at home and then presented at the health center, where uterine inversion was diagnosed.

[1] Uniject is a registered trademark of BD (Becton, Dickinson and Company).

Introduction

In Mali, as in many developing countries, national health statistics are characterized by high rates of maternal morbidity and mortality. The maternal mortality ratio is estimated at 464 maternal deaths per 100,000 live births (Mali Demographic and Health Survey, 2006).

Complications during pregnancy and childbirth are the most significant causes of death among women of reproductive age. Less than one percent of these deaths occur in more developed countries, showing that the large majority of these deaths can be prevented if there are sufficient resources and health services available.

More than half of these maternal deaths occur in the first 24 hours after childbirth, and most of these deaths are due to postpartum hemorrhage (see Figure 1). Postpartum hemorrhage (PPH), or excessive bleeding after childbirth, is the single most important direct cause of maternal deaths in developing countries. Approximately 25 percent of all maternal deaths globally are due to hemorrhage; with percentages varying from less than 10 percent to almost 60 percent in different countries. A 2006 WHO systematic review found 34% of maternal deaths in Africa were due to hemorrhage.[2] Even if a woman survives PPH, she could be severely anemic and suffer chronic health problems. Where maternal mortality is high, and resources are limited, the introduction of active management of the third stage of labor (AMTSL)[3], a feasible, low-cost, and evidence-based intervention to prevent PPH, can greatly improve survival of women and, consequently, their infants.

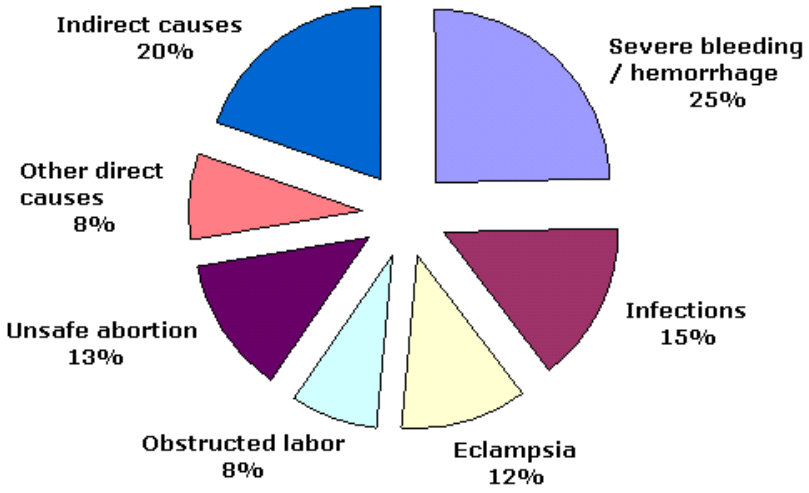


Figure 1. Global data: causes of maternal death. Other direct causes include ectopic pregnancy, embolism, anesthesia-related. Indirect causes include anemia, malaria, heart disease, and HIV/AIDS.[4]

[2] Khalid S. Khan, Daniel Wojdyla, Lale Say, A. Metin Gulmezoglu, Paul FA van Look. WHO analysis of causes of maternal death: a systematic review. *Lancet.* 2006; 367:1066-74.

[3] The components of AMTSL are: (1) Administration of a uterotonic drug within one minute after the baby is born (oxytocin is the uterotonic of choice), (2) Controlled cord traction (CCT) with counter traction to support the uterus; and (3) Uterine massage immediately after delivery of the placenta.

[4] WHO. *The World Health Report 2005.* Available at: http://www.who.int/whr/2005/chapter4/en/index1.html.

The Division for Reproductive Health (DSR) of the National Department of Health (DNS) in Mali made the training of all skilled birth attendants in AMTSL a national priority in 2007. To increase AMTSL coverage to greater than 80%, however, would require training auxiliary midwives (*matrones*), who conduct the majority of vaginal births in peripheral facilities but are not considered skilled birth attendants. To study the safety and feasibility of training *matrones* to apply AMTSL, the DNS, with assistance from USAID projects (POPPHI, Capacity, *Assistance Technique Nationale*, and *Projet Keneya Ciwara*), trained *matrones* to apply AMTSL in selected sites of a demonstration project. Training in AMSTL was conducted between September and December 2006, sites were closely monitored for 12 months, and endline data were collected between September and December 2007.

Another important part of increasing access to AMTSL is ensuring the availability of oxytocin at all facilities where births are taking place. Making oxytocin available, however, raises important issues of potential misuse for induction and augmentation purposes. In addition, storage of oxytocin is especially challenging in the heat of Mali's desert environment, which often necessitates logistics management that is not required in more moderate climates. POPPHI/ HealthTech staff believed that the oxytocin-Uniject device with a time-temperature indicator (TTI) could address the need to increase availability of oxytocin in a hot climate where the cold chain is limited in some levels of the health care pyramid. The DNS, however, needed national data to show the feasibility and safety of introducing oxytocin-Uniject devices with TTI for the prevention of PPH.

The study of oxytocin-Uniject devices with TTI was added onto the demonstration project assessing the feasibility and safety of training *matrones* to apply AMTSL. The time needed to import the devices was greatly underestimated, however, and devices were not distributed until August 2007, when only three months were left for the demonstration project. To facilitate the study, the DSR authorized distribution to 3 reference health centers (CSRéfs) and 30 community health centers (CSComs) in Bamako in addition to 1 district hospital, 2 district CSRéfs, and 9 peripheral CSComs from the *matrone* demonstration project. Devices were provided free of charge. Although the oxytocin-Uniject device with TTI is not yet commercially available, PATH has estimated that pharmaceutical companies should be able to offer the product at a price between US$0.35 and $0.60 if there is high-volume demand. Initial pricing of smaller quantities may be higher.[5] Currently, oxytocin in Mali is supplied in 5- or 10-IU ampoules that require a sterile, disposable syringe, and costs for clients are 300 to 350 CFA francs[6] for the syringe and 200 to 250 CFA francs per 10-IU ampoule of oxytocin ($0.60 to $0.70 total).

The oxytocin-Uniject device is a plastic, nonreusable, disposable syringe prefilled with a single dose of 10 IU of oxytocin in 1 mL. The oxytocin is enclosed in a sealed blister, and a permanent needle is attached. The devices used in this study were packaged in two types of foil wrappers. One had a notch to facilitate opening, and the second had to be cut open with a sharp object.

[5] Personal communication with Steve Brooke, Advisor for Commercialization and Corporate Partnerships in PATH's Technology Solutions Global Program.

6 The CFA franc (in French: franc CFA or FrCFA) is a currency used in twelve francophone West African countries, as well as in Guinea-Bissau and in Equatorial Guinea. The ISO currency code is XOF for the West African CFA franc. It has a fixed exchange rate to the euro: 100 CFA francs = 1 French (nouveau) franc = 0.152449 euro; or 1 euro = 655.957 CFA francs.

There was no tracking of the two different packaging types, however.

After the Uniject device is removed from the foil pouch, it is activated by pushing the needle cap and the blister together. The cap is then removed, and the needle is inserted into the injection site. The dose is delivered by squeezing the blister until it fully collapses. The device is slightly overfilled to compensate for the small amount of oxytocin and air that remain in the blister. For this study, the Uniject devices were prefilled to deliver 10 IU of oxytocin in 1 mL, and needles suitable for adult intramuscular injection (23-gauge, 25 mm) were used.

Each foil pouch had a TTI (called a vaccine vial monitor when used with vaccine), a small, colored sticker in which one area becomes darker in relation to its cumulative exposure to heat. Oxytocin can withstand moderate heat exposure for some time, but substantial heat exposure reduces potency. Therefore, the TTI on the product package helps ensure that oxytocin given to a woman is potent while allowing more flexibility for field transport and storage. Use of the TTI represents a novel application of PATH vaccine vial monitor technology. With a donation of TTIs from the producer, TempTime Inc., PATH and the manufacturer incorporated TTIs with the lot of oxytocin-Uniject devices used in Mali.

The oxytocin-Uniject units were specially manufactured in accordance with international standards by a GMP-compliant pharmaceutical company located in Buenos Aires, Argentina, the Instituto Biologico Argentino SAIC (also known as BIOL, for short). BIOL has developed the oxytocin-Uniject product through a collaborative agreement with PATH, with support from USAID under the HealthTech program. The expiration date for the prefilled Uniject devices was set for December 2007, when study activities were scheduled to be completed.

Methods

The evaluation of the oxytocin-Uniject device with TTI was conducted in three districts in Mali: Bamako, Koulikoro, and Gao. Each district is located in the region that bears the same name (see Figure 2). Sites selected to participate included 33 in Bamako that had participated in a pilot project in 2002 and 12 from the *matrone* demonstration project in Koulikoro and Gao.

The health system in Mali follows the administrative divisions. Each region has a regional hospital; each district has at least one reference health center (CSRéf) with operative capacity; and communes have community health centers (CSComs) that provide essential maternal, newborn, pediatric, and adult health care services. The *matrone* demonstration sites included 1 regional hospital, 2 district CSRéfs, and 9 CSComs; sites in Bamako included 3 CSRéf and 30 CSComs.

Figure 2. Map of Mali.

The target population was women giving birth vaginally in designated facilities. The total number of expected births per month for all these facilities combined is 5,018.

Planning and preparations for importation of oxytocin-Uniject devices with TTI for use in *matrone* study sites required special authorization from the Department of Pharmaceuticals and Medications (DPM) of the Ministry of Health in Mali (see Appendix 3). Special permission to import was received on June 18, 2007, and oxytocin-Uniject units were received in Bamako, Mali, in August 2007. The oxytocin-Uniject units were distributed to sites in Gao and Koulikoro, as well as sites in Bamako selected by the DSR (see Appendix 2). Estimation of the number of units needed was based on the estimated number of vaginal births in each facility. For the purpose of this study, the oxytocin-Uniject device was only to be used for AMTSL and not for labor induction, labor augmentation, or PPH treatment. Any unused devices were to be destroyed at the close of the project.

A detailed distribution plan was developed by the DSR, POPPHI, IntraHealth International, and USAID projects Capacity, Assistance Technique Nationale (ATN), and Projet Keneya Ciwara (PKC). Oxytocin-Uniject devices with TTI were distributed in August and September 2007 by the DNS and Capacity/PKC staff or consultants to all of the sites. The devices were stored under standard cold chain conditions (2ºC to 8ºC) for international transport and stored at the national pharmacy in Bamako. Because of a lack of refrigerator space, Uniject devices were stored in cool rooms in their original shipping carriers until distribution to the facility. They were then transported via cold boxes to health facilities. At the time of distribution, discussions were held with providers, facility managers, and pharmacy managers about proper storage of the devices. DNS and Capacity/PKC staff ensured appropriate storage before leaving the facility. Providers and

pharmacy managers were instructed to document the date that devices were taken out of the cold chain and to record the number of devices with TTIs indicating that the device should be discarded.

Training materials developed by PATH for Vietnam were translated into French and adapted for use in Mali by the POPPHI project. In July 2007, a POPPHI representative oriented DNS and Capacity/PKC technical staff to the training materials and the oxytocin-Uniject device with TTI. DNS and Capacity/PKC staff trained 47% of providers (66/140 respondents) interviewed on site in the use of the Uniject device at the time the units were distributed. The trained providers then performed a scaled-down version of the training for other birth attendants in the facility who were not present for the formal training. Of providers interviewed, 50% (70/140 respondents) were trained by colleagues, 1.4% (2/140 respondents) read the printed instructions to learn how to use the device, and two providers interviewed did not provide a response to the question about who had trained them.

The training course included use of the Uniject device, elimination of used devices, interpretation of the TTI, and documentation of AMTSL and use of the oxytocin-Uniject device with TTI. The training course included a practical session to practice activating and administering oxytocin in the Uniject device. The formal training course was designed to last 2 hours and 15 minutes. As seen in Table 1, formal training was considerably more time-consuming than informal transfer of skills.

Table 1. Time for training to use oxytocin-Uniject device by type of trainer

	No response	<1 hour	1–2 hours	>2 hours	Total
Taught by colleagues in the health facility	0	59	8	3	70 (50%)
Taught by DNS and Capacity/PKC clinical trainers	0	19	41	6	66 (47.1%)
Read the instructions	0	2	0	0	2 (1.4%)
No response	1	1	0	0	2 (1.4%)
Total	1 (0.7%)	81 (57.9%)	49 (35%)	9 (6.4%)	

When asked if they felt the training they received was adequate to prepare them to use the oxytocin-Uniject device, 77.1% (108) felt that it was. When evaluated by type of training or trainer, 75.7% (53/70) who were trained by colleagues, 80.3% (53/66) who were trained by DNS and Capacity/PKC personnel, and 100% (2/2) who read the instructions felt the training they received was adequate.

Ninety-seven percent of providers (136/140) felt competent to manipulate the oxytocin-Uniject devices after training activities were completed. When evaluated by type of training or trainer, 97.1% (68/70) trained by colleagues, 97% (64/66) trained by DNS and Capacity/PKC personnel, and 100% (2/2) of self-taught providers felt competent after training activities. Both providers who did not give a response to the type of trainer/training felt competent at the end of training activities.

Only 127 (90.7%) of the providers trained actually gave an injection with the oxytocin-Uniject device. Of these, 92.1% (117/127) felt confident after only one injection, and 7.9% (10/127) felt confident after two or more injections.

Any and all cadres at these sites trained in AMTSL were authorized to use the oxytocin-Uniject devices for the practice of AMTSL in place of oxytocin supplied in ampoules. Providers were instructed to cease using oxytocin in ampoules for AMTSL from the time that oxytocin-Uniject devices were distributed until all devices were used. When AMTSL was performed, providers were instructed to write "AMTSL + oxytocin-Uniject" or "AMTSL + oxytocin ampoules" in the delivery register on the same line as the woman who was offered and received AMTSL.

In order to collect accurate data on selected obstetric complications that adequately responded to concerns of the DSR and DNS, DNS and Capacity/PKC staff sensitized providers about the importance of careful documentation of obstetric complications, maternal deaths, stillbirths, and newborn deaths in the DNS-approved registers and notebooks. PPH was defined as vaginal bleeding after childbirth exceeding 500 mL. Blood loss was estimated subjectively by each provider.

Supervisory forms had already been developed to monitor the *matrone* demonstration sites, so existing supervisory forms were adapted by the POPPHI representative to include monitoring use of oxytocin-Uniject devices with TTI. Data to be collected included:

1. Number of vaginal births at the facility, number of selected obstetric complications, number of vaginal births with AMTSL/oxytocin in ampoules, number of selected obstetric complications in women who were offered and received AMTSL/oxytocin in ampoules, number of vaginal births with AMTSL/oxytocin-Uniject devices, and number of selected obstetric complications in women who were offered and received AMTSL/oxytocin-Uniject devices.
2. Observations of providers applying AMTSL.
3. Storage conditions in the pharmacy and delivery room, number of ampoules and Uniject devices in stock, and number of Uniject devices with a TTI indicating the device should be discarded.
4. Quality of documentation in facility registers and availability of equipment and supplies for infection prevention practices and the practice of AMTSL.

Objectives

The primary objectives for evaluating use of oxytocin-Uniject devices with TTI in Mali were as follows:

- To determine the safety of using these devices in terms of two outcomes: selected obstetric complications (ruptured uterus, retained placenta, PPH, and uterine inversion) and needlestick injuries.
- To determine the impact on coverage of AMTSL.
- To document logistical issues when using these devices for AMTSL.
- To evaluate the acceptability of the Uniject device to providers, pharmacy managers, and management staff.

- To document experience with the TTI.
- To document lessons learned from this experience to assist programs in developing countries planning to use oxytocin-Uniject devices with TTI.

Design

At present, oxytocin provided in 5-IU and 10-IU ampoules (two 5-IU ampoules are needed to provide 10 IU of oxytocin) is used for AMTSL. The oxytocin-Uniject device is not yet available at the national level in Mali and was only distributed to *matrone* demonstration project sites in Koulikoro and Gao and selected health centers in Bamako. Providers were instructed to use only oxytocin-Uniject devices for AMTSL as long as they were available. The proposed strategy was to evaluate use of oxytocin 10 IU in the Uniject device by comparing historical controls with results among women who received AMTSL after the oxytocin-Uniject device was made available. The statistical analysis was planned to involve a weighted average of a simple "before" versus "after" comparison for each hospital or medical center that adjusted for the change in availability of the oxytocin-Uniject device (see Figure 3).

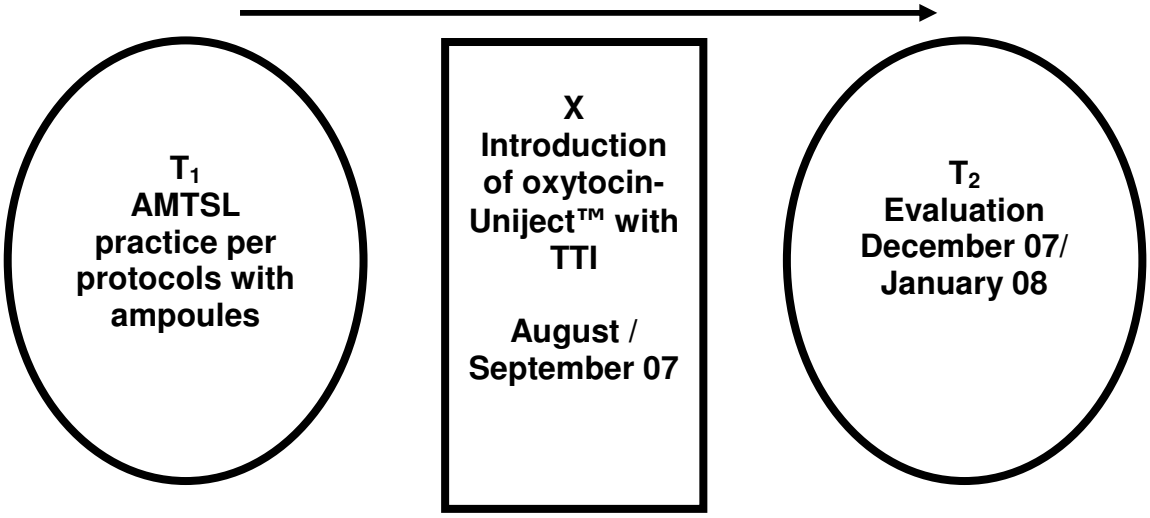


Figure 3. Schematic of initial strategy for evaluating effects.

In reality, it was virtually impossible to make "before" and "after" comparisons because providers used both presentations of oxytocin simultaneously. Oxytocin in ampoules could not be removed before use of the Uniject device started because oxytocin in ampoules is used for other purposes besides AMTSL—labor induction, labor augmentation, and management of PPH. Instead of making before-and-after comparisons, project staff compared outcomes of vaginal births (1) without AMTSL, (2) with AMTSL using oxytocin in ampoules, and (3) with AMTSL using oxytocin-Uniject devices.

Data for comparisons were collected from information documented by providers in registers, notebooks, or reports as follows:

- Application of AMTSL and type of oxytocin used: partograph form and the delivery register.
- Selected complications: delivery register, referral notebook, hospital register, and monthly reports.
- Maternal and fetal deaths: death register and monthly reports.

Personnel responsible for training providers in the use of the Uniject device observed newly trained providers to ensure competency. No observations were planned for the endline evaluation because an assumption was made that no devices would remain at this time.

Additional data were collected by interviews and observation at the time of the endline evaluation on availability and condition of equipment and supplies needed to apply AMTSL and ensure infection prevention practices. All other data on acceptability, feasibility, and safety were collected from interviews with providers, facility managers, and pharmacy managers.

Materials

The two technology innovations introduced in this evaluation were:

- Oxytocin in the Uniject device.
- Use of TTIs on all oxytocin-Uniject devices.

Apart from these innovations, health facilities were responsible for:

- Maintaining the standard cold chain prior to distribution of oxytocin (either in the Uniject device or ampoules) to the delivery room.
- Maintaining standard equipment for infection-prevention practices.
- Purchasing supplies and consumables for infection prevention and AMTSL.
- Ensuring the availability of DNS-approved and -required registers, notebooks, and forms, as well as correct documentation in them.
- Documenting movement of oxytocin to the facility and within the facility.
- Posting job aids for AMTSL.

Data collection and analysis

An endline evaluation was conducted from December 2007 to January 2008 by the DNS and Capacity/PKC/ATN staff and consultants using tools adapted by the POPPHI representative from existing PATH tools. This period was chosen because it coincided with the endline evaluation at the *matrone* demonstration sites in Koulikoro and Gao scheduled for 12 months after training activities were completed. Data were collected at all of the Bamako sites at the same time and included retrospective data for six months, from July to December 2007. Observations of the facility and interviews with health center managers, pharmacy managers, and providers were all conducted during the endline evaluation. Table 2 summarizes data collection methods.

Table 2. Data collection methods, data sources, and sample sizes

Data collection method	Data sources and sample sizes
Interviews	Providers conducting births (140)
	Managers of health care facilities (41)
	Pharmacy managers (13)
Observations	Facilities: 1 hospital, 5 CSRéfs, and 39 CSComs
Inventory	Delivery registers, facility managers, pharmacy managers, providers

A complete review of data from the *matrone* study was prepared by Capacity/IntraHealth International and presented to the DNS in May 2008. In this report, presentation of details on methodology is limited to those relating to safety, feasibility, and acceptability of oxytocin-Uniject devices.

Observations

The environment was observed using inventory tools to evaluate availability and storage of uterotonic drugs, and availability of consumables needed to practice AMTSL and recommended infection prevention practices. Data were collected from registers at each facility on the number of vaginal births; number of vaginal births with AMTSL (either oxytocin in ampoules or oxytocin-Uniject devices); number of complications; and number of maternal deaths and stillborns (a distinction was not made between macerated and fresh stillborns). Observation data were collected at the time of the visit by the interviewers/observers.

Interviews

Project staff interviewed providers conducting births, pharmacy managers, and health facility managers. Individuals were interviewed to document personal information, information about training to use the oxytocin-Uniject device, experience with the device and with the TTI, and logistical issues associated with using the device with TTI for the practice of AMTSL.

Sampling

The chosen methodology involved using a convenience sample. Providers present at the health care facility at the time of data collection were interviewed. Many questionnaires with information on number and types of providers in each facility were not correctly filled in, making it impossible to say what proportion of all eligible providers were interviewed. Providers not present at the time the interviews were conducted were not sought out for interviews, nor was information about them gathered—making it impossible to know how the absence of their comments affects overall results or if the providers and managers interviewed were representative of all providers and managers. Those interviewed included 60 midwives, 31 obstetrical nurses, 36 *matrones*, 10 providers who came under the classification of "other" (nursing assistants, medical students or interns, etc.), and 3 whose cadre was missing. No physicians were interviewed. Tables 3 and 4 summarize the number of providers interviewed by region and by type of facility.

Table 3. Summary of providers interviewed in each region

Provider type	Region			Total
	Bamako	Gao	Koulikoro	
Midwife	56	2	2	60 (42.9%)
Obstetrical nurse	15	8	8	31 (22.1%)
Matrone	15	8	13	36 (25.7%)
Other	6	4	0	10 (7.1%)
Not identified	3	0	0	3 (2.1%)
Total	95 (67.9%)	22 (15.7%)	23 (16.4%)	140 (100%)

Table 4. Summary of providers interviewed by type of facility

Provider type	Type of facility			Total
	Hospital	CSRéf	CSCom	
Midwife	0	32	28	60 (42.9%)
Obstetrical nurse	1	7	23	31 (22.1%)
Matrone	1	6	29	36 (25.7%)
Other	0	2	8	10 (7.1%)
Not identified	0	0	3	3 (2.1%)
Total	2 (1.4%)	47 (33.6%)	91 (65%)	140 (100%)

Sixty-eight of the providers interviewed (48.6%) had worked at that facility for five years or more, 53 (37.9%) had worked in the facility for between one and five years, and 17 (12.4%) had worked at the facility for less than one year. Among those interviewed, 26 (18.6%) were less than 30 years old, 74 (52.9%) were between 30 and 45 years old, and 39 (27.9%) were older than 45 years old. One provider did not provide her/his age. The majority of providers interviewed (97 providers, or 69.3%) had worked as a health care provider for more than five years, 27 (19%) had worked as a health care provider for one to five years, and 13 (9.3%) had worked less than a year as a provider. Three providers did not provide a response to this question. Of the providers interviewed, 11 (7.3%) had assisted at more than 100 births during the three months preceding the interview, 35 (24.8%) had assisted at between 50 and 99 births, 40 (28.5%) had assisted at between 21 and 49 births, and 32 (23.3%) had assisted at 20 or fewer births. Four of the providers interviewed (3.3%) had not assisted at any births during the three months preceding the interview, 9 (6.6%) did not know how many births they had attended, and data for 13 (9.5%) of the providers were missing.

Forty-five facilities received oxytocin-Uniject devices and were evaluated using the inventory tools. Table 5 summarizes the types of facilities observed in each region.

Table 5. Number of various types of facilities observed in each region

Facility type	Region			Total
	Bamako	Gao	Koulikoro	
Hospital	0	1	0	1
CSRéf	3	1	1	5
CSCom	30	4	5	39
Total	33	6	6	45

Facility and pharmacy managers who were on site at the time of the evaluation were interviewed. Information on the total number of managers was missing for many of the questionnaires. Table 6 summarizes the number of pharmacy and facility managers interviewed stratified by region and type of facility.

Table 6. Number of pharmacy and facility managers interviewed by region and facility type

Facility type	Pharmacy managers				Facility managers			
	Region			Total	Region			Total
	Bamako	Gao	Koulikoro		Bamako	Gao	Koulikoro	
Hospital	0	1	0	1	0	1	0	1
CSRéf	2	1	1	4	2	1	1	4
CSCom	2	3	3	8	24	5	7	36
Total	4	5	4	13	26	7	8	41

Data Collection

Interviewers/observers were midwives and doctors from the DNS or regional health care facilities, Capacity/PKC/ATN staff, and consultants. Interviewers/observers were trained for data collection in one day by a statistician consultant hired by IntraHealth. Data collection tools consisted of the four types previously mentioned: interviews with providers, pharmacy managers, and facility managers, and observation of the site.

Each team of data collectors had one supervisor whose role was to support the interviewers in accomplishing the data collection and to review forms to check for completeness and accuracy. Interview forms were to be collected and reviewed by the supervisor on a continuous basis as interviews were completed, with any remaining forms collected at the end of the last day of interviewing.

Data Handling

Survey data (observations of facilities and interviews of providers, pharmacy managers, and facility managers) were entered and analyzed with EpiInfo[7], version 3.5. Answers for open-ended questions were grouped into categories to facilitate data entry.

In most cases, simple frequencies were calculated for all of the variables. In some cases, frequencies were stratified by type of provider, type of oxytocin used (ampoules or Uniject device), type of facility, region, etc. A Fisher's exact test[8] was used to evaluate statistical significance of differences in rates of PPH and retained placenta for vaginal births without AMTSL, AMTSL with oxytocin in ampoules, and AMTSL with the oxytocin-Uniject device.

[7] Epi Info™ is a public domain software package designed for the global community of public health practitioners and researchers. It provides for easy form and database construction, data entry, and analysis with epidemiologic statistics, maps, and graphs.

[8] **Fisher's exact test** is a statistical significance test used in the analysis of categorical data where sample sizes are small. It is named after its inventor, R. A. Fisher, and is one of a class of exact tests. The test is used to examine the significance of the association between two variables in a 2 x 2 contingency table. The p-value from the test is computed as if the margins of a 2 by 2 table are fixed.

Results

Major findings from interviews and observations are presented below. Forty-five site observations were made, 41 facility managers, 13 pharmacy managers and 40 providers were interviewed. Differences were considered statistically significant when the probability value was less than 0.05 using the Fisher's exact test.

Safety

The safety of using oxytocin-Uniject devices was evaluated in terms of the number of selected obstetric complications (ruptured uterus, retained placenta, PPH, and uterine inversion) and the number of needlestick injuries reported by providers using the device.

Needlestick injuries

Observations and questionnaires revealed no unusual safety problems. Of 140 providers interviewed, only 5 (3.6%) had needlestick injuries with the oxytocin-Uniject device (3 were *matrones*, 1 was an obstetrical nurse, and 1 was not identified by provider type). This is roughly equivalent to the rates of 3.01 to 3.77 hollow-bore needlestick injuries per 100 full-time equivalent employees found in Australian hospital employees prior to an intervention to prevent needlestick injuries.[9] Responses for the number of needlestick injuries were missing for all 5 providers, and there is therefore no numerator with which to calculate the percentage of sticks for all 15,000 injections administered. No reuse was reported (or expected, because Uniject is a WHO-approved autodisable device).

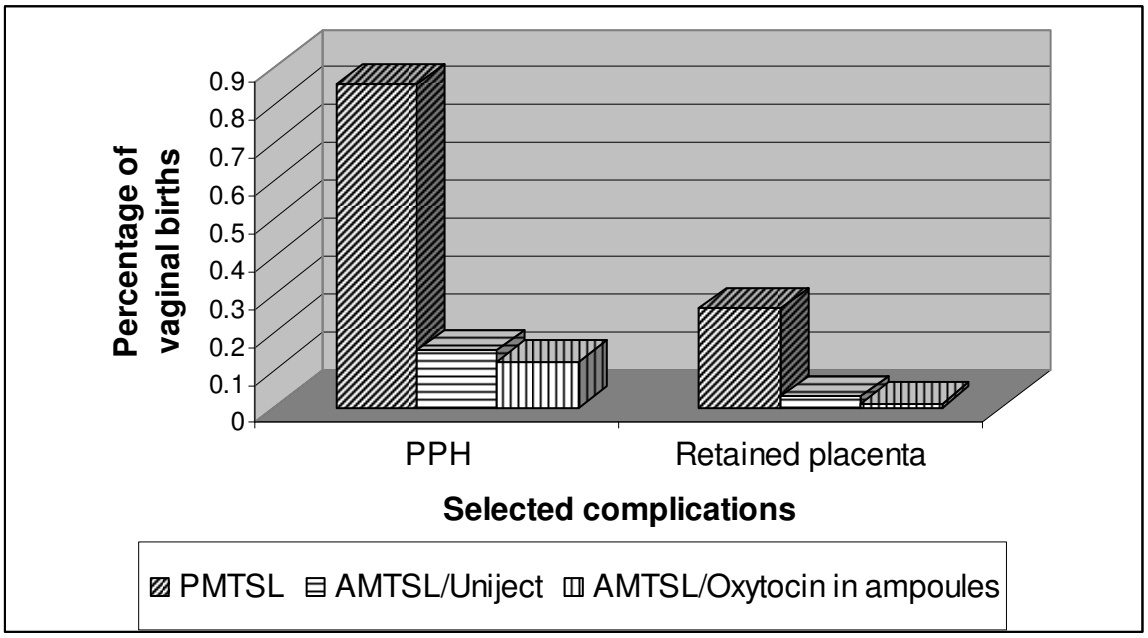
Malian national protocols require disposal of all sharps in an MOH-approved sharps container. These are to be incinerated when they reach the "full" line, which is when the box is approximately three-quarters full. When asked what the provider would do with the safety box or container of used Uniject devices/sharps at the end of the day, the vast majority of providers (81.8%) said they would leave the safety box in the delivery room until it is full. Twenty-two providers (16.1%) said they would burn and bury the box at the end of each day. Because observations of safety boxes were not included, it is impossible to evaluate how they were actually being used in the different facilities.

Incidence of selected obstetric complications

Additional concerns about safety include (1) potential misuse of the product to induce or augment labor and (2) effectiveness of oxytocin in the Uniject device. Comparison of average rates of selected obstetric complications for AMTSL with oxytocin ampoules versus oxytocin in a Uniject device shows no significant difference in occurrence of retained placenta or PPH. This suggests that oxytocin-Uniject devices were at least as effective as the oxytocin ampoules that are already available. Data collected do show a significant reduction in the percentage of women who gave birth vaginally who had PPH and retained placenta when they received AMTSL, either with oxytocin in ampoules or oxytocin in a Uniject device. Although the benefits of AMTSL are well known, it is still powerful to see the impact of AMTSL on complication rates. Table 7 and

[9] Whitby M, McLaws M-L, Slater K. Needlestick injuries in a major teaching hospital: the worthwhile effect of hospital-wide replacement of conventional hollow-bore needles. *American Journal of Infection Control*. 200X;36(3):180–186.

Figure 4 provide an overview of selected obstetric complication rates calculated using data collected over a six-month period.



PMTSL: Physiologic management of third stage of labor
AMTSL: Active management of the third stage of labor

Figure 4. Comparison of percentages of births with selected obstetric complications occurring by type of third-stage management.

Table 7. Percentage of vaginal births with selected obstetric complications by type of third-stage management

Type of management	Vaginal births	PPH		Retained placenta	
		No. cases	%	No. cases	%
All vaginal births	30,973	54	0.17	11	0.036
Vaginal births with AMTSL/oxytocin ampoules	14,438	18	0.12	2	0.014
Vaginal births with AMTSL/oxytocin-Uniject	15,003	23	0.15	5	0.033
Vaginal births without AMTSL	1,532	13	0.85*	4	0.261*

*Comparison of PPH percentages with or without AMTSL: 1-tail p = 1.67034e-06 / 2-tail p = 1.67034e-06.
Comparison of retained placenta percentage with or without AMTSL: 1-tail p = 0.00148665 / 2-tail p = 0.00148665.

The CSRéf serves as a level 1 facility providing essential obstetric services, including blood transfusions and cesarean operations. Consequently, one would hope and expect that the majority

of vaginal births occur at the community health center level. A larger proportion of obstetric complications would be expected to occur in vaginal births taking place at the CSRéf. It is interesting to note that rates of PPH were twice as high for births in community health centers (CSComs), though rates of retained placenta were three times as high in the CSRéfs (Table 8). This finding speaks to the importance of ensuring that providers at the CSCom level are trained in basic obstetric care and that they have the necessary equipment, medications, and supplies to provide initial management for obstetric complications.

Table 8. Number of vaginal births and selected complications by type of facility

Facility type	Vaginal births		PPH			Retained placenta		
	No. cases	% of births	No. cases	% of births	% of all cases	No. cases	% of births	% of all cases
CSRéf	10,116	32.7	11	0.11	20.4	6	0.06	54.5
CSCom	20,857	67.3	43	0.21	79.6	5	0.02	45.5
Total	30,973	100	54	0.17	100	11	0.04	100

All cases of uterine rupture were reported to have occurred in women who had labored or given birth at home and presented at the health care facility with the rupture. This appears to show that there was no increase in complications (uterine rupture) related to oxytocin misuse. During the six months of data collection, there were seven deaths from PPH in all of the facilities. Unfortunately, the evaluation tools were constructed in a way that does not allow assessing whether they gave birth vaginally, where they gave birth, if they received AMTSL, or whether AMTSL was practiced with oxytocin ampoules or the oxytocin-Uniject device.

Coverage

Application of AMTSL requires the presence of a skilled birth attendant, a uterotonic drug, cold chain for storage of injectable uterotonic drugs in the pharmacy or facility store room, and equipment and supplies for injection safety and infection prevention. Providers in the Gao and Koulikoro sites were trained to apply AMTSL as one of the *matrone* demonstration project interventions, and providers in Bamako were trained as part of an intervention in a pilot project conducted in 2002 to evaluate AMTSL within the Malian context. None of the sites was provided with uterotonic drugs, cold chain equipment, or any equipment and supplies for injection safety and infection prevention prior to the introduction of oxytocin-Uniject devices. When the oxytocin-Uniject devices were distributed free of charge to facilities, it was speculated that this would have a great impact on AMTSL coverage. Interestingly, Table 9 and Figure 5 show that AMTSL coverage was already high when oxytocin-Uniject devices were distributed and peaked at 96.1% during month 4. Although coverage rates were slightly higher in month 4 than in month 3 and lower in month 5 than in month 4, these differences were not statistically significant.

Table 9. AMTSL coverage by type of third-stage management and oxytocin used

	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Total
Total vaginal births	4,414	5,079	5,723	5,692	5,109	4,956	30,973
Vaginal births with physiologic management of third stage of labor	254 (5.75%)	269 (5.30%)	291 (5.08%)	223 (3.92%)	247 (4.83%)	248 (5.00%)	1,532 (4.95%)
Vaginal births with AMTSL	4,160 (94.2%)	4,810 (94.7%)	5,432 (94.9%)	5,469 (96.1%)	4,862 (95.2%)	4,708 (95.0%)	29,441 (95.1%)
AMTSL with oxytocin ampoules	4,160 (94.2%)	4,732 (93.2%)	3,538 (61.8%)	628 (11.0%)	394 (7.7%)	986 (19.9%)	14,438 (46.6%)
AMTSL with oxytocin-Uniject	0	78 (1.5%)	1,894 (33.1%)	4,481 (85%)	4,468 (87.5%)	3,722 (75.1%)	15,003 (48.4%)

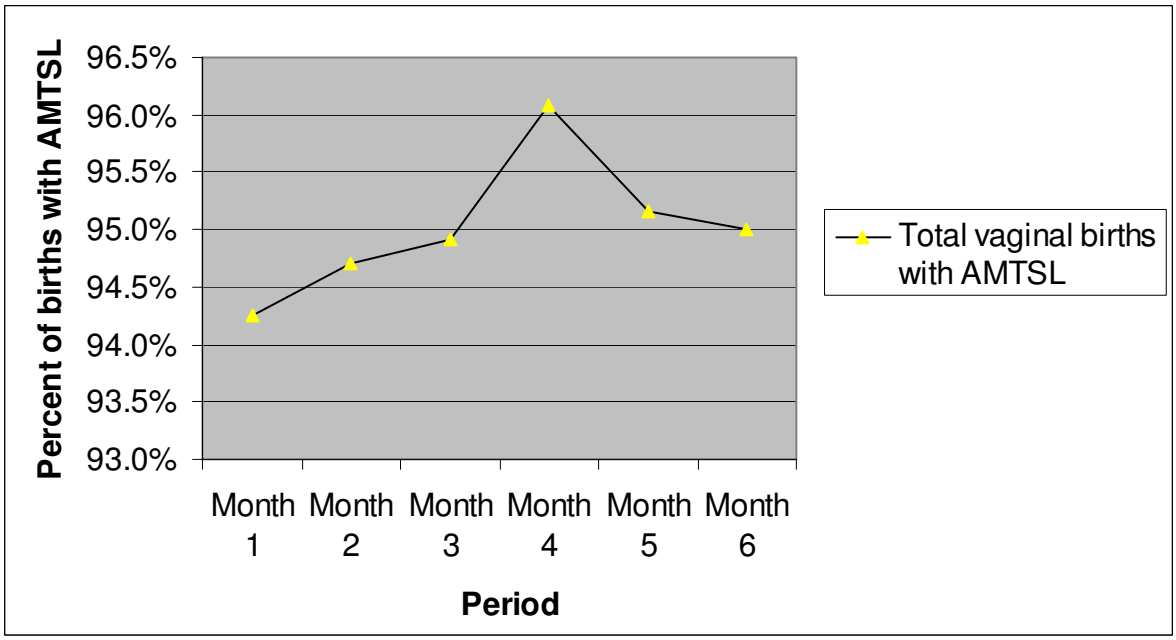


Figure 5. AMTSL coverage over time.

It is difficult to attribute this small increase or decrease in coverage rate to the presence of oxytocin-Uniject devices because use of the devices peaked in month 5, not in month 4 (see Figure 6 and Table 10). The phenomenon we see in Figure 6 is that oxytocin-Uniject devices merely replaced or complemented oxytocin in ampoules, and when there were no more devices, AMTSL coverage did not decrease. This is an important finding for program managers—providers will find ways to implement interventions they feel are effective and safe and improve the care they provide.

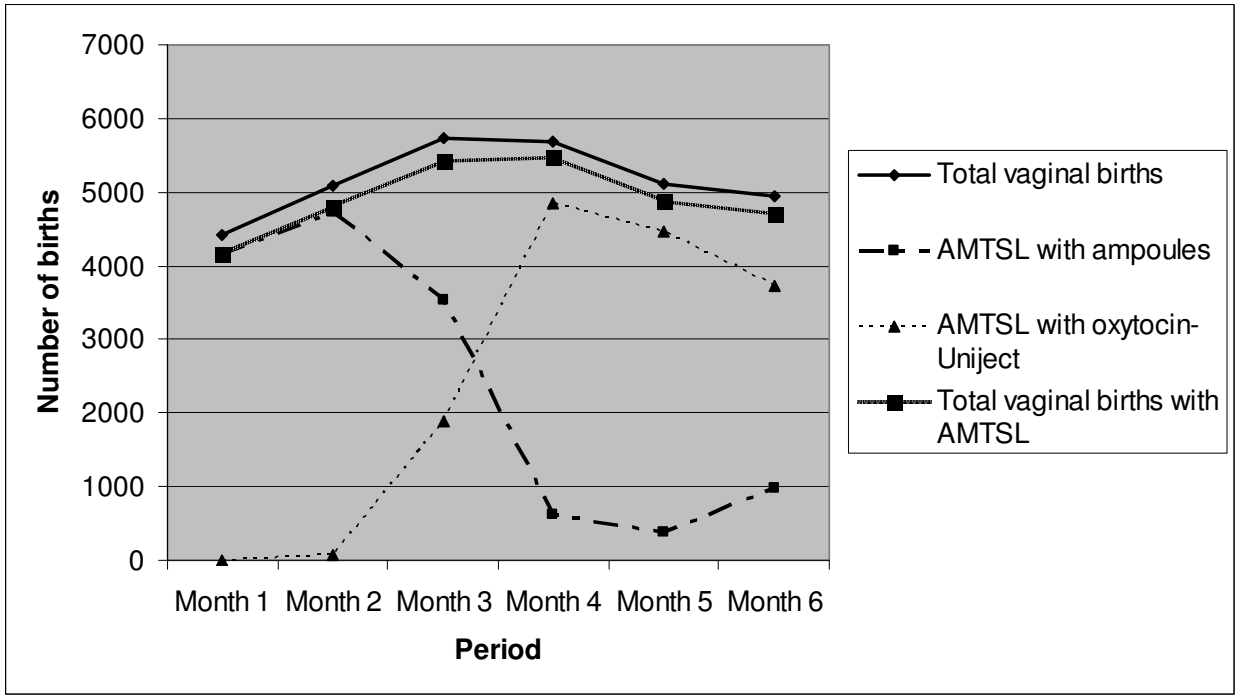


Figure 6. Numbers of vaginal births with AMTSL over time.

When data are stratified by the type of facility (Table 10), it is striking that AMTSL coverage is significantly higher at the CSCom level, where a large percentage of vaginal births occur. Although the reasons for this difference in coverage are unclear, the difference may be related to the fact that higher cadres of providers who have not been in trained in AMTSL attend vaginal births at the CSRéf level.

Table 10. AMTSL coverage by type of facility

Facility type	Vaginal births	AMTSL		Physiologic management of the third stage of labor	
		No. cases	%	No. cases	%
CSRéf	10,116	8,763	86.6%	1,353	13.37%
CSCom	20,857	20,678	99.1%	179	0.86%
Total	30,973	29,441	95.1%	1,532	4.95%

When data are analyzed by whether births occurred in the *matrone* demonstration sites or in the Bamako 2002 AMTSL pilot sites, it is interesting to note AMTSL coverage is significantly higher in sites where *matrones* are applying AMTSL (Table 11). Although AMTSL coverage in the Bamako pilot sites is less than that in the *matrone* demonstration sites, it is nevertheless

striking to note that AMTSL levels remain high in spite of the fact that the intervention took place nearly six years prior to data collection for the oxytocin-Uniject study.

Table 11. AMTSL coverage by zone

	Vaginal births	AMTSL		Physiologic management of the third stage of labor	
		No. cases	%	No. cases	%
Matrone study sites	2,521	2,515	99.8%	6	0.24%
Bamako 2002 pilot sites	28,452	26,926	94.6%	1,526	5.36%
Total	30,973	29,411	95.1%	1,532	4.95%

As previously shown in Table 10, most births with AMTSL occur in CSComs. Vaginal births in CSComs are usually attended by *matrones* and account for a large percentage of vaginal births in health facilities. There is, therefore, potential to have an impressive impact on maternal morbidity and mortality from PPH when *matrones* are authorized to apply AMTSL and oxytocin is made available at even the most peripheral health centers.

Acceptability

Acceptability of the oxytocin-Uniject devices was evaluated by interviews with providers and health care facility managers. When providers were asked which type of syringe they preferred for administering oxytocin, 99.3% (139/140) said that they preferred the oxytocin-Uniject device. Reasons they gave for their preference were:

- Don't have to load the syringe 12 (8.6%)
- Reduces the number of syringes needed 3 (2.1%)
- Easy to place in the injection safety box, easy to handle, more practical 112 (80.0%)
- Can only use it once 8 (5.7%)
- Fewer needlestick injuries 20 (14.3%)
- Economize on syringes 4 (2.9%)
- Efficient/easy to use 11 (7.9%)

When health facility managers were asked to list advantages of the oxytocin-Uniject device, 80.5% (33/41) listed the simplicity of the device, 41.5% (17/41) noted the fact that the device was already loaded with the dose ready to use, and 17.1% (7/41) noted that the TTI added an additional advantage and ensured the quality of the product. Each of the following advantages was listed by only one manager: less pain for the woman, sharper needle, only able to use it once, less waste, easier to store.

While the vast majority of providers (113 / 80.7%) felt that there were no disadvantages of the oxytocin-Uniject device, four (2.9%) noted that the foil pouch was difficult to open, two (1.4%)

noted that a disadvantage of the devices was that additional training was required when first introducing the devices, and two (1.4%) felt that there were cases of PPH after the oxytocin-Uniject device was used. Clarification of this last statement was neither sought nor recorded, so it is impossible to say what prompted these two providers to state this. Fourteen providers (10%) did not provide a response, one response was illegible, one provider said the devices were not available, and one provider said she/he didn't know.

The majority of health care facility managers (68.3%) felt there were no disadvantages to use of the oxytocin-Uniject device, but 17.1% (7) felt that storage of the units was a disadvantage and 4.9% (2) noted that the need to cut the foil wrapper with a sharp object was a disadvantage. Each of the following advantages was listed by only one manager: can only be used once, cannot be used in IVs, appears to hurt more, providers need to be trained to use it.

All 13 of the pharmacy managers interviewed thought they could use the oxytocin-Uniject devices to improve management of uterotonic drugs but did not specify how.

Only 9 providers (6.4%) responded that women had refused to be injected with the oxytocin-Uniject device. When asked if they knew why the women had refused, 22.2% (2/9) stated it was because the women didn't know the product, 11.1% (1/9) said the women felt it would be painful, and one said the women were afraid. Three providers (33.3%) didn't know why the women refused, and two (22.2%) did not respond to the question.

When health facility managers were asked about reactions of women who had received an injection with the oxytocin-Uniject device, the majority (70.7%) felt that there were no negative reactions from women, 9.8% (4) said that women were happy because it was free, and 2.4% (1) felt that women thought it caused less pain than traditional injections. One facility manager noted that some women felt they were being given an injection for contraception without their consent. Although some women fear being given contraceptive injections against their will, because DepoProvera® in the Uniject device is not yet available in Mali, it is probably safe to assume that this fear was related to any injection after birth and not particularly to the Uniject device. This last issue would normally be addressed by careful sensitization of the population and women in labor to the new product. Only 26.8% (11) of health facility managers informed the community about the availability of the oxytocin-Uniject device and AMTSL either during health talks, health committee meetings, or when women were in labor.

Logistics

Making quality oxytocin available in the delivery room is essential for increasing uptake of AMTSL and preventing PPH. The oxytocin-Uniject device is presented in a foil pouch with a TTI on each pouch. Although this presentation means that more room is needed for storage, the TTI ensures that any oxytocin administered has not been exposed to temperatures that would reduce its effectiveness. An important part of the evaluation was to assess the feasibility of storing and using oxytocin-Uniject devices in the heat of the Mali desert environment, which usually necessitates logistic management that is not required in more moderate climates.

The Uniject device consumes considerably more cold chain volume per dose than oxytocin in ampoules. In spite of this, only 19% of health center directors (8/42) cited storage problems as a disadvantage of the oxytocin-Uniject devices, and only 1 of 13 pharmacy managers interviewed

(7.7%) felt that oxytocin-Uniject devices created a storage problem. With 15,000 units distributed, only 1 of 30 health centers visited had 10 units that should have been discarded (TTI indicated that the product had been exposed to high temperatures for too long). CSCom staff particularly appreciated that the quality of oxytocin in the Uniject device with the TTI could be verified for those devices kept out of the cold chain for various periods of time. Average maximum temperatures in Mali from July to December are between 31°C and 43°C.[10]

Of all of the providers interviewed, only 9.3% (13) had come across defective or expired units. Among the providers reporting problems, 2 (14.4%) noted clear defects of the product (blocked syringe and empty blister), 8 (61.5%) said the product was no longer usable because the TTI indicated excessive heat exposure, 2 (14.4%) did not know why the units were defective, and 1 did not provide an answer. Eighty-eight percent (121) of providers interviewed could correctly interpret the TTI on the foil pouch. Four providers (2.9%) indicated that between 1 and 3 units were discarded because the inner square of color was either the same color or darker than the outer circle. Among all facilities visited, only one observer (2.4%) found oxytocin-Uniject units in a delivery room that needed to be discarded. There were no units stored in the stock room or the pharmacy sale area with a TTI indicating excessive heat exposure.

Only 1 of 13 pharmacy managers interviewed (7.7%) responded that he had encountered problems storing the oxytocin-Uniject devices in the cold chain, and only 19% (8/42) of health facility managers cited storage problems as a disadvantage of the oxytocin-Uniject devices. However, three pharmacy managers (23.1%) reported encountering additional cold chain problems, such as electricity outages and refrigerators in poor working condition. Two pharmacy managers said that they used portable vaccine cold boxes to store oxytocin-Uniject devices in the delivery rooms. Interviewers/observers noted that 87.8% of the facilities (36/41) had either a refrigerator or a portable cold box to store oxytocin in the delivery room. Although the TTI provides a means to evaluate the unit's cumulative exposure to heat *and* oxytocin can be stored outside of the refrigerator for three months at 30°C or less, providers preferred keeping the oxytocin in a cold box. This did not appear to create a barrier for the practice of AMTSL because providers still kept oxytocin in the delivery room even if cold boxes were not available.

[10]BBC World Weather. Available at: http://goafrica.about.com/gi/dynamic/offsite.htm?zi=1/XJ/Ya&sdn=goafrica&zu=http%3A%2F%2Fwww.bbc.co.uk%2Fweather%2Fworld%2Fcity_guides%2Fcity.shtml%3Ftt%3DTT000380. Accessed September 3, 2008.

Discussion

Major findings of the Mali oxytocin-Uniject study include:

- **Safety of using oxytocin-Uniject devices for AMTSL**
  - Although only five providers reported needlestick injuries when administering oxytocin in the Uniject device, it was impossible to calculate the number of needlestick injuries for all 15,000 exposures.
  - The number of cases of ruptured uteri is probably too small to detect a change, but all recorded cases of uterine rupture were, by report, in women who presented at the health care facility with the rupture. Although not conclusive, this suggests that providers administering oxytocin in the Uniject device appear to not have misused oxytocin for augmentation purposes.
  - Women who received oxytocin in a Uniject device for AMTSL had similar rates of PPH and retained placenta as those who received oxytocin in ampoules.
- **Impact on coverage of AMTSL when using oxytocin-Uniject devices for AMTSL**
  - Coverage of AMTSL was high when the oxytocin-Uniject device with TTI was introduced and did not increase significantly after its introduction.
  - Providers performed AMTSL regardless of the type of oxytocin available at the health facility and regardless of whether the product was free or involved a charge.
- **Logistical issues when using oxytocin-Uniject devices for AMTSL**
  - Most health facility and pharmacy managers did not feel that the oxytocin-Uniject device created a burden on the cold chain system.
  - The majority of facilities found a way to keep oxytocin cool in the delivery room, and those facilities without cold chain still had high rates of AMTSL coverage, which suggests that oxytocin was accessible at the time that the third stage of labor was managed.
  - All pharmacy managers felt that the oxytocin-Uniject device could improve overall management of uterotonic drugs at their facilities although they did not qualify their response.
- **Acceptability of the Uniject device to providers, pharmacy managers, and management staff**
  - By provider and facility manager report, the oxytocin-Uniject device was refused by a very small percentage of women who were offered it for the practice of AMTSL.
  - The oxytocin-Uniject device was preferred to traditional syringes by providers administering injections.
  - Health facility and pharmacy managers reported more advantages than disadvantages to using oxytocin-Uniject devices.

- Most providers felt competent to use the oxytocin-Uniject device after formal or informal training.

- **Experience with the TTI**
  - The majority of providers interviewed could correctly interpret the TTI on the foil pouch.
  - Providers and pharmacy managers felt that having the TTI was a distinct advantage because providers could easily tell if the unit had been exposed to prolonged high temperatures that would decrease its effectiveness.
  - The inclusion of the TTI has important advantages for facilities in locations where the heat of the desert creates unique cold chain challenges.

Significance

This evaluation demonstrated high levels of acceptability of the oxytocin-Uniject device and relative ease of training health care providers in its use, meaning that its introduction for use by most cadres should be relatively easy. Although the Uniject device consumes considerably more cold chain volume per dose than oxytocin in ampoules, this was not considered a major disadvantage by pharmacy and facility managers. The TTI offers flexibility in storage and has the potential for increasing access to AMTSL in facilities where the cold chain either does not exist or is limited. When women were offered AMTSL with the oxytocin-Uniject device, there was not a significant difference in the number of cases of PPH and retained placenta, indicating that oxytocin in the Uniject device is at least as effective as oxytocin in ampoules. These positive elements must be considered with the fact that the oxytocin-Uniject device could be offered at a price of US$0.35 to $0.60 if there is high-volume demand, which is comparable to what is being paid by consumers now for a syringe and an ampoule of 10 IU of oxytocin ($0.60 to $0.70). The challenge in future oxytocin-Uniject programs will be to maximize these benefits to increase coverage of AMTSL in ways that standard syringes and ampoules cannot. Such situations might include community health centers without cold chains or where *matrones* are conducting the vast majority of births.

Limitations

The biggest limitation of the study was the use of a convenience sample rather than a randomized sample or trial. Use of a simple “before-and-after” methodology to evaluate the safety and feasibility of using oxytocin-Uniject devices within the Mali *matrone* demonstration project was possible because:

- The hospitals or medical centers served a stable population over the period of the evaluation.
- Other aspects of patient management remained constant over the period of the evaluation.
- Criteria for outcome evaluation were constant over the period of the evaluation.
- Patient preferences for AMTSL were constant over the period of the evaluation.
- Health cadre practice of AMTSL was relatively constant over the period of the evaluation (providers were trained in and practicing AMTSL before this evaluation).

- Oxytocin-Uniject devices were not available at any health care facilities in Mali, and all oxytocin-Uniject units were supplied by the project.

An additional limitation was that interviewers/observers used facility registers to gather all data on number of births, practice of AMTSL with ampoules or oxytocin-Uniject devices, maternal complications, stillbirths, and maternal deaths. Collecting data from these sources holds the inherent risk of incomplete or inconsistent reporting, and the unexpectedly low rate of complications before and during the distribution of oxytocin-Uniject devices might raise questions about the accuracy of the data on complications. However, the comparison data come from the same data source and would thus likely have the same bias.

Some diversion from plans while implementing data collection may have affected results as well. Data quality, for example, was to have been ensured by a supervisor whose role was to support the interviewer in accomplishing the data collection and review forms to check for completeness and accuracy. In spite of this and for reasons not clear to the authors, many questionnaires were either not complete or not completed correctly, and retrospective information had to be sought to either clarify or correct information on the questionnaires. For example, a physician collecting data for 20 of the facilities visited in Bamako did not collect data on maternal deaths and stillbirths for the two months preceding introduction of oxytocin-Uniject devices and incorrectly filled in all of his questionnaires.

At the endline evaluation, data were to be collected on the number of oxytocin-Uniject units distributed, the number of units found at each facility with TTIs indicating that they could still be used, and the number with TTIs indicating that they should be discarded. Unfortunately, these data were unusable because it appeared that observers/interviewers had not understood what was being asked of them.

Although these limitations should be kept in mind when reviewing the data and conclusions, we think the results give a reasonably accurate portrayal of the realities of using oxytocin-Uniject devices for the practice of AMTSL in Mali.

Recommendations

This study showed that 10 IU of oxytocin in a Uniject device with TTI can be successfully used by *matrones* and other birth attendants as part of an effective AMTSL program. In addition, the simplicity and ease of use of the device are appreciated by providers and managers alike.

The major next step is to create a strategy and implementation plan for incorporating use of the oxytocin-Uniject device into routine pharmacy ordering systems from the most peripheral to the national level. Such a plan needs to take into consideration differing scenarios, including choosing which health facilities will most benefit from use of the oxytocin-Uniject devices and which will continue to use oxytocin in ampoules. Many other factors need to be considered as well, including registration of the product; the logistics of delivering and storing oxytocin-Uniject devices at national, regional, and district pharmacy storage areas; distribution of oxytocin-Uniject units to peripheral health care facilities; development of protocols for storage at peripheral facilities and in delivery rooms; training providers how to use the devices; and monitoring data on the impact of using the oxytocin-Uniject devices.

Appendix 1: Summary list of key field staff

Data management

Idrissa Toure

Data collection

Dr. Coulibaly Hamma
Dr. Diallo Binta
Dr. Doucouré Arkia
Mme. Konaté Haby
Mme. Konaté Ramata
Mme. Sanogo Astan
Mme. Sanogo Bintou
Mme. Sanogo Fatoumata
Dr. Tangara Bakary
Mme. Touré Aminata
Dr. Traoré Demba
Mme. Traoré Safiatou

Data entry

Mr. Bylla Baba Dicko
Mme. Harama Assetou
Dr. Modibo Kanté
Mr. Moussa Kouyaté

Appendix 2: Distribution of oxytocin-Uniject devices

CERCLE	Naissances Attendues	Accouchement CSCOM	Accouchement CSREF	Accouchement par Mois	Accouchement par Trimestre
GAO	9,161	1,672	585	188	564
KOULIKORO	8,386	3,664	468	344	1,033
COMMUNE1	12,851	10,558	2,790	1,112	3,337
COMMUNE4	10,967	8,447	2,577	919	2,756
COMMUNE5	12,510	9,586	6,554	1,345	4,035
COMMUNE6	18,898	9,157	4,164	1,110	3,330
					15,056

CERCLE	ACC/Trim	Boite de 70	Carton de 24
GAO	564	8	0.3
KOULIKORO	1,033	15	0.6
COMMUNE1	3,337	48	2.0
COMMUNE4	2,756	39	1.6
COMMUNE5	4,035	58	2.4
COMMUNE6	3,330	48	2.0
	15,056	**215**	**9.0**

Appendix 3: Special authorization to import oxytocin-Uniject devices

MINISTERE DE LA SANTE

SECRETARIAT GENERAL

REPUBLIQUE DU MALI
UN PEUPLE – UN BUT-UNE FOI

AUTORISATION SPECIALE D'IMPORTATION DE MEDICAMENTS
N° 2007/06/09MS-SG

VU la Loi N° 62-56 du 6 Août 1962 portant adhésion du Mali à la Convention Unique de 1961 sur les Stupéfiants modifiée par le Protocole de 1972 ;
VU la Loi N° 01-078/AN-RM du 18 juillet 2001 relative à la répression des infractions en matière de substances vénéneuses et de stupéfiants ;
VU le Décret N° 195/PG-RM du 12/08/1998 fixant la liste des stupéfiants ;
VU le Décret N° 04- 557/P-RM du 01 décembre 2004 instituant l'Autorisation de mise sur le marché des médicaments à usage Humain et vétérinaire;
VU le Décret N° 89-194/P-RM du 15 Juin 1989 portant règlement du Commerce Extérieur ;
VU le Décret N°04-141/P-RM du 02 mai 2004 portant nomination des membres du gouvernements, modifié par le décret 05-281/P-RM du 20 juin 2005 ;
VU l'Arrêté N° 01-2699/MICT-SG du 16 octobre 2001 portant fixation de la liste des produits prohibés à l'importation et à l'exportation ;
VU la Lettre N° 2218/MS-SG du 07 décembre 2000 du Ministre de la Santé adressée au Ministre de l'Économie et des Finances ;
VU la lettre N° 078/2007 / IntraH

DECLARE AVOIR AUTORISE L'IMPORTATION PAR :

Nom: Intra HEALTH INTERNATIONAL inc. University of North Carolina
Adresse: Intra HEALTH INTERNATIONAL inc. University of North CAROLINABP 2243, Hamdallaye ACI 2000, Immeuble TOUNKARA BAMAKO/MALI
Des produits pharmaceutiques suivants :

SPE:Nom	Laboratoires	laboratoire fabricant	Quantités	Décision
OXYTOCINE sous la forme UNIJECT	INSTITUTO BIOLOGICO ARGENTINO S.A.I.C.	NSTITUTO BIOLOGICO ARGENTINO S.A.I.C. Direccio y Administracion: Pte. J.E. Uriburu 153- c1027aae Capital Federal Tel: 4953-7215	20 000	Acceptée

DUREE DE VALIDITE : Six (06) mois à compter de la date de signature de la présente autorisation.

BAMAKO, le

Ampliation :
- Direction Nationale des Douanes du Mali 1
- Inspection de la Santé 1
- Direction de la Pharmacie et du Médicament 1
- Direction Nationale de la Santé 1
- Laboratoire Nationale de la Santé 1

18 JUIN 2007

P/LE MINISTRE DE LA SANTE /PO
LE SECRETAIRE GENERAL

DABA DIAWARA

MINISTERE DE LA SANTE – Secrétaire Général – LE SECRETAIRE GENERAL

Appendix 4: Data collection tools

Initiative de la prévention de l'hémorragie du post-partum
Etude sur la faisabilité d'introduire ocytocine dans le dispositif Uniject – République du Mali
Collecte de données de fin de projet

Nom de la Structure	
Type de Structure *(cochez un)*	**1. Hôpital** **2. CSREF** **3. CSCOM**
Région	
District	
Nom de l'enquêteur	
Nom du Chef de Poste	
Date	**Jour ____ Mois ____ Année ____**
Début/fin de la visite	**hrs.___ min ___/ hrs.___ min.___**

Accoucheurs dans la formation sanitaire:

Liste de vérification d'observation pour la GATPA (cas réel seulement)		
Nombre de prestataires effectuant les accouchements à la formation sanitaire	Médecins	
	Sages femmes	
	Infirmières obstétriciennes	
	Infirmiers	
	Matrones	
	Autres (spécifier)	
Nombre de prestataires formés en la GATPA	Médecins	
	Sages femmes	
	Infirmières obstétriciennes	
	Infirmiers	
	Matrones	
	Autres (spécifier)	
Nombre de prestataires formés à utiliser les dispositifs ocytocine-Uniject	Médecins	
	Sages femmes	
	Infirmières obstétriciennes	
	Infirmiers	
	Matrones	
	Autres (spécifier)	
Nombre de prestataires formés en GATPA et observées pendant la visite de supervision	Médecins	
	Sages femmes	
	Infirmières obstétriciennes	
	Infirmiers	
	Matrones	
	Autres (spécifier)	

Description de sources des données (i.e. affiches, registres, observation avec la liste de vérification, etc)

_____

I. DOCUMENTATION / STATISTIQUES																	
MOIS A ENREGISTRER /																**TOTAL**	
Quel est le nombre total de femmes qui ont accouché par voie basse dans cette structure (y compris les accouchement à complication).																	
	Parmi toutes les femmes qui ont accouché par voie basse, combien ont été assistées par la catégorie de prestataire suivante?	Médecin	Sage	Infirmier	Matrone	Médecin	Sage	Infirmier	Matrone	Médecin	Sage	Infirmier	Matrone	Médecin	Sage	Infirmier	Matrone
	Accouchement par voie basse																
Parmi toutes les femmes qui ont accouché par voie basse, combien ont eu les complications suivantes?																	
	Catégorie de prestataire qui a effectué l'accouchement	Médecin	Sage	Infirmier	Matrone	Médecin	Sage	Infirmier	Matrone	Médecin	Sage	Infirmier	Matrone	Médecin	Sage	Infirmier	Matrone
	Anémie sévère (hémoglobine ≤7)																
	Hémorragie pendant la grossesse																
	Hémorragie du post-partum																
	Déchirure des parties molles																
	Rétention placentaire																
	Rupture utérine																
	Inversion utérine																
	TOTAL																
Parmi tous les accouchements par voie basse, quel est le nombre total des femmes qui ont reçu la **GATPA/ocytocine en ampoule** dans cette structure.																	
	Parmi toutes les femmes qui ont reçu la GATPA, combien ont été assistées par la catégorie de prestataire suivant?	Médecin	Sage	Infirmier	Matrone	Médecin	Sage	Infirmier	Matrone	Médecin	Sage	Infirmier	Matrone	Médecin	Sage	Infirmier	Matrone
	Accouchement par voie basse + GATPA																
Parmi toutes les femmes qui ont accouché par voie basse et qui ont reçu la **GATPA/ocytocine en ampoule**, combien ont eu les complications suivantes?																	
	Catégorie de prestataire qui a effectué l'accouchement	Médecin	Sage	Infirmier	Matrone	Médecin	Sage	Infirmier	Matrone	Médecin	Sage	Infirmier	Matrone	Médecin	Sage	Infirmier	Matrone
	Anémie sévère (hémoglobine ≤7)																
	Hémorragie pendant la grossesse																

I. DOCUMENTATION / STATISTIQUES																
MOIS A ENREGISTRER /																**TOTAL**
Quel est le nombre total de femmes qui ont accouché par voie basse dans cette structure (y compris les accouchement à complication).																
	Hémorragie du post-partum															
	Déchirure des parties molles															
	Rétention placentaire															
	Rupture utérine															
	Inversion utérine															
	TOTAL															

I. DOCUMENTATION / STATISTIQUES																
MOIS A ENREGISTRER /																**TOTAL**
Parmi tous les accouchements par voie basse, quel est le nombre total des femmes qui ont reçu la **GATPA/ocytocine-Uniject** dans cette structure.																
	Parmi toutes les femmes qui ont reçu la GATPA, combien ont été assistées par la catégorie de prestataire suivant?	Médecin	Sage	Infirmier	Matrone	Médecin	Sage	Infirmier	Matrone	Médecin	Sage	Infirmier	Matrone	Médecin	Sage	Infirmier	Matrone
	Accouchement par voie basse + GATPA																
Parmi toutes les femmes qui ont accouché par voie basse et qui ont reçu la **GATPA/ocytocine-Uniject**, combien ont eu les complications suivantes?																
	Catégorie de prestataire qui a effectué l'accouchement	Médecin	Sage	Infirmier	Matrone	Médecin	Sage	Infirmier	Matrone	Médecin	Sage	Infirmier	Matrone	Médecin	Sage	Infirmier	Matrone
	Anémie sévère (hémoglobine ≤7)																
	Hémorragie pendant la grossesse																
	Hémorragie du post-partum																
	Déchirure des parties molles																
	Rétention placentaire																
	Rupture utérine																
	Inversion utérine																
	TOTAL																
Parmi les cas de grossesses avec une HPP qui se sont présentées à cette structure, quel est le nombre total de femmes référées ?																
Parmi les cas de grossesse avec une HPP, quel est le nombre de femmes ayant reçu une transfusion sanguine dans cette structure ?																

I. DOCUMENTATION / STATISTIQUES																
MOIS A ENREGISTRER /													**TOTAL**			
Nombre total de décès maternels (à cause spécifique) ***(jusqu'à 42 jours après la naissance):***																
	Catégorie de prestataire qui a effectué l'accouchement	Médecin	Sage	Infirmier	Matrone	Médecin	Sage	Infirmier	Matrone	Médecin	Sage	Infirmier	Matrone	Médecin	Sage	Infirmier	Matrone
	Hémorragie pendant la grossesse																
	Hémorragie du Post-partum																
	Travail prolongé / obstrué																
	INFECTION																
	Pré-éclampsie/Eclampsie																
	Avortement																
	Rupture utérine																
	Autre (*spécifier*):																
	TOTAL																
	Nombre total de décès fœtal et de mort-nés																

II. INVENTAIRE DES INFRASTRUCTURES			
Items	**Disponibilité**	**Quantité : *(si la réponse est 1 ou 2)***	**Remarques :**
Documents 1 = Disponible et rempli / 2 = Disponible mais pas rempli / 0 = Non, pas disponible			
Registre d'accouchement			
Rubrique pour indiquer le/la prestataire qui a effectué l'accouchement			
Rubrique concernant la délivrance du placenta dans les registres ou sur les fiches de rapports			
Rubrique concernant une complication / un décès dans les registres ou sur les fiches de rapports			
Registre de référence / évacuation			
Registre d'hospitalisation			
Registre de décès			
Equipement nécessaire pour la GATPA			
Réfrigérateur disponible au dépôt de vente de médicaments			
Réfrigérateur (ou thermos) disponible dans les magasins			
Réfrigérateur (ou glacière) disponible en salle d'accouchement			
Thermomètre (pour la surveillance de la chaîne de froid)			

Items	Disponibilité	Quantité : *(si la réponse est 1 ou 2)*	Remarques :
Pour les éléments suivants : 1. Oui 2. Non			
Ampoules/Dispositifs Uniject d'ocytocine identifiés par date d'entrée dans la pharmacie			
Ampoules/Dispositifs Uniject d'ocytocine identifiés par date d'entrée dans le magasin			
Ampoules/Dispositifs Uniject d'ocytocine identifiés par date d'entrée dans la salle d'accouchement			

Informations supplémentaires sur les dispositifs d'Uniject	
	Nombre
1. Nombre de dispositifs livrés	
2. Nombre de dispositifs non utilisables dans le dépôt de vente (dispositifs dont le carré intérieur de l'ITT est la même couleur que l'anneau extérieur)	
3. Nombre de dispositifs non utilisables dans la salle d'accouchement (dispositifs dont le carré intérieur de l'ITT est plus sombre que l'anneau extérieur)	
4. Nombre de dispositifs défectueux	
5. Nombre d'accidents avec exposition du sang avec les dispositifs ocytocine-Uniject	

	MÉDICAMENTS NÉCESSAIRES POUR LA GATPA*	***système chaîne de froid***	***protégé de la lumière***	***Compte physique***	***Compte sur fiches de Stock***	***Consommation moyenne mensuelle***	***No de jours de rupture pendant le dernier mois***	***Raisons de ruptures (écrire)***
		1. Oui ; 0. Non						
Dépôt de vente	Ocytocine (10 IU/ 1ml dispositif d'Uniject) – dispositifs dont le carré intérieur de l'ITT est plus clair que l'anneau extérieur							
	Ocytocine (10 IU/ 1 ml ampoule)							
	Ergométrine 0.2 mg/ml							
Salle d'accouchement	Ocytocine (10 IU/ 1ml dispositif d'Uniject) – dispositifs dont le carré intérieur de l'ITT est plus clair que l'anneau extérieur							
	Ocytocine (10 IU/ 1 ml ampoule)							
	Ergométrine 0.2 mg/ml							

*Si d'autres dosages ont été trouvé e.g. 5 i/u d'ocytocine, compter 2 ampoules comme une ; ou 0.4 ou 0.5 mg of ergométrine, compter une comme deux.

REMERCIER LE STAFF POUR LEUR TEMPS !

Initiative de la prévention de l'hémorragie du post-partum

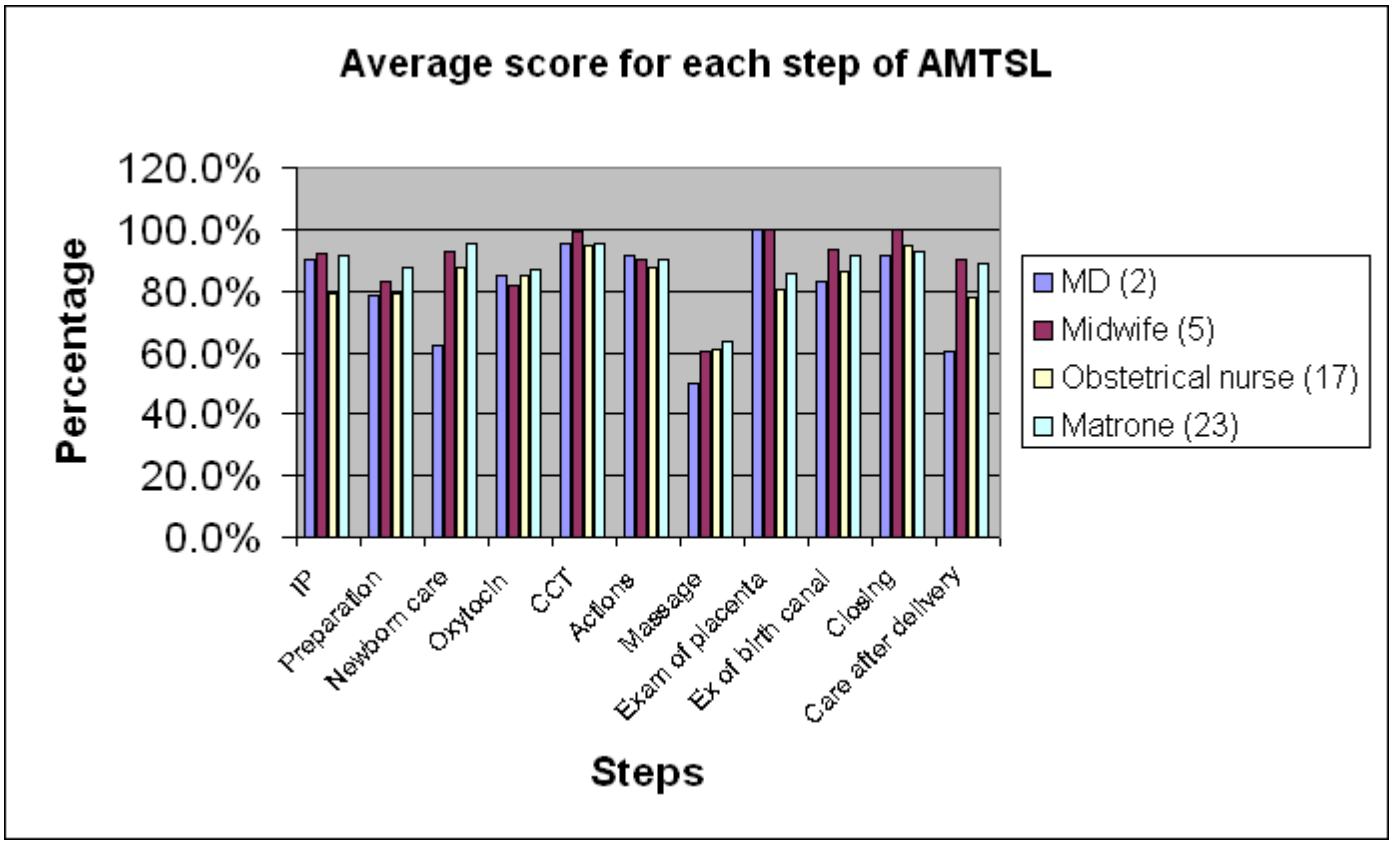
Etude sur la faisabilité d'introduire ocytocine dans le dispositif Uniject – République du Mali

Provider observations - RESULTS

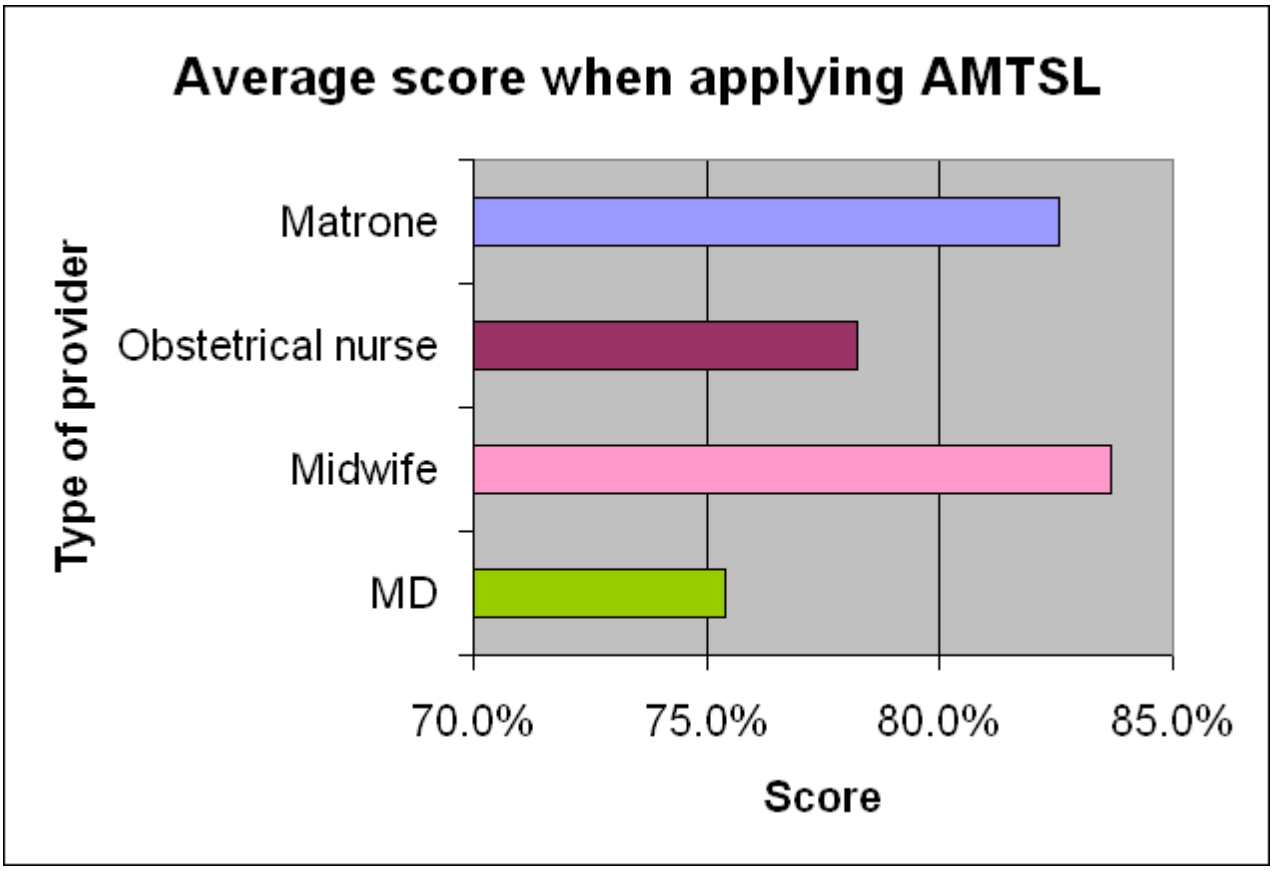
Nom de la Structure	
Type de Structure *(cochez un)*	**1. Hôpital** **2. CSREF** **3. CSCOM**
Région	
District	
Nom de l'enquêteur	
Nom du Chef de Poste	
Date	**Jour ____ Mois ____ Année ____**

	Gao			Koulikoro		Total
	Hospital	**CSRéf**	**CSCom**	**CSRéf**	**CSCom**	
Physician	0	0	0	0	2	2
Midwife	0	0	2	2	1	5
Obstetrical nurse	0	3	7	1	6	17
Matrone	0	2	11	2	8	23
Other	0	0	0	0	0	0
Total	0	5	20	5	17	47

	MD (2)	Midwife (5)	Obstetrical nurse (17)	Matrone (23)
IP	90.0%	92.0%	79.4%	91.7%
Preparation	78.6%	82.9%	79.4%	87.3%
Newborn care	62.5%	92.5%	87.5%	95.1%
Oxytocin	85.0%	82.0%	84.7%	87.0%
CCT	95.5%	99.1%	94.9%	95.3%
Actions	91.7%	90.0%	87.3%	89.9%
Massage	50.0%	60.0%	60.8%	63.8%
Exam of placenta	100.0%	100.0%	80.4%	85.5%
Exam of birth canal	83.3%	93.3%	86.3%	91.7%
Closing	91.7%	100.0%	94.6%	92.8%
Care after delivery	60.0%	90.0%	77.5%	88.7%



Average scores	
MD	75.4%
Midwife	83.7%
Obstetrical nurse	78.2%
Matrone	82.5%



"✓"dans la case si la tâche/activité est exécutée de manière **satisfaisante** – 1 point
« **X** » si elle n'est **pas exécutée** de manière satisfaisante ou - ½ point
N/O si elle n'est pas observée – 0 point
N/A si elle n'est pas applicable (le superviseur peut poser des questions pour cette tâche et cocher selon la réponse.

Catégorie de prestataire observé - cas #1: Méd / SF / IO / Inf / Matrone / Autre
Catégorie de prestataire observé - cas #1: Méd / SF / IO / Inf / Matrone / Autre
Catégorie de prestataire observé - cas #1: Méd / SF / IO / Inf / Matrone / Autre

	#1	#2	#3	COMMENTAIRES
Prévention des infections avant le deuxième stade (6 points)				
1. Prépare la seringue avec l'ocytocine 10 unités				
2. Aide la femme à vider sa vessie quand la deuxième période de l'accouchement s'approche				
3. Avant d'effectuer l'accouchement :				
• Se met un tablier en plastique ou en caoutchouc.				
• Se lave les mains soigneusement avec de l'eau et du savon et les sécher.				
• Se met des gants **stériles**				
4. Aide la femme à se mettre dans la position qu'elle désire pour ses efforts expulsifs et son accouchement (par exemple, accroupie, semi assise, etc.)				
Compétence/activité exécutée de manière satisfaisante				
Préparation à l'accouchement (cette étape n'est pas évaluée)				
1. Prépare le matériel nécessaire.				
2. Laisse la patiente pousser spontanément.				
3. Soutient la position qu'elle a choisie pour accoucher.				
4. Explique à la patiente (et à l'accompagnant) la technique qui sera effectuée, l'écoute et répond attentivement à ses questions et préoccupations.				
5. Se rassure discrètement que la femme veut que l'accompagnant reste dans la salle d'accouchement				
6. Apporte un soutien affectif continu et la rassure, si faisable.				
7. Effectue l'accouchement				
Compétence/activité exécutée de manière satisfaisante				
Soins immédiats au bébé (4 points)				
1. Pose l'enfant sur le ventre de sa mère. Le sèche entièrement immédiatement après la naissance.				
2. Apprécie la respiration, **la coloration** du bébé et réagit selon le besoin				

	#1	#2	#3	COMMENTAIRES
3. Essuie les yeux du bébé avec un tissu propre				
4. Place le bébé en contact peau contre peau sur le ventre de sa mère et les recouvre avec un tissu/serviette propre et sec. Veille à ce que sa tête soit bien couverte.				
Compétence/activité exécutée de manière satisfaisante				
Administrer l'ocytocine (5 points)				
1. Informe la femme et son accompagnant sur ce qui va être fait et les encourager à poser des questions.				
2. Ecoute ce que la femme et son accompagnant ont à dire.				
3. Palpe le ventre de la mère pour exclure la présence d'un deuxième bébé.				
4. Administre l'ocytocine (Si **l'établissement n'a pas d'ocytocine**, injecter 0,2 mg d'ergométrine en IM ou 1 mL de Syntométrine en IM)				
5. Place un récipient stérile (p.ex. : plateau) – ou un récipient propre si un récipient stérile n'est pas disponible **- sous les fesses de la femme.**				
Compétence/activité exécutée de manière satisfaisante				
Traction contrôlée du cordon (11 points)				
1. Clampe et sectionne le cordon 2 à 3 minutes après la naissance du bébé. Noue le cordon quand la femme et le bébé sont en sécurité et la GATPA aura été réalisée.				
2. Clampe le cordon à proximité du périnée en utilisant une pince porte-tampons.				
3. Maintien le cordon et la pince dans une main				
4. Place l'autre main juste au-dessus du pubis de la patiente pour palper des contractions utérines				
5. Maintien une légère tension sur le cordon en attendant une contraction utérine				
6. Lors d'une contraction utérine, applique doucement mais fermement une traction sur le cordon durant une contraction tout en appliquant une traction contraire sur l'abdomen.				
7. Si la manœuvre ne réussit pas immédiatement, attend la prochaine contraction et répète la traction contrôlée sur le cordon et la contre-traction sur l'utérus				
8. Lorsque le placenta est visible, le recueillit dans les deux mains.				
9. Utilise un mouvement en douceur vers le haut et vers le bas ou une action de torsion pour délivrer les membranes.				
10. Ne relâche la contre traction sur l'utérus qu'au moment où le placenta soit visible à la vulve				
11. Met le placenta dans le récipient prévu (p.ex. : bassin hygiénique).				

	#1	#2	#3	COMMENTAIRES
Compétence/activité exécutée de manière satisfaisante				
Actions à prendre si la GATPA ne se déroule pas comme décrite ci-dessus : (3 points)				
1. Si **les membranes se déchirent**, examine la partie supérieure du vagin et du col avec des gants désinfectés et utilise une pince porte-tampons pour retirer tous les débris de membranes.				
2. Si **le placenta ne se décolle pas** de la paroi utérine après quatre (4) essais d'une traction contrôlée, redoute un placenta accreta **procède à une intervention ou évacue la femme**				
3. Si **le cordon a été préalablement rompu**, demande à la femme de s'accroupir et faire expulser le placenta. Si le placenta n'est pas délivré après cette intervention, procède à la délivrance artificielle.				
Compétence/activité exécutée de manière satisfaisante				
Massage Utérin (2 points)				
1. Masse immédiatement le fond utérin à travers la paroi abdominale jusqu'à ce que l'utérus se contracte.				
2. Montre à la femme comment masser son propre utérus et comment savoir si l'utérus ne se contracte pas suffisamment				
Compétence/activité exécutée de manière satisfaisante				
Examen du Placenta (3 points)				
1. Examine la face maternelle et foetale du placenta et les membranes pour voir **si elles** sont **complètes** et s'ils y a des anomalies.				
2. Inspecte l'insertion du cordon et en examine l'extrémité sectionnée.				
3. Incinère le placenta (ou le décontamine et place dans un récipient étanche pour l'enterrer).				
Compétence/activité exécutée de manière satisfaisante				
Examen du Canal Génital (6 points)				
1. Inspecte la partie inférieure du vagin et le périnée pour voir s'il y a des lacérations/déchirures.				
2. Répare l'épisiotomie si elle a été effectuée ou les déchirures génitales ou procède à l'évacuation.				
3. Lave délicatement la vulve, le périnée, les fesses, et le dos avec de l'eau tiède et du savon et fait sécher avec un tissu propre et doux.				
4. Place un tissu propre comme garniture				
5. Met la femme à l'aise.				
6. Evalue la perte de sang.				
Compétence/activité exécutée de manière satisfaisante				
Clôture (6 points)				

	#1	#2	#3	COMMENTAIRES
1. Avant de se retirer les gants, met les linges souillés dans un récipient et jette les compresses de gaze et autres déchets dans un récipient étanche ou un sac en plastique.				
2. Place les instruments dans une solution chlorée à 0,5% pendant 10 minutes pour les décontaminer.				
3. Immerge les deux mains gantées dans une solution chlorée à 0,5% et retire les gants en les tournant à l'envers.				
4. Place les gants dans un récipient étanche ou un sac en plastique.				
5. Se lave les mains soigneusement avec de l'eau et du savon et les sèche avec un linge propre sec et individuel ou à l'air				
6. Enregistre tous les résultats. Enregistre le nom et le profil du prestataire qui a effectué l'accouchement et indique que la GATPA a été appliquée dans le cahier de garde et le registre d'accouchements.				
Compétence/activité exécutée de manière satisfaisante				
Soins après la délivrance (5 points)				
1. Montre à la femme comment sentir son utérus pour voir s'il est dur et comment elle peut le masser elle-même pour le maintenir contracté et prévenir l'hémorragie.				
2. Essaie d'aider la femme à uriner aussitôt que possible après l'accouchement				
3. Si la femme a choisit d'allaiter son bébé au sein, aide-la à initier l'allaitement au sein				
4. Surveille étroitement la nouvelle accouchée et le nouveau-né pendant les 6 premières heures du post-partum				
5. Enregistre tous les résultats.				
Compétence/activité exécutée de manière satisfaisante				
TOTAL				
Préparation avant le deuxième stade (6 points)				
Préparation à l'accouchement (cette étape n'est pas évaluée)				
Soins immédiats au bébé (4 points)				
Administration de l'ocytocine (5 points)				
Traction contrôlée du cordon (11 points)				
Actions à prendre si la GATPA ne se déroule pas normalement : (3 points)				
Massage Utérin (2 points)				
Examen du Placenta (3 points)				
Examen du Canal Génital (6 points)				

	#1	#2	#3	COMMENTAIRES
Clôture (6 points)				
Soins après la délivrance (5 points)				
Total				
Nombre d'étapes « non applicables »				
Pourcentage (___/(51-No d'étapes « N/A »)) x 100				

REMERCIER LA CLIENTE ! REMERCIER LE STAFF POUR LEUR TEMPS !

Initiative de la prévention de l'hémorragie du post-partum

Etude sur la faisabilité d'introduire ocytocine dans le dispositif Uniject – République du Mali

Interview avec le Chef de Poste

Nom de la Structure	
Type de Structure ***(cochez un)***	**1. Hôpital** **2. CSREF** **3. CSCOM**
Région	
District	
Nom de l'enquêteur	
Nom du Chef de Poste	
Date	**Jour ____ Mois ____ Année ____**
Début/fin de l'interview	**hrs.___ min ___/ hrs.___ min.___**

1 Les prestataires, qu'avaient-ils aimé des dispositifs ocytocine-Uniject? *(Note à l'enquêteur: Noter les réponses données)*

2. Quels problèmes étaient rencontrés par les prestataires avec l'utilisation des dispositifs ocytocine-Uniject? *(Note à l'enquêteur: Noter les réponses données)*

3. Quelles étaient les réactions des bénéficiaires aux injections d'ocytocine-Uniject? *(Note à l'enquêteur: Noter les réponses données)*

4. Enumérer les avantages et les inconvénients des dispositifs ocytocine-Uniject de point de vue sécurité des injections? *(Note à l'enquêteur: Noter les réponses données)*

5. Les prestataires, comment disposent-ils des dispositifs ocytocine-Uniject? Enumérer des problèmes qu'ils auraient rencontrés avec la disposition des dispositifs. *(Note à l'enquêteur: Noter les réponses données)*

6. Quels facteurs pourraient influencer la couverture de la GAPTA? *(Note à l'enquêteur: Noter les réponses données)*

7. La couverture en la GATPA, a-t-elle été influencée par l'introduction des dispositifs ocytocine-Uniject ? *(Note à l'enquêteur: Noter les réponses données)*

8. Quels problèmes logistiques avez-vous rencontrés avec la commande et l'entreposage des dispositifs ocytocine-Uniject? Qu'avez-vous fait pour y faire face? *(Note à l'enquêteur: Noter les réponses données)*

9. Quels consommables deviez-vous commander pour l'administration des dispositifs ocytocine-Uniject? *(Note à l'enquêteur: Noter les réponses données)*

10. Avez-vous informé la communauté de la disponibilité des dispositifs ocytocine-Uniject et la GATPA? Si oui, comment? *(Note à l'enquêteur: Noter les réponses données)*

11. Pensez-vous que l'introduction des dispositifs ocytocine-Uniject a été une réussite? Qu'est-ce que nous aurions du faire pour améliorer l'introduction ? *(Note à l'enquêteur: Noter les réponses données)*

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Initiative de la prévention de l'hémorragie du post-partum

Etude sur la faisabilité d'introduire ocytocine dans le dispositif Uniject – République du Mali

Interview avec les gestionnaires de pharmacie

Nom de la Structure	
Type de Structure *(cochez un)*	**1. Hôpital** **2. CSREF** **3. CSCOM**
Région	
District	
Nom de l'enquêteur	
Catégorie du prestataire interviewé	
Date	**Jour ____ Mois ____ Année ____**
Début/fin de l'interview	**hrs.___ min ___/ hrs.___ min.___**

1. La dotation des dispositifs ocytocine-Uniject, a-t-elle changé la façon dont vous faisiez la commande des utérotoniques? *(Note à l'enquêter: Noter les réponses données)*

2. Décrire les avantages logistiques d'utiliser les dispositifs ocytocine-Uniject. *(Note à l'enquêter: Noter les réponses données)*

3. Décrire les inconvénients logistiques d'utiliser les dispositifs ocytocine-Uniject. *(Note à l'enquêter: Noter les réponses données)*

4. Aviez-vous des problèmes à entreposer des dispositifs ocytocine-Uniject dans la chaine de froid ? *Cocher une des réponses*	☐ Oui ☐ Non Si oui, décrire les problèmes :

4.a. Si oui, comment avez-vous fait face aux problèmes de la chaine de froid que vous aurez rencontrés? *(Note à l'enquêter: Noter les réponses données)*

5. Décrire d'autres problèmes avec la chaine de froid que vous auriez rencontrés. *(Note à l'enquêter: Noter les réponses données)*

6. Aviez-vous utilisé de stratégies innovatrices pour entreposer les dispositifs ocytocine-Uniject dans le cas où il y avait des problèmes avec la chaine de froid? *(Note à l'enquêter: Noter les réponses données)*

7. Pensez-vous pouvoir utiliser les dispositifs ocytocine-Uniject pour améliorer la gestion des utérotoniques? *(Note à l'enquêter: Noter les réponses données)*

Initiative de la prévention de l'hémorragie du post-partum

Etude sur la faisabilité d'introduire ocytocine dans le dispositif Uniject – République du Mali

Interview avec les prestataires ayant utilisé les dispositifs ocytocine-Uniject

Nom de la Structure	
Type de Structure *(cochez un)*	**1. Hôpital** **2. CSREF** **3. CSCOM**
Région	
District	
Nom de l'enquêteur	
Catégorie du prestataire interviewé	
Date	**Jour ____ Mois ____ Année ____**
Début/fin de l'interview	**hrs.___ min ___/ hrs.___ min.___**

1. Quand avez-vous été formé à utiliser le dispositif ocytocine-Uniject? *Noter les dates de la formation*	
2. Qui vous a formé? *Noter les noms des personnes et leur organisation*	
3. La formation, combien de temps a-t-elle pris? *Noter le nombre d'heures ou de jours*	
4. Pensez-vous que la formation que vous avez reçu était adéquate / suffisante ? *Cocher une des réponses*	☐ Oui ☐ Non

5. Avez-vous des suggestions pour améliorer la formation? *(Note à l'enquêteur: Noter les réponses données)*

6. Etiez-vous capable de manipuler correctement le dispositif ocytocine-Uniject après la formation? *Cocher une des réponses*	☐ Oui ☐ Non
7. Combien d'injections avec le dispositif ocytocine-Uniject devriez-vous faire à une femme avant de vous sentir compétent à le faire? *Noter le nombre d'injections*	

8. Administriez-vous des injections régulièrement avant de recevoir la formation en l'utilisation du dispositif ocytocine-Uniject? *Cocher une des réponses*	☐ Oui ☐ Non
8.a. Si oui, laquelle des seringues préférez-vous pour donner l'injection de l'ocytocine? *Cocher une des réponses*	☐ Ocytocine-Uniject ☐ Autres seringues ☐ N/A

9. Pourquoi? *(Note à l'enquêteur: Noter les réponses données)*

10. Pensez-vous que les femmes préfèrent recevoir l'injection avec le dispositif ocytocine-Uniject ou avec d'autres seringues? *Cocher une des réponses*	☐ Ocytocine-Uniject ☐ Autres seringues ☐ Ne sait pas

11. Pourquoi? *(Note à l'enquêteur: Noter les réponses données)*

12. Y avait-il des femmes qui ont refusé d'être injectée avec le dispositif ocytocine-Uniject? *Cocher une des réponses*	☐ Oui ☐ Non

12.a. Si les femmes ont refusé, savez-vous pourquoi? *(Note à l'enquêteur: Noter les réponses données)*

13. A peu près combien d'injections avez-vous fait avec le dispositif ocytocine-Uniject? *Cocher une des réponses*	☐ <5 ☐ 5 à 10 ☐ 11 à 20 ☐ >20
14. Y avait-il des dispositifs défectueux? *Cocher une des réponses. Si la réponse est « oui » noter le nombre de dispositifs qui étaient défectueux*	☐ Oui ☐ Non ☐ Ne sait pas Combien: _____

14.a. S'il y avait de dispositifs défectueux, savez-vous pourquoi ? *(Note à l'enquêteur: Noter les réponses données)*

15. Comment pourriez-vous savoir que le dispositif ocytocine-Uniject est toujours efficace en regardant l'indicateur temps-température? *Noter les réponses données*	
16. Combien de dispositifs ocytocine-Uniject ont été jetés parce que le carré de l'indicateur temps-température était soit de la même couleur soit plus sombre que le cercle? *Cocher une des réponses. Si la réponse est « oui » noter le nombre de dispositifs qui étaient jetés parce que l'indicateur temps-température a changé de couleur*	☐ Oui ☐ Non ☐ Ne sait pas Combien: _____
17. Etiez-vous blessé par une piqûre d'un dispositif ocytocine-Uniject? *Cocher une des réponses*	☐ Oui ☐ Non Combien de fois: _____

18. Qu'allez-vous faire avec la boîte de sécurité à la fin de cette journée? *Cocher une des réponses*	☐ Laisser la boîte dans la salle d'accouchement jusqu'à ce qu'elle soit remplie ☐ Bruler et enterrer la boîte aujourd'hui ☐ Ne sait pas ☐ Autres réponses (spécifier):
19. Combien de temps servez-vous dans cette formation sanitaire? *Cocher une des réponses*	☐ < 6 mois ☐ 6 mois à 1 an ☐ 1 an à 5 ans ☐ > 5 ans ☐ Autre (spécifier):

20. Combien d'âge avez-vous? *Cocher une des réponses*	☐ <30 ans ☐ 30 à 45 ans ☐ > 45 ans
21. Depuis combien d'années travaillez-vous en tant que prestataire des services de santé? *Noter les réponses données*	☐ < 6 mois ☐ 6 mois à 1 an ☐ 1 an à 5 ans ☐ > 5 ans ☐ Autre (spécifier):
22. Combien d'accouchements avez-vous effectués pendant les trois derniers mois ? *Noter le nombre d'accouchements*	
23. Combien d'accouchements avez-vous effectués pendant l'année passée (2006) ? *Noter le nombre d'accouchements*	

24. Quels étaient les bienfaits les plus importants d'avoir utilisé les dispositifs ocytocine-Uniject pour la GATPA? *Noter les réponses données*	
25. Quels étaient les inconvénients des dispositifs ocytocine-Uniject? *Noter les réponses données*	
26. Comment pourriez-vous améliorer l'utilisation des dispositifs ocytocine-Uniject afin d'augmenter la couverture de la GATPA? *Noter les réponses données*	