Pilot Introduction of Oxytocin in Uniject® During Active Management of the Third Stage of Labor (AMTSL) at the Institutional Level in Guatemala

A Report Evaluating the Acceptability and Feasibility of Introducing Oxytocin in the Uniject® Device for AMTSL

March 2010

GOBIERNO DE ÁLVARO COLOM · GUATEMALA · MINISTERIO DE SALUD PÚBLICA Y ASISTENCIA SOCIAL
ASOCIACION de GINECOLOGIA Y OBSTETRICIA GUATEMALA
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Acknowledgements

We extend special thanks to all the health providers and facility managers in the six health facilities where the study took place who agreed to share their perspectives with the research team. We would also like to thank all the women who gave birth at the facilities during the time of the pilot. Without them, none of this work would have been possible.

Thanks also to the research team from the Ministerio de Salud y Asistencia Social (MSPAS), Asociación de Ginecología y Obstetricia de Guatemala (AGOG), Health Care Improvement Project (HCI), and PATH who worked continuously to ensure that all details of the project were taken care of thank you to the group of trainers from MSPAS and AGOG who visited the facilities several times to train, to monitor the progress of the project and to collect data for the study. Thank you also to the technical reviewers who gave valuable input on the design of the study, and the proofreader and editor who ensured that the format of the protocol as well as the final report of the study was well presented.

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This project was made possible by the generous support of the American people through the United States Agency for International Development (USAID) under the terms of the Prevention of Postpartum Hemorrhage Initiative (POPPHI) Cooperative Agreement #GHS-I-02-03-00028-00 and the HealthTech Cooperative Agreement #GPH-A-00-01-00005-00. Additional funds for the implementation of the project were obtained through the USAID mission in Guatemala through HCI. The contents of this report are the responsibility of PATH and do not necessarily reflect the views of USAID or the US Government.

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List of Acronyms

AD	Autodisable
AECAMN	Auxiliar de Enfermería Calificada para la Atención Materna y Neonatal/Auxiliary Nurses Qualified for the Attention of Mothers and Neonates
AGOG	Asociación de Ginecología y Obstetricia de Guatemala
AMTSL	Active Management of the Third Stage of Labor
BIOL	Instituto Biológico Argentino SAIC
CAP	Centro de Atención Permanente/Center for Permanent Attention
CAIMI	Centro de Atención Integrada Materno Infantil/Center for Integral Attention of Maternal and Child Health
HCI	Health Care Improvement Project
CI	Confidence Interval
IU	International Units
MSPAS	Ministerio de Salud y Asistencia Social
POPPHI	Prevention of Postpartum Hemorrhage Initiative
PPH	Postpartum Hemorrhage
TOT	Training of Trainers
TTI	Time-Temperature Indicator
USAID	United States Agency for International Development
WHO	World Health Organization

1. Executive summary

Postpartum hemorrhage (PPH), or excessive bleeding after childbirth, is the single most important direct cause of maternal deaths in developing countries. According to the World Health Organization, about 14 million women worldwide suffer severe postpartum blood loss each year. Over 100,000 of these women die within a few hours after childbirth. PPH is responsible for approximately 25% of maternal mortality worldwide. Data from 2005 revealed that the maternal mortality rate in Guatemala was 240 per 100,000 live births, one of the highest in Latin America.

Decreasing maternal mortality is a top priority for the Ministry of Health and Social Welfare of Guatemala (MSPAS). Guatemala has adopted international guidelines for active management of the third stage of labor (AMTSL) for the prevention of PPH and has made great efforts to train health professionals to apply AMTSL to prevent PPH. Despite all of the efforts that the government has put into place to fight PPH, it still continues to be the leading cause of maternal mortality in the country. In an effort to find additional solutions to this problem, MSPAS, through the Department of Sexual and Reproductive Health, identified oxytocin in the Uniject®* device (oxytocin in Uniject) as a potential solution for increasing access to AMTSL and thus addressing this problem.

The pilot introduction aimed to replace oxytocin in ampoules with oxytocin in Uniject in facilities. MSPAS, in collaboration with the United States Agency for International Development (USAID), the Association of Gynecology and Obstetrics of Guatemala (AGOG), Prevention of the Postpartum Hemorrhage Initiative (POPPHI), and PATH conducted the three-month pilot introduction as part of Guatemala's ongoing PPH prevention initiative. Data from the pilot introduction allowed PATH, with assistance from MSPAS, USAID, and AGOG to evaluate the acceptability of oxytocin in Uniject by providers and managers as well as the feasibility and fit with the system.

The research was conducted in six facilities in six districts in the state of Alta Verapaz. MSPAS chose pilot districts based on high maternal mortality rates. Health providers who attended births at selected health facilities and facility managers participated in the pilot introduction and evaluation portion of the study. Some health providers received training but did not use oxytocin in Uniject because they had to rotate to a different department during the time frame of the pilot.

An inventory of current practices and a post-intervention questionnaire were completed by health workers and facility managers before the training and at the end of the pilot, respectively. During the pilot introduction, monitors from MSPAS and AGOG visited the facilities once per month to collect data on the number of births, to monitor the stock and storage of oxytocin in Uniject, to report any maternal deaths and any problems that occurred with the use of Uniject, and to reinforce the correct use of AMTSL as needed.

A total of 205 health workers and 6 facility managers participated in the study. Of those, 89 providers and 6 facility managers completed post-intervention questionnaires about their experience using oxytocin in Uniject as a component of AMTSL. However, health workers rotated during the three-month pilot to other departments and only 77 of the providers who answered the post-intervention questionnaire used the product during the pilot. A total of 3154

* Uniject is a registered trademark of BD.

women gave birth at the six health facilities during the pilot (including 2338 vaginal births and 816 cesarean births). Of those births, 2487 or 79% used oxytocin in Uniject. One divergence from the original study design was not using oxytocin in Uniject for all births (including cesarean and vaginal births). Two of the health facilities could not use oxytocin in Uniject for cesarean births because the facility did not have cold chain equipment in the surgery room and/or facility management decided it was not logistically feasible.

In general, providers and managers found oxytocin in Uniject to be an acceptable device to administer the dose of oxytocin during the AMTSL procedure to prevent PPH. In regards to ease of use, providers found the preparation, activation, and administration of oxytocin in Uniject very easy. However, no statistically significant difference was seen between ease of preparation and administration of oxytocin in ampoules and syringes vs. oxytocin in Uniject. Among the advantages described by providers in regards to acceptability and feasibility of oxytocin in Uniject are:

- **Decrease in time to prepare medication.** 93% of providers reported it took them less time to prepare the dose of oxytocin when they used oxytocin in Uniject.
- **Improved quality of AMTSL services provided to patients.** 64% of providers and 100% of managers reported a large improvement in the quality of AMTSL services provided to patients.
- **Safety to health workers.** Conversations with providers during monitoring visits revealed they felt that oxytocin in the Uniject device was safer for the health workers than ampoules and standard syringes. Reasons given for this perception included anecdotal information regarding cuts when trying to open ampoules.
- **Easier to track.** As oxytocin is a controlled medication in Guatemala, providers need to track all product that is used. Providers reported that tracking the product is much easier with oxytocin in Uniject because instead of saving the broken ampoules, they can save the aluminum Uniject pouch, thus eliminating any risk of being cut by the broken ampoules.

The presence of a time-temperature indicator (TTI)[†] on each Uniject package was also highly accepted by providers and facility managers, and they found the TTI to be very easy to interpret.

This evaluation demonstrated high levels of acceptability of oxytocin in Uniject and relative ease of training health care providers on its use, meaning that its introduction for use by most cadres should be relatively easy. However, MSPAS currently faces several challenges that affect the overall performance of the current PPH prevention program in the country, and this could potentially affect country decisions about wide-scale introduction of oxytocin in Uniject.

Given the particular challenges being faced by MSPAS, it is possible that the benefits offered by oxytocin in Uniject would likely outweigh its disadvantages. In addition, oxytocin in Uniject could be used as an important tool to:

- Raise awareness in the country regarding PPH and the use of AMTSL.
- Guarantee the pharmacological activity of the medication.

There are several factors that limit the significance of this study. However, the results give a reasonably accurate portrayal of the realities of using oxytocin in Uniject for the practice of AMTSL in Guatemala.

[†] A TTI, called a vaccine vial monitor or VVM when used with vaccines, is a small colored sticker that changes color in relation to its cumulative exposure to heat.

Oxytocin in Uniject could potentially address some of the challenges that the country is facing in implementing their national PPH prevention program. We recommend that MSPAS consider the national introduction of oxytocin in Uniject to increase access to AMTSL and improve the impact of their carefully developed PPH prevention strategy.

2. Introduction

The country of Guatemala has adopted international standards for prevention of postpartum hemorrhage (PPH), including promoting active management of the third stage of labor (AMTSL), which is currently the evidence-based procedure for all facility-based births in the country. AMTSL includes the intramuscular (IM) administration of 10 IU of oxytocin. Despite government efforts to fight PPH, AMTSL is not correctly practiced by all providers, and PPH still continues to be the leading cause of maternal mortality in the country. In an effort to find additional solutions to this problem, the Ministry of Health and Social Welfare of Guatemala (MSPAS), through its Department of Sexual and Reproductive Health, identified oxytocin in the Uniject®‡ device (oxytocin in Uniject) as a potential solution for increasing access to AMTSL and helping to address this problem.

As a way to determine whether oxytocin in Uniject is a good solution for supporting AMTSL practices in the country, MSPAS, in collaboration with the United States Agency for International Development (USAID), the Association of Gynecology and Obstetrics of Guatemala (AGOG), the Prevention of Postpartum Hemorrhage Initiative (POPPHI), and PATH, conducted a three-month pilot introduction of oxytocin in Uniject for PPH prevention at the institutional level in the context of AMTSL. After the pilot introduction, PATH assisted MSPAS, USAID, and AGOG evaluate the results.

This project provided data on initial country-level experience with oxytocin in Uniject, including feedback in regards to provider and manager acceptability as well as the feasibility of introduction into the health system. Data from this study will allow MSPAS to consider the broader adoption of oxytocin in Uniject for Guatemala.

3. Background

3.1 PPH as the leading cause of maternal mortality worldwide

PPH, or excessive bleeding after childbirth, is the single most important direct cause of maternal deaths in developing countries. According to the World Health Organization (WHO), about 14 million women worldwide suffer severe postpartum blood loss each year. Over 100,000 of these women die a few hours after childbirth. PPH is responsible for around 25% of maternal mortalities worldwide,[1] reaching as high as 60% in some countries. PPH can also be a cause of long-term severe morbidity, and a further 12% survive with severe anemia.[2,3] The maternal mortality rate in Guatemala is 240 per 100,000 live births, one of the highest in Latin America.[4]

The majority of cases of PPH occur in the immediate postpartum period (within 24 hours after birth) and 70%–90% of these are due to uterine atony, a failure of the uterus to properly contract after the child is born.[5,6] Retained placenta and genital lacerations account for most of the remaining postpartum hemorrhages. Management of PPH depends upon the cause of hemorrhage; it is vital to determine the source of bleeding and take prompt action to arrest it. Treatment generally requires rapid action at a well-equipped facility where surgery, drugs, and blood transfusions are available. Prevention should be the primary strategy for all births,

‡ Uniject is a registered trademark of BD.

particularly where most births occur at lower-level facilities like community-level health centers or at home.

3.2 AMTSL to prevent PPH

To prevent PPH, WHO recommends that a skilled birth attendant provide AMTSL to all women giving vaginal birth. The AMTSL procedure includes the following steps:[7]

- **Administration of a uterotonic within one minute of birth of the baby and after ruling out the presence of an additional baby.** WHO recommends the use of oxytocin (10 IU IM) as the uterotonic of choice because it is effective within 2–3 minutes after injection, has minimal side effects, can be used in all women, and is more stable in storage than other uterotonics such as ergometrine. Administration of a uterotonic drug stimulates uterine contractions that (1) facilitate separation of the placenta from the uterine wall, resulting in rapid delivery of the placenta and (2) compress maternal blood vessels at the placental site after delivery of the placenta.
- **Delivery of the placenta by controlled cord traction.** Controlled cord traction (CCT) facilitates rapid delivery of the placenta and emptying of the uterus. This step needs to be performed during a uterine contraction.
- **Uterine massage after delivery of the placenta.** Uterine massage stimulates uterine contractions and removes clots that may inhibit uterine contraction.

Research has shown that AMTSL decreases the incidence of PPH (by up to 60%), the length of third-stage labor, the percentage of third-stage labor instances lasting longer than 30 minutes, the need for blood transfusion, and the need for uterotonic drugs to manage PPH.[8,9] WHO and international professional organizations such as the International Federation of Gynecology and Obstetrics, the International Confederation of Midwives, and other partner agencies concerned with maternal health all recommend the systematic application of AMTSL at all vaginal births.

3.3 Practice of AMTSL and use of oxytocin in Guatemala

MSPAS Guatemala adopted international guidelines for AMTSL and has made great efforts to train health professionals to practice AMTSL to prevent PPH. While MSPAS has made progress towards achieving the goal to reduce morbidity and mortality due to PPH by ensuring access to AMTSL, they still face multiple challenges.

One challenge to the correct practice of AMTSL is the presentation of oxytocin. Most facilities carry ampoules with 5 IU of oxytocin. Because the recommended guideline for the use of oxytocin for PPH prevention in Guatemala is to use 10 IU IM within one minute after birth, providers must use two 1-mL doses of 5 IU each in glass ampoules. In addition, most facilities are currently administering oxytocin by disposable syringe and needle, which involves assembling the syringe, breaking ampoules, and loading the medication into the syringe.

Another important part of increasing access to AMTSL is ensuring the availability of oxytocin at all facilities where births are taking place. This is a challenge where the cold chain is limited or nonexistent. Oxytocin can withstand moderate heat exposure for some time, but substantial heat exposure reduces potency. Without a time-temperature indicator (TTI) on the product package or without tracking storage temperature of the product carefully, the provider has no way of ascertaining if the oxytocin given to a woman is potent. Based on results of a survey performed by AGOG and POPPHI in 2007, storage of oxytocin at health facilities in Guatemala varies from

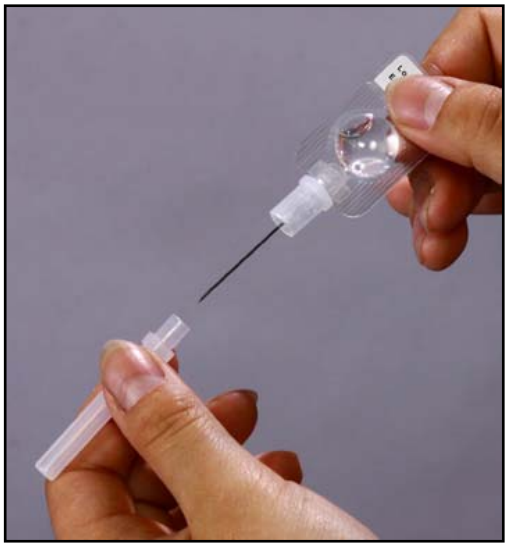
place to place, and not all facilities have access to a refrigerator, especially in some primary care clinics. About 13% of facilities interviewed stored oxytocin at room temperature for indefinite periods of time while others stored it at the recommended temperature of 2°C–8°C. Often times these facilities rely on the Expanded Program on Immunization cold chain system of nearby hospitals to store the drug, and this can cause delays in getting the medication to the clinic when needed. In addition to storage, some health facilities in Guatemala reported stock-outs and irregular supply of oxytocin.[10]

Another important challenge that the country faces is the large number of home births occurring due to lack of access to health services, geographical challenges for transportation, and the cultural diversity of the population. The percentage of institutional births is only 40%. While this initial pilot introduction will not include use of oxytocin in Uniject in home births, the potential for this in the future is of strong interest to MSPAS.

The government of Guatemala has a strong interest in exploring potential solutions that can contribute to decreased maternal mortality due to PPH. As a first step, MSPAS will seek solutions to address challenges in the institutions and could potentially evaluate if and how they can be introduced at the community level. Oxytocin in Uniject has been identified by the government as one potential solution to increase access to AMTSL and help reduce maternal mortality due to PPH.

3.4 Oxytocin in Uniject

Oxytocin in Uniject is a nonreusable, disposable syringe prefilled with a single dose of 10 IU of oxytocin in 1 mL. This injection-ready format is an alternative mechanism to the delivery of oxytocin for AMTSL. Oxytocin in Uniject offers some advantages over a standard ampoule and needle-syringe delivery format. The main benefits of oxytocin in Uniject are:



Oxytocin in Uniject.

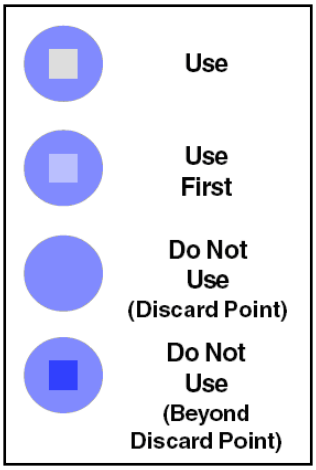
- **Single dose** to minimize wastage and facilitate outreach to individual patients.
- **Prefilled** to ensure that the correct dose is given and to simplify administration, procurement, and logistics.
- **Nonreusable** to minimize patient-to-patient transmission of bloodborne pathogens through needle reuse.
- **Easy to use** to allow use by health workers who do not normally give injections.
- **Compact size** for easy transport and disposal.

Oxytocin in Uniject is enclosed in a sealed blister, and a permanent needle is attached. The device is packaged in a foil wrapper.

Each foil pouch includes a TTI. Oxytocin can withstand moderate heat exposure for some time, but substantial heat exposure reduces potency. The TTI, called a vaccine vial monitor or VVM when used with vaccines, allows precise monitoring of cumulative temperature exposure during transportation and storage. TTIs are small, circular indicators, printed directly on vial labels or adhered to the tops of vials. The inner square is chemically active and changes color irreversibly from light to dark with exposure to heat over time. By comparing the color of the inner square to

the reference color, a health worker can determine whether the vaccine has been exposed to heat. Important decisions on whether to use or discard the medication and which medication should be used first are now clear due to the TTI.[11] This will help ensure that oxytocin given to a woman is potent while allowing more flexibility for field transport and storage and increasing access to facilities with limited or no cold chain.

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.



A quick and easy reference for interpreting a TTI.

4. Methods

4.1 Purpose

The purpose of the study was to assess the acceptability of oxytocin in Uniject by providers and facility managers and to assess the feasibility of introducing this device for delivering oxytocin within the existing health system.

The research project included two linked activities, of which the key activity was the introduction of oxytocin in Uniject for AMTSL as a component of PPH prevention at the institutional level. The two linked activities were:

1. Pilot introduction of oxytocin in Uniject for PPH prevention at the institutional level. This activity aimed at replacing the current practice of using oxytocin in ampoules and syringes with the use of oxytocin in Uniject for PPH prevention at the institutional level**.**
2. Evaluation of user acceptability and feasibility of integrating oxytocin in Uniject within the current system.

Following the pilot introduction of oxytocin in Uniject, users and facility managers provided their opinion on oxytocin in Uniject as a delivery mechanism to administer the dose of oxytocin for AMTSL. The primary objectives of the evaluation were to:

- Assess health worker and manager acceptability of oxytocin in Uniject.
- Evaluate fit with the system and identify sustainability issues resulting from introduction of oxytocin in Uniject.

4.2 Setting and participants

The research was conducted in six districts in the state of Alta Verapaz: Coban, San Cristobal, Fray Bartolomé, La Tinta, Chisec and Carchá. The districts were chosen by MSPAS based on maternal mortality rates. The state of Alta Verapaz is one of the poorest states in the country and has one of the highest maternal mortality rates in the country (266 per 100,000 live births).[4] Six health facilities (one in each of the districts) participated in the study. The health facilities that

participated ranged from primary health clinics to reference hospitals. See Table 1 for a description of participating health facilities.

Table 1: Description of health facilities that participated in the pilot	
Health facilities	**Type of health facility**
Centro de Atención Permanente/Center for Permanent Attention (CAP) of Chisec	Primary
CAP of Carchá	Primary
Centro de Atención Integrada Materno Infantil/Center for Integral Attention of Maternal and Child Health (CAIMI) of San Cristobal	Secondary
Hospital of Coban	District
Hospital of La Tinta	District
Hospital of Fray Bartolomé	District
Total	**6 health facilities**

The study used a convenience sample to engage participants. Health providers who attend births as well as facility managers at the selected health facilities participated in the pilot introduction and evaluation portion of the study. Some health providers received training but did not use oxytocin in Uniject because they had to rotate to a different department during the time of the pilot introduction. Women who went to the clinic to give birth were included as part of the pilot introduction component of the project.

4.3 Materials

A total of 3500 units of oxytocin in Uniject were donated by Instituto Biológico Argentino, SAIC (BIOL) for this study. Each of the units had a TTI to monitor heat exposure during transport and storage throughout the pilot. The Department of Sexual and Reproductive Health at MSPAS received the doses and maintained them in the cold chain until they were distributed to the participating health facilities. At the facilities, oxytocin in Uniject was kept inside the cold chain during the pilot period (2°C –8°C) either at the pharmacy or the labor room.

Oxytocin in Uniject was used ONLY for the preventive dose of PPH during vaginal and cesarean births. Health facilities were responsible for procuring oxytocin in ampoules for other purposes (e.g., treatment of PPH, induction, conduction, etc.). The stock of oxytocin in Uniject was monitored by the pharmacist at each health facility. The stock was labeled “for use during the pilot study only,” and pharmacists were advised to dispense this product only for PPH prevention during vaginal or cesarean births.

In Guatemala, oxytocin is a controlled medication. Thus pharmacists dispense a certain quantity of product to the labor room and the surgery room weekly or daily depending on consumption at that facility. To account for used product, pharmacists require a prescription by a physician and proof that the product was used (used ampoules). This same mechanism was used during the pilot, except that providers only showed the empty foil wrapper instead of the used ampoules.

In addition to the oxytocin and the TTI, health facilities were responsible for providing cold chain equipment (refrigerators, cool boxes) to store oxytocin in Uniject at the recommended temperature and infection control equipment (e.g., alcohol wipes, safety boxes, etc.).

4.4 Training

PATH conducted a three-day training of trainers (TOT) in AMTSL and the use of oxytocin for master trainers from MSPAS and AGOG.

Following the TOT, 11 trainers (8 from AGOG and 3 from MSPAS) facilitated the training of health care providers and facility managers at the participating health facilities. The training for providers and managers lasted two days and consisted of:

- Refresher training in AMTSL practice.
- Use of oxytocin in Uniject (activation, use, and waste disposal).
- Interpretation of the TTI.

Trainers used anatomical training models, training tools on use of oxytocin in Uniject, TTIs, and a participative methodology. Following training, participants were certified using a certification checklist to ensure proficiency. See Annexes 1–3 for the training and competency certification tools for the use of oxytocin in Uniject and the TTI.

4.5 Data collection and analysis

An inventory of current practices was completed by health care providers and facility managers before training, and a post-intervention questionnaire was completed at the end of the pilot study See Annexes 4–6 for the inventory of current practices and the post-intervention questionnaires. The inventory collected information on AMTSL practices at the facility and the use of oxytocin during the AMTSL procedure.

The post-intervention questionnaire collected information on acceptability of oxytocin in Uniject as a delivery method to administer the dose of oxytocin for AMTSL as well as information on challenges with storage and acceptability of the TTI to monitor heat exposure of the oxytocin in Uniject.

During the pilot introduction, monitors from MSPAS and AGOG visited the facilities once per month to collect data on the number of births, the supply of oxytocin in Uniject, any maternal deaths, and any problems that occurred with the use of the Uniject device. If there were any issues related to training, monitors provided refresher training on AMTSL and the use of the Uniject device.

Data were entered and analyzed using Epi Info™[§] version 3.5.1 using a univariate analysis.

To evaluate feasibility and fit within the Guatemalan health system, researchers from PATH and MSPAS met in Guatemala from October 25 to November 4, 2009, to identify issues that were applicable to the introduction and use of oxytocin in Uniject with AMTSL in the context of PPH prevention strategies. The visit was divided in two parts:

1. Visits to all six health facilities to observe AMTSL practices and logistical issues related to the use of oxytocin in Uniject for AMTSL. During this visit, researchers had conversations with health providers from each facility to observe AMTSL practices and the use of oxytocin in Uniject. In addition to health providers, the research team also had conversations with individuals responsible for the procurement, purchase, and stock of oxytocin at the facility level.

[§] 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.

2. Interviews with key stakeholders at the central and state level. A total of ten key stakeholders from various offices within MSPAS were interviewed. Stakeholders provided important information on procurement policies and budget issues related to the use of oxytocin for PPH prevention.

4.6 Informed consent

Participation in the evaluation of acceptability by providers and managers was strictly voluntary and questionnaires were completed without identifiers.

Administration of oxytocin for AMTSL is the current standard of practice in the national guidelines. Therefore, women who received oxytocin in Uniject for AMTSL were exempt from needing to consent.

4.7 Ethical review

The study protocol was approved by PATH's Research Ethics Committee and by the Human Research Subjects Committee of MSPAS.

5. Results

5.1 Inventory of current practices

Results from managers

A survey to assess current AMTSL practices and use of oxytocin at the participating health facilities was conducted prior to training. All six facility managers consented to answer the questionnaire. See the table below for a summary of the results from managers.

Table 2: Summary results from managers on the current AMTSL practices (Inventory of current practices)

Facility	Does your facility provide the dose of oxytocin during AMTSL		Describe the process that your facility uses to administer the dose of oxytocin during AMTSL	Does your facility store oxytocin between 2ºC–8ºC?		If your facility does not store the oxytocin between 2ºC–8ºC, why not?	Does your facility have a regular supply of oxytocin for AMTSL?	
	Yes	No		Yes	No		Yes	No
Hospital of Coban	x		10 IU of oxytocin		x	It is not a practice in my facility	x	
Hospital of Fray Bartolomé	x		No answer		x	No answer	x	

Table 2: Summary results from managers on the current AMTSL practices (Inventory of current practices)								
Facility	**Does your facility provide the dose of oxytocin during AMTSL**		**Describe the process that your facility uses to administer the dose of oxytocin during AMTSL**	**Does your facility store oxytocin between 2ºC–8ºC?**		**If your facility does not store the oxytocin between 2ºC–8ºC, why not?**	**Does your facility have a regular supply of oxytocin for AMTSL?**	
	Yes	**No**		**Yes**	**No**		**Yes**	**No**
Hospital of La Tinta	x		"2 ampoules of 5IU with a disposable syringe following cleaning and disinfection of the area"		x	It is not a practice in my facility	x	
CAP of Chisec	x		"10 IU 1 minute after birth"	x		-		x
CAIMI of San Cristobal	x		" 1 ampoule at 10 drops per minute"	x		-	x	
CAP of Carchá	x		"After birth"	-	x	It is not a practice in my facility	x	
Total	**6 (100%)**	**0 (0%)**	-	**2 (33%)**	**4 (67%)**	-	**5 (83%)**	**1 (17%)**

The reason given for stock-outs was that there was no regular supply at the health coordinating area and therefore health facilities did not receive supplies. Managers also reported that when they did not have any stock of oxytocin, they either borrowed oxytocin from other areas (e.g., the surgery room) or asked the mothers' relatives to purchase the product at the pharmacy.

One health facility manager reported that they ordered oxytocin on a monthly basis, and the rest reported that they ordered it every four months.

Managers also reported that to ensure women receive their dose of oxytocin during AMTSL, access to a regular supply of the product, reinforcement of national regulations, and training of health personnel are needed.

Results from providers

Out of 205 providers, 162 consented to answer the questionnaire prior to training. Of these, 56 (35%) were from Coban, 40 (25%) from Fray Bartolomé, 27 (17%) from Chisec, 14 (8%) from Carchá, 13 (8%) from San Cristobal, and 12 (7%) from La Tinta.

Practice of AMTSL at health facilities

An overwhelming majority of providers reported that their hospitals offer AMTSL to all women that give birth at their facilities. In addition, the majority of providers reported that they perform all three steps of the AMTSL procedure (see Table 3 for the components of AMTSL that are being practiced at each facility).

Table 3: Practice of AMTSL at participating health facilities
n= 162

	Use of AMTSL at health facilities				**Use of uterotonic**			**Controlled cord traction**			**Uterine massage**		
	Yes	**No**	**S***	**NR***	**Yes**	**No**	**NR**	**Yes**	**No**	**NR**	**Yes**	**No**	**NR**
Hospital of Coban	50	1	4	1	54	0	2	52	0	4	51	0	5
Hospital of Fray Bartolomé	36	0	0	4	37	0	3	36	0	4	37	0	3
Hospital of La Tinta	12	0	0	0	12	0	0	12	0	0	12	0	0
CAP of Chisec	26	0	1	0	27	0	0	27	0	0	27	0	0
CAIMI of San Cristobal	12	0	0	1	13	0	0	12	0	1	12	0	1
CAP of Carchá	9	0	1	4	11	2	1	11	1	2	13	0	1
Total	**145 (89%)**	**1 (1%)**	**6 (4%)**	**10 (6%)**	**154 (95%)**	**2 (1%)**	**6 (4%)**	**150 (92%)**	**1 (1%)**	**11 (7%)**	**152 (94%)**	**0 (0%)**	**10 (6%)**

*S: Sometimes, NR: No response.

Preparation and administration of oxytocin

Table 4 summarizes information regarding the difficulty preparing and administering oxytocin in ampoules during AMTSL.

Table 4: Preparation and administration of oxytocin
n= 162

	Difficulty preparing oxytocin in ampoules	**Difficulty administering oxytocin in ampoules**
Very easy	102 (63%)	107 (66%)
Somewhat easy	27 (17%)	33 (20%)
Somewhat difficult	23 (14%)	2 (1 %)
Very difficult	2 (1%)	3 (2%)
No response	8 (5%)	17 (11%)
Total	**162 (100%)**	**162 (100%)**

Providers reported several reasons for having difficulty preparing the oxytocin in ampoules. The most common reasons given by providers were:

- Problems with the glass ampoules. “They are difficult to break.”
- Filling the oxytocin into a syringe can be difficult.
- “It takes too much time to break ampoules and fill syringe when we have too much work in the labor room.”
- “Sometimes the birth has complications and we don’t have time to prepare the medication.”

5.2 Evaluation of acceptability and ease of use by providers and facility managers

Evaluation of acceptability by providers and managers was performed after the three-month pilot introduction. A post-intervention questionnaire was used to gather information on providers’ and managers’ experience using oxytocin in Uniject as a component of AMTSL. Of the 205 providers that participated in the study, 89 completed the post-intervention questionnaire. Of those 89 who answered the post-intervention questionnaire only 77 had the opportunity to use the product during the pilot study. The reason for this situation is that in Guatemala health workers rotate from various wards, and although all 89 received training, 12 providers had to rotate to a different ward. For the purpose of this analysis, we will only include the data analysis for the acceptability portion of the 77 providers that used the product during the pilot study.

All six facility managers completed the post-intervention questionnaire.

Description of participants

Of the 77 providers who used oxytocin in Uniject during the pilot study and who responded to the post-intervention questionnaire, the great majority were auxiliary nurses (n= 62, 81%) followed by nurses (n= 8, 10%) and physicians (n= 5, 6%). See Table 5 for more information on providers.

Table 5: Description of providers

Institution	Auxiliary nurses	Nurses	AECAMN*	Medical doctor (General practitioner)	OBGYN	Other**	Total (%)
Coban	2	1	0	2	0	**0**	**5 (6%)**
Fray Bartolomé	24	3	0	0	0	**2**	**29 (37%)**
La Tinta	8	1	0	0	0	**0**	**9 (11%)**
Chisec	10	1	0	1	0	**0**	**12 (15%)**
San Cristobal	14	1	0	1	0	**0**	**16 (21%)**
Carchá	4	1	0	1	0	**0**	**6 (8%)**
Total	**62 (81%)**	**8 (10%)**	**0 (0%)**	**5 (6%)**	**0 (0%)**	**2 (3)**	**77 (100%)**

* AECAMN (English translation): Auxiliary Nurses Qualified for the Attention of Mothers and Neonates.
** “Other” refers to 1 anesthesiologist and 1 head nurse.

The majority of the providers who answered the post-intervention questionnaire were from Fray Bartolomé, followed by San Cristobal, Chisec, La Tinta, Carchá, and Coban respectively.

Although Coban is the largest hospital in the pilot area, health workers at that hospital were in a mandatory training at the time the interviews took place. The same situation occurred in Carchá and La Tinta.

The experience of providers attending births varied widely, with the majority having less than 5 years of experience attending births. See Annex 7 for a detailed table on years of experience attending births by provider type.

The 6 facility managers were interviewed, one per facility. Of the 6 managers, 3 (50%) considered themselves nursing officers, 1 (16.7%) a medical officer, 1 (16.7%) a business manager, and 1 (16.7%) was designated as "other."

Usage of oxytocin in Uniject

A total of 3154 births were attended at the six health facilities during the pilot (including vaginal births and cesarean sections). Of those, 2487 used oxytocin in Uniject (79% utilization rate). See Annexes 8–10 for more detailed information on the number and types of births that took and utilization of oxytocin in Uniject during the study.

Ease of use

See Table 6 for summary information on ease of use of oxytocin in Uniject by providers.

Table 6: Ease of use of oxytocin in Uniject
Data from providers
n=77

Categories	**Ease of preparing the oxytocin in Uniject**	**Ease of activating the oxytocin in Uniject**	**Ease of administering the oxytocin in Uniject**
Very easy	71 (92.21%)	66 (86 %)	62 (80%)
Somewhat easy	6 (8%)	1 (1 %)	10 (13%)
Somewhat difficult	0	1 (1 %)	2 (3%)
Very difficult	0	8 (11 %)	0
No response given	0	1 (1%)	3 (4%)
Total	**77 (100%)**	**77 (100%)**	**77 (100%)**

Some providers reported that, "Changing from oxytocin in ampoules to oxytocin in Uniject created a little difficulty at the beginning, but as the pilot went on, it was easier to utilize oxytocin in Uniject routinely." "Using oxytocin in Uniject gave us the advantage of preparing the medication faster because we did not have to break two ampoules at a time when we were busy trying to follow many steps."

In addition, all six (100%) facility managers reported that the packaging of oxytocin in Uniject made the work of their staff easier.

Although the percentage values for ease of preparation and administration of oxytocin in Uniject vs. oxytocin in ampoules were higher, there is no statistically significant difference between ease

of preparation and administration or oxytocin for either methods of delivery (Uniject vs. ampoules). See Table 7 for details.

Table 7: Comparison of ease of use of oxytocin in Uniject vs. oxytocin in ampoules					
		Oxytocin in Uniject		**Oxytocin in ampoules**	
	Categories	***n* (%)**	**95% CI (%)**	***n* (%)**	**95% CI (%)**
Ease of preparation	Very easy	71 (92%)	83.8-97.1	102 (63%)	55-70.4
	Somewhat easy	6 (8%)	2.9-16.20	27 (17%)	11.3-23.3
	Somewhat difficult	0 (0%)	N/A	23 (14%)	9.2-20.5
	Very difficult	0 (0%)	N/A	2 (1%)	0.1-4.4
	No response	0	N/A	8 (5%)	2.2-9.5
	Total	**77 (100%)**	**-**	**154 (100%)**	**-**
Ease of administration	Very easy	62 (80%)	69-88.7	107 (66%)	.58.2-73.3
	Somewhat easy	10 (13%)	6.4-22.6	33 (20%)	14.5-27.4
	Somewhat difficult	2 (3%)	0.3-9.1	2 (1%)	0.1-4.4
	Very difficult	0 (0%)	N/A	3 (2%)	0.4-5.3
	No response	3 (4%)	0.8-11	17 (11%)	6.2-16.3
	Total	**74 (100%)**	**-**	**145 (100%)**	**-**

Defective units of oxytocin in Uniject

Facility managers at La Tinta and Carchá (n=2, 33%) reported to have defective Uniject devices at their facilities during the pilot study. Carchá reported damage to the label, and Chisec reported problems with the TTI; these defects were not specified during the interview. The rest of the facilities (n=4, 67%) did not report any defective Uniject devices. There were in total three defective devices.

Regular supply

The hospital of La Tinta and the CAP of Carchá reported having low stock of oxytocin in Uniject during the pilot study. The low stock was due to an increase in the number of births at these facilities during the time of the pilot. This low stock situation was corrected when the research team visited the facilities during month 2 of the study. Facilities did not report stock-out of oxytocin in Uniject during the time of the pilot.

Storage of oxytocin in Uniject

Five (83%) of the managers did not report any challenges in storing oxytocin in Uniject at the recommended temperature. Two managers (17%) reported that they did not have enough storage space or cold chain equipment (refrigerators) to store the product according to the recommendations.

Time required to prepare the dose of oxytocin for AMTSL

When asked about time needed to prepare the oxytocin for AMTSL, 92% of the providers (n=71) said that it took them less time to prepare the oxytocin in Uniject than with ampoules, 6% (n=2) said it took them the same amount of time, and 2% (n=1) said it took more time with oxytocin in Uniject than with ampoules.

Quality of services

A total of 65% (n=50) of providers said there was a large improvement in quality of AMTSL services provided to patients when the oxytocin in Uniject was used, 13% (n=10) said there was a small improvement in quality, 7% (n=6) said there was a decline in quality, and 15% (n=12) said that there was no change.

In addition, all six (100%) facility managers reported that the Uniject device had improved the quality of AMTSL services provided at their facilities.

Waste disposal

Providers were asked how disposal of Uniject compared with disposal of standard disposable syringes and ampoules. A total of 57% (n=44) said it was easier to dispose of the Uniject, 9% (n=7) said there was no difference, and 35% (n=27) said it was more difficult to dispose of the Uniject than disposable syringes. No specific reasons were provided from the 35% (n=27) of providers that reported more difficulty in disposing of the Uniject than standard disposable syringes. Of the 6 facility managers, 3 (50%) also reported that disposing of the Uniject devices was more difficult than standard disposable syringes, 2 (33.3%) reported that there was no difference in the difficulty of the disposal, and 1 (16.6%) said that it was easier. None of the managers reported problems with disposal of oxytocin in Uniject during the pilot in the post-intervention questionnaire.

Managers reported that used Uniject devices were disposed of in plastic containers, safety boxes, or jerry cans following standard precautions for infection prevention.

Instructions for use

Providers reported the following suggestions to improve the instructions for use of oxytocin in Uniject:

- "Include information on cold chain on the poster."
- "Rotate personal in the labor and delivery room so all health workers have the opportunity to know about the product and use it."
- "Develop a pamphlet that can be used by each health worker."

Packaging of oxytocin in Uniject

Providers were asked to share comments in regards to the packaging of oxytocin in Uniject. A few comments from providers include: "It is easy to manipulate," and one provider reported that "It was difficult to open the package."

Interest in continuing to use oxytocin in Uniject

Of the providers interviewed, 91% (n=70) said they would use oxytocin in Uniject after the pilot and 7% (n=5) said they would not use the device after the pilot. For the 7% that reported they would not use the device after the pilot, the following reasons were specified:

- "There will be no more oxytocin in Uniject after the pilot."
- "Because I am in a different ward and we don't use it there."
- "Because there will be no regular stock."

All 6 (100%) of the facility managers interviewed said they are interested in continuing to use oxytocin in Uniject after the pilot. Managers commented that "Guatemala has a scarcity of

human recourses, which increases the work load for each health worker. Oxytocin in Uniject facilitates the timely administration of the preventative dose of oxytocin during AMTSL."

Maternal deaths during the pilot (include information)

During the pilot study, there were 4 maternal deaths, 2 of those in the Hospital of La Tinta and 2 in the Hospital of Coban.

Acceptability of the TTI

The following table summarizes the data collected on provider acceptability of the TTI.

Table 8: Acceptability of TTI by providers ***n=77***	
	Experience using the TTI during the pilot, n=72
Very easy	(57) 74 %
Somewhat easy	(12) 16%
Somewhat difficult	(3) 4%
Very difficult	(0) 0%
No response	(5) 6
Total	**(77) 100%**
	Change in time required to prepare and administer oxytocin compared to previous practices, n=73
Took more time with TTI	(3) 4%
Took same amount of time	(13) 17 %
Took less time with TTI	(57) 74%
No response	(4) 5%
Total	**(77) 100%**
	Unusable oxytocin in Uniject according to the TTI, n=75
Yes	(3) 4%
No	(72) 93%
No response	(2) 3%
Total	**(77) 100%**
	Changes that the TTI has made in the quality of AMTSL services, n=77
Large increase in quality	(57) 74%
Small increase in quality	(9) 12%
Decrease in quality	(0) 0%
No change	(11) 14 %
No response	(0)
Total	**(77) 100%**

Of the managers, 83% (n=5) felt that interpretation of the TTI was very easy and 1 (17%) said it was somewhat easy. In addition, 100% of managers responded that they would like to continue using the TTI after completion of the pilot.

5.3 Feasibility and fit within the system

To evaluate feasibility and fit within the Guatemala health system, researchers from MSPAS and PATH visited Guatemala on October 25 through November 4, 2009. The purpose of this trip was to identify issues that were applicable to the use of oxytocin in Uniject for AMTSL in the context of a PPH prevention strategy. The visit was divided into three parts:

1. Visit to all six health facilities to observe practices of AMTSL and logistical issues related to the use of oxytocin in Uniject for AMTSL. The research team had conversations with a total of 12 providers (2 nurses, 2 physicians, and 8 auxiliary nurses) and 6 individuals from the pharmacy.
2. Interviews with key stakeholders at the central and state level. A total of ten key stakeholders from various offices within MSPAS were interviewed.
3. This section was complemented by a separate cost study comparing the cost of introducing oxytocin in Uniject with the standard practice (two 5-IU ampoules with one standard disposable syringe).

The main findings from the visit and informal interviews with key stakeholders are summarized in the following categories: AMTSL practice, storage of oxytocin in Uniject, use of oxytocin in Uniject, and stock of oxytocin in Uniject and oxytocin in ampoules.

AMTSL practice

It is important to note that during the visit to health facilities, no births occurred, so there was no opportunity to observe how providers were practicing AMTSL. In only one of the six facilities visited was the practice of AMTSL described correctly by providers. The rest of the facilities reported failures in either the step for uterine massage or the step for CCT.

Uterine massage immediately after the delivery of the placenta was reported and recognized as a key action when applying AMTSL. However, the follow-up required every 15 minutes during the first two hours following delivery was not always done due to lack of time or staff.

In regards to CCT, providers from five facilities said they do not wait for a uterine contraction to perform the controlled cord traction. Most of them reported that they wait five minutes to perform CCT, and one of them said that the they perform CCT immediately after the administration of oxytocin in Uniject.

Storage of oxytocin in Uniject

Oxytocin in Uniject was stored in the cold chain (between 2°C and 8°C) in all facilities visited.

In general, oxytocin in Uniject was stored with other medications that also require cold chain storage. We observed that even the laboratory and delivery room had either a refrigerator or a cold box to temporarily store the oxytocin required to attend births.

Two of the hospitals visited (Hospital of Fray Bartolomé and Hospital of Coban) had utilized their maximum cold chain storage space and see capacity as a challenging issue if oxytocin in Uniject were to replace ampoules.

There is a cold chain crisis at the regional coordinating office. This office performs procurement of medicines and supplies for CAPs, CAIMIs, and other health care posts. Employees at this office reported that when they receive vaccines there is not sufficient space to store any other medications that require the cold chain.

Use of oxytocin in Uniject

Based on observations from the visit, providers used oxytocin in Uniject according to the instructions for use. In only two facilities (Hospital of La Tinta and Hospital of Coban) the research team observed that the oxytocin in Uniject was being recapped, which is against the national guidelines for biosafety.

Oxytocin in Uniject was used exclusively for prevention of PPH in all vaginal births at the participating health facilities. Although the protocol for the pilot project specified that during the three-month pilot introduction health facilities would use oxytocin in Uniject for both vaginal and cesarean births, the Hospital of Coban and Hospital of La Tinta did not use the product for cesarean births. Reasons given for the change of plans were:

- **Low stock.** This was the case at Hospital of La Tinta where the number of births increased in the past year. The amount of doses calculated for the pilot were not enough to cover the increased demand; therefore the hospital administration decided to use the oxytocin in Uniject only for vaginal births. This situation was corrected immediately after the visit. More doses of oxytocin in Uniject were supplied to cover the increased demand in services.
- **Logistics.** This was the case at the Hospital of Coban where there was no place to store the oxytocin in Uniject in the cold chain in the surgery room. Also, they use oxytocin in the IV fluids and consider this to be easier than to provide an IM injection (as is specified in the protocol) at the time of the surgery.

Providers also shared their opinions about oxytocin in Uniject during the feasibility visit. They see the following benefits for oxytocin in Uniject in comparison to oxytocin in ampoules:

- **Easier to use than oxytocin in ampoules.**
- **Less preparation time.** Nurses said that oxytocin in Uniject saves them one to two minutes of preparation time for the PPH prevention dose of oxytocin during AMTSL.
- **Less wastage of medication.** Some nurses and auxiliary nurses said that oxytocin in Uniject eliminates the risk of wasting product because they do not have to open ampoules and draw content with a syringe.
- **Safer.** Some nurses said that they had experienced cuts when trying to open oxytocin in ampoules. This risk is completely eliminated with oxytocin in Uniject.
- **Easier to account for product.** Oxytocin is a controlled product in Guatemala. Therefore, nurses have to account for every product used. In the past, they had to show the empty glass ampoules to the pharmacy, but with oxytocin in Uniject, they can show the empty envelope, which decreases the risk of biohazard accidents with sharp objects.

Stock of oxytocin in Uniject and oxytocin in ampoules

The number of institutional births in Guatemala has increased due to a new social program created by the government called Mi Familia Progresa (My Family Progresses). This program provides a stipend to pregnant women who go to the clinic for prenatal care, give birth at an institution, and bring their children in for regular checkups. This increase in demand for services related to births was not estimated when planning for the pilot project. Therefore some institutions had low stocks of oxytocin in Uniject for the three-month pilot introduction. This situation was corrected after the visit to the facilities. Additional units were distributed to the health facilities that reported low stocks of product.

There was no supply of oxytocin in ampoules for treatment of PPH at the three smaller facilities visited (CAPs and a CAIMI). In these institutions, we found only a small stock of donated oxytocin (ampoules of 10 IU) that expired October 30, 2009. Reasons for this irregular supply are:

- A fiscal deficit at the central and district level is impacting provision of required medications for smaller health facilities (there is a 50% shortage of medications at these facilities, so the issue does not only pertain to oxytocin).
- Increased demand for services. Government policies to increase the number of hours at CAPs in addition to programs such as Mi Familia Progresa have increased demand for services at these health facilities.
- The same budget is allocated to the regional offices despite the increased demand for services.
- Slow procurement processes at the central level. Some of the purchase orders have been at the central level for six months without being processed.

6. Discussion

6.1 Acceptability and ease of use

The perception of acceptability of oxytocin in Uniject reported by providers and managers during this pilot study is similar to those reported in other studies.[12,13,14] In general, providers and managers found oxytocin in Uniject to be an acceptable mechanism to deliver the preventive dose of oxytocin for AMTSL. In regards to ease of use, most providers found the preparation, activation, and administration of oxytocin in Uniject very easy, though no statistically significant difference was seen between ease of use of ampoules vs. Uniject. Providers reported two linked advantages with using oxytocin in Uniject:

1. **Decrease in time to prepare medication.** 93% of providers reported it took them less time to prepare the dose of oxytocin when they used oxytocin in Uniject. In light of the human resource constraints reported by managers and various stakeholders in Guatemala, this benefit offered by the product would be of interest for the country. In most cases, nurses and auxiliary nurses are alone when attending a birth, and they need to attend to the needs of the mother, the baby, and perform AMTSL.
2. **Improved quality of AMTSL services provided to patients.** 64% of providers and 100% of managers (n=6) reported a large improvement in the quality of AMTSL services provided to patients. Although no specific reasons were given for this perception, we can infer that the features of the product as well as having a stock of oxytocin available to provide to patients can be two of the reasons for this response.

Aside from the high acceptance levels reported for oxytocin in Uniject, providers and managers also reported high levels of acceptance for the TTI. The majority of providers and managers, 79% and 83%, respectively, found that interpreting the TTI was very easy.

Although providers and managers perceived oxytocin in Uniject as an acceptable delivery mechanism, they also reported other challenges that are important to consider:

- **Storage.** All facilities stored oxytocin in Uniject within the recommended temperature (2°C–8°C). However, challenges to store the product were reported by 17% of the facilities, in particular the large facilities, such as hospitals.
- **Waste disposal.** 50% of the managers interviewed in the post-intervention questionnaire reported oxytocin in Uniject to be more difficult to dispose of than regular syringes. Although half of the managers reported difficulty with disposal of the Uniject device in comparison with standard disposable syringes, none of them reported challenges with disposal of the product during the time of the pilot. These results are for the most part different from results from other studies where managers find Uniject easier to dispose of than standard disposable syringes. Some potential explanations for this discrepancy are:
    - Managers who answered the post-intervention questionnaire are not currently practicing clinical medicine at the moment and are not familiar with disposal of either Uniject or standard disposable syringes.
    - We can also hypothesize that the novelty of the device could affect the perception of how easy/difficult it is to dispose of the device.

Oxytocin in Uniject is actually smaller than a conventional autodisable (AD) syringe. Since oxytocin in Uniject is smaller, more Uniject devices can be placed in a disposal container. A standard 5-liter disposal box that holds 100 AD syringes will hold about 400 Uniject devices. This has considerable implications for reduction of medical waste.

6.2 Feasibility and fit within the Guatemala health system

This evaluation demonstrated high levels of acceptability of the oxytocin in the 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. However, MSPAS currently faces several challenges that affect the overall performance of the current PPH prevention program in the country, and this could potentially affect country decisions about wide-scale introduction of oxytocin in Uniject.

Cost implications

Stock-outs of oxytocin in ampoules as well as other essential medicines were reported in three of the six facilities visited. The financial constraints of the government along with a complicated procurement process at the national level contribute to this problem. Small health facilities that depend on the health coordinating office reported stock-outs of up to one year for this lifesaving product. Stock-outs of oxytocin disrupt the provision of quality AMTSL services in the facilities. To complicate the stock-out situation, the demand for maternal services has increased due to the Mi Familia Progresa program, and compensation for this increase has not yet occurred. Therefore, the stock-out of essential medicines, including oxytocin, is even higher.

The Practice of AMTSL

In addition to the budget situation, Guatemala still needs to strengthen and standardize the practice of AMTSL among maternity services. Of all places visited, only one described the practice of AMTSL correctly even though MSPAS and other cooperating agencies such as the Health Care Improvement Project (HCI) and AGOG have provided numerous training sessions to health personal at these facilities. One of the challenges is that health workers rotate from service to service, and there is no supervision or in-service training system in place. This

discontinuity prevents health workers from becoming proficient in the procedure. Absence of the uterotonic also prevents health workers from performing AMTSL.

While training and other interventions are necessary to address gaps in AMTSL practice, introduction of oxytocin in Uniject could theoretically improve the availability and quality of AMTSL services through the following mechanisms:

- **Prefilled dose of 10 IU of oxytocin.** The fact that the Uniject device is prefilled with 10 IU is an advantage for the following reasons:
  - This presentation could improve the chance that the provider administers the correct dose of oxytocin according to the standard correct dose of oxytocin.
  - Eliminating the need to break open two ampoules and fill a syringe will save time, which is particularly important for facilities where birth attendants are alone.
- **Ease of use.** This characteristic could improve the chances that the provider administers the dose of oxytocin according to standard, within one minute after birth of the baby. Additionally, this could make oxytocin available for use by cadres who may have difficulty manipulating a needle and syringe.
- **Inclusion of TTI to ensure potency of oxytocin.** Introduction of oxytocin in the Uniject device with the TTI would ensure that the oxytocin a provider administers for the practice of AMTSL is potent.

Cold chain requirements

Another consequence of the budget crisis at the MSPAS level is the lack of availability of cold chain equipment to allow for proper storage of oxytocin in the health services. Only 40% of the facilities reported storing oxytocin (in ampoules) in the cold chain, and 40% of the facilities also reported challenges with storage of oxytocin in Uniject, especially large hospitals. All facilities visited stored oxytocin in Uniject with other medications. For small facilities, this was not an issue because the quantity of medications required was not as high as that for large hospitals.

Although the Uniject device consumes considerably more cold chain volume per dose than oxytocin in ampoules, facility managers did not consider this a major disadvantage. In addition the TTI offers flexibility in storage in facilities where the cold chain either does not exist or is limited. A few possible examples of cold chain flexibility in oxytocin in Uniject programs include:

- **Transportation outside the cold chain.** Since transportation can be an expensive, but quick, segment of the cold chain, it may be feasible to transport oxytocin in Uniject without refrigerated trucks, cold boxes, or ice.
- **Out of cold chain storage at delivery points.** In situations such as health care centers without sufficient cold chain capacity, oxytocin in Uniject could be stored without refrigeration prior to use.
- **Air conditioned storage.** At points in the cold chain where there are large volumes of medications requiring the cold chain, oxytocin in Uniject devices could be stored in air-conditioned rooms rather than 2°C–8°C cold chain refrigerators.

TTIs and the relative heat stability of oxytocin create opportunities for reducing dependence on a 2°C–8°C cold chain. While care must always be taken to avoid leaving unprotected units in

direct sunlight or in hot environments (such as in lab coat pockets, etc), there are tremendous opportunities for simplifying logistics and improving accessibility to AMTSL through a more flexible cold chain for oxytocin in Uniject.

Disposal of used units

One important consideration in regards to waste disposal is that recapped Uniject devices were observed in safety boxes in two of the six facilities visited. Recapped standard syringes were also observed in the same facilities were oxytocin in Uniject was being recapped.

Overall fit

Given the particular challenges being faced by MSPAS, it is possible that the benefits offered by oxytocin in Uniject would likely outweigh its disadvantages. In addition, oxytocin in Uniject could be used as an important tool to:

- Raise awareness in country in regards to PPH and use of AMTSL. In previous studies, oxytocin in Uniject was seen as an instrument to help providers get motivated to use AMTSL correctly.[13] This will also allow for more capacity building of health providers.
- Guarantee pharmacological activity of medication. Using oxytocin in Uniject can also be an opportunity for health workers to get trained on proper storage and maintenance of oxytocin to guarantee that the product administered to patients is active. In addition, the TTI offers an advantage to store the product under more flexible conditions, which can be a potential solution to large hospitals that report challenges with storage capacity.

6.3 Limitations of the study

There are several factors that limit the significance of this study. The sample used for this study was a convenience sample and was not randomized. Since the study was designed to operate within routine health services, randomization was not considered feasible. In addition, the provider response rate post-intervention was not as high as we expected (only 43%). This was due to previous commitments of some institutions to provide training to their employees during the time of the structured interviews. Both of these factors make it difficult to generalize the results.

There were no comparisons done between practice of AMTSL pre- and post-intervention. Therefore, we cannot conclude that the use of oxytocin in Uniject increased the willingness of providers to perform the procedure or improved the quality of how it was practiced. Although this was not a variable in our study, this association could increase the value of the intervention.

It would have been useful to have a study with a longer duration to allow for more health workers in the designated areas to use the product. Some of the health workers received the training but had to rotate to be part of other services. This situation prevented some trained health workers from using oxytocin in Uniject during the time of the pilot. A longer time frame for the study would have overcome this limitation.

One divergence from the original study design was not using oxytocin in Uniject for all births (including both cesarean sections and vaginal births). Two of the health facilities could not use the oxytocin in Uniject for cesarean sections because the facility did not have cold chain equipment in the surgery room or the management at the facility decided it was not logistically feasible. Although this variation occurred, it was important to discover that it is not always feasible to use oxytocin in Uniject within the logistical context of some hospitals for cesarean

sections. As reported by providers and managers, using oxytocin in Uniject during vaginal births makes more sense because of the benefits seen in this context (specifically, the decreased time needed for preparation while providers must perform multiple other activities).

In addition, the cultural diversity of Guatemala is a factor that limits our ability to generalize findings from the pilot to the entire country. For example, Alta Verapaz has a unique geographical and accessibility situation that makes the state completely different from the rest of the country. Including other states to reflect more diversity in the design of the study would have been ideal.

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 in Uniject devices for the practice of AMTSL in Guatemala. While some inferences can be made from the results, data from this study is applicable only to the participating health facilities, and it is not possible to generalize this information to the rest of the country. However, because this project was a pilot demonstration, the lessons learned from this project can be used to inform decisions about interventions for PPH prevention programs, including introducing oxytocin in Uniject for AMTSL.

7. Conclusions and recommendations

This pilot study showed that 10 IU of oxytocin in a Uniject device with a TTI can be successfully used by birth attendants for AMTSL as part of an effective PPH prevention program, at the facility level. In addition, the TTI offers the advantage of storing the product under more flexible conditions, which can be a potential solution to large hospitals that report challenges with cold chain capacity. Finally, providers and managers in the state of Alta Verapaz appreciated the simplicity and ease of use of the device and considered oxytocin in Uniject to be an acceptable mechanism of delivery of the recommended uterotonic for AMTSL. Advantages of oxytocin in Uniject as seen by providers include:

1. Decreased time to prepare medication.
2. Improved quality of AMTSL services provided to patients.
3. Safety for the health worker.
4. Ease of monitoring stock.

The next step is to initiate discussions at the government level around national introduction of oxytocin in Uniject as part of a comprehensive PPH prevention program that includes AMTSL. Lessons learned from this pilot can be extrapolated to other situations and settings where oxytocin in Uniject could be introduced. Once MSPAS has decided to introduce oxytocin in Uniject on a national level, they will need to create a strategy and implementation plan for incorporating the use of the oxytocin in Uniject device into the national PPH prevention strategy. Such a plan needs to take into consideration differing scenarios, including choosing how oxytocin in Uniject will be used (for prevention or treatment or both) and which health facilities will most benefit from use of the oxytocin in Uniject devices and which will continue to use oxytocin in ampoules. Other factors that need to be considered include (but are not limited to):

1. Logistics of delivering and storing oxytocin in Uniject devices in national, regional, district, and facility cold chains.

2. Distribution of oxytocin in Uniject to peripheral health care facilities.
3. Development of protocols for storage at peripheral facilities and in delivery rooms.
4. Training of providers on how to use the devices when applying AMTSL.
5. Monitoring of data on the impact of using oxytocin in Uniject.

Guatemala has adopted international standards for PPH prevention. The country has introduced AMTSL as part of routine care for all births. Providers in all of the states in the country have been trained to apply AMTSL. However, there is a need to standardize the procedure among health care providers and ensure the availability of oxytocin at every birth. The introduction of oxytocin in Uniject, a new and innovative device, could serve as a tool to raise awareness about PPH and the use of AMTSL to prevent it. In addition, use of the TTI on oxytocin in Uniject could allow health workers to improve the impact of applying AMTSL to prevent PPH by helping them to ensure the pharmacological activity of each dose.

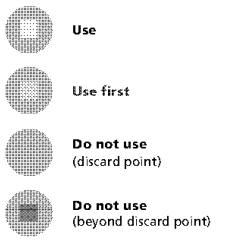
Oxytocin in Uniject could potentially address some of the challenges that Guatemala is facing in implementing their national PPH prevention program. We recommend that MSPAS consider the national introduction of oxytocin in Uniject to increase access to AMTSL and improve the impact of their PPH prevention strategy.

8. Annexes

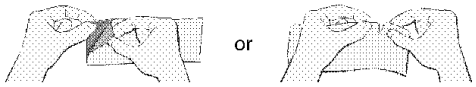
Annex 1. Job aid for the use of oxytocin in Uniject

Using Oxytocin in the Uniject™ Device (10 IU in 1 ml)

1 Check the time-temperature indicator and confirm the oxytocin is ok to use. If not, discard and get a new Uniject™ device containing oxytocin.

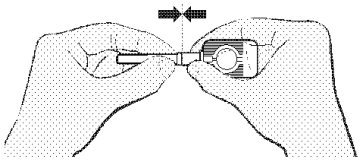


2 Open the foil pouch and remove the Uniject™ device.

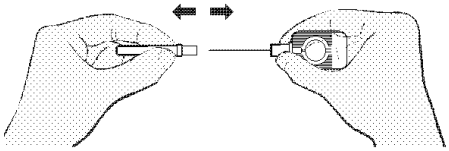


3 Activate the Uniject™ device.

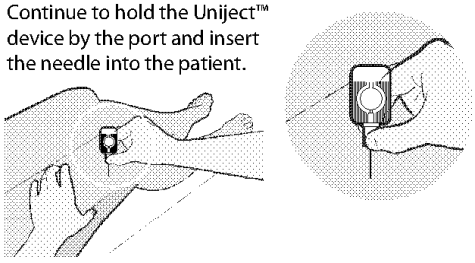
- Hold the Uniject™ device by the port with the forefinger and thumb.
- With a firm, rapid movement push the needle shield into the port.
- Listen for the click indicating that the Uniject™ device has been activated.
- Continue to push firmly until the gap between the needle shield and port is closed.



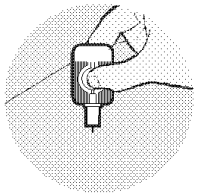
4 Remove the needle cap.



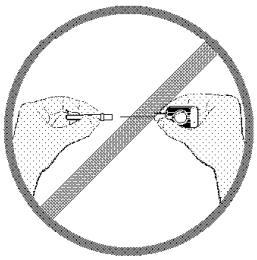
5 Continue to hold the Uniject™ device by the port and insert the needle into the patient.



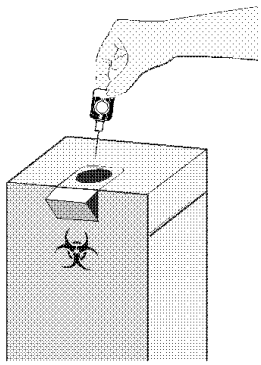
6 Squeeze the reservoir firmly to inject the oxytocin. After the reservoir completely collapses, remove the Uniject™ device.



7 Do **not** re-cap the used Uniject™ device.



8 Discard the used Uniject™ device according to established medical waste disposal procedures.



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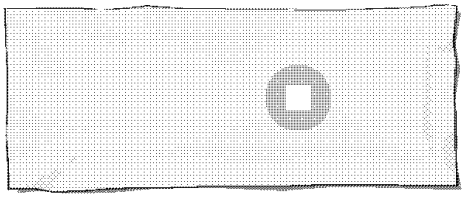
Annex 2. Job aid for the use of the TTI

Reading time-temperature indicators with the Uniject® device

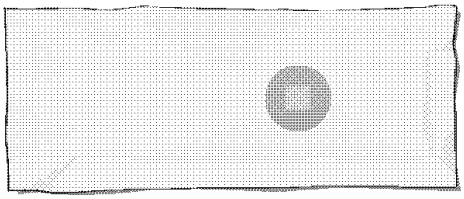
USE

Inner square is lighter than outer circle.



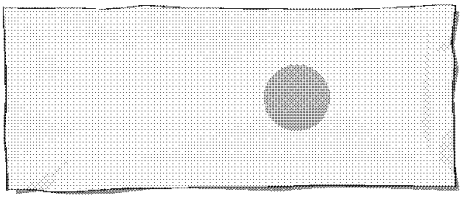
USE FIRST

Inner square is lighter than outer circle.



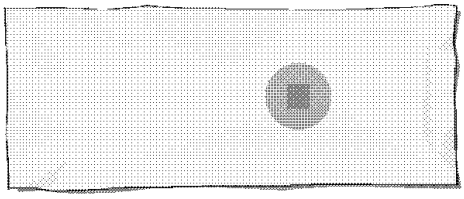
DO NOT USE

Discard point!
Inner square matches outer circle.



DON'T USE

Beyond discard point!
Inner square is darker than outer circle.



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Annex 3. Competency certification checklist

Competency certification checklist for using the Uniject Device

Training facilitators **only** should use the following checklist to evaluate the participant's performance first in a simulated situation before with a client.

Checklist directions

Rate the performance of each step or task using the following rating scale:

1 = Performs the step or task completely and correctly.

0 = Unable to perform the step or task completely or correctly or the step/task was not observed.

N/A (not applicable) = Step was not needed.

Checklist for using the Uniject device						
Date	_____/_____/_____ (month/day/year)					
Evaluated in a simulated situation (S) or with a client (C)						
Step / Task	**Rating**					
Prepare the woman during the first stage of labor (7 points)						
1. Checks the TTI and confirms oxytocin is ok to use. If not, discard and get a new Uniject device containing oxytocin.						
2. Opens the foil pouch and remove the Uniject.						
3. Holds the Uniject by the port with the forefinger and thumb.						
4. With a firm, rapid movement pushes the needle shield into the port.						
5. Listens for the click indicating that the Uniject device has been activated.						
6. Continues to push firmly until the gap between the needle shield and port is closed.						
7. Removes the needle shield.						
8. Continues to hold the Uniject by the port and inserts the needle into the patient.						

Checklist for using the Uniject device					
Date	_____/_____/_____ _ (month/day/year)				
Evaluated in a simulated situation (S) or with a client (C)					
Step / Task	**Rating**				
Prepare the woman during the first stage of labor (7 points)					
9. Squeezes the reservoir firmly to inject the oxytocin.					
10. After the reservoir collapses completely, removes the Uniject**.**					
11. Does not re-shield used Uniject**.**					
12. Discards the used Uniject according to established medical waste disposal procedures.					
Points					

Annex 4. Inventory of current practices

Provider Questionnaire

Data Entry Record # :_____

1.	**Date**	_ _/_ _/_ _ _ _ **(month/day/year)**
2.	**Facility code**	
3.	**Does your facility provide active management of the third stage of labor (AMTSL) for women?**	1. Yes ..... ☐ 2. No ***(→ Skip to #7)*** ..... ☐ 3. Sometimes ..... ☐
4.	**Which AMTSL steps below do <u>you yourself</u> provide?** *(Check all appropriate responses)*	1. Administration of a uterotonic drug within one minute after the baby is born? Yes ☐ No ☐ 2. Controlled cord traction? Yes ☐ No ☐ 3. Uterine massage immediately after delivery of the placenta? Yes ☐ No ☐
5.	**Do you provide oxytocin to women during AMTSL?**	1. Yes ..... ☐ 2. No ..... ☐ 3. Sometimes ..... ☐
6.	**Describe the way you prepare and administer oxytocin during AMTSL? What materials do you use?** _____ _____ ***(Skip to # 8)***	
7.	**If you do not provide a maternal dose of oxytocin to mothers during the third stage of labor, why not?** *(Mark all that apply)* ***(→ Skip to # 14 after answering this question)***	1. This is not a practice in my facility ..... ☐ 2. This is not part of my job responsibilities ..... ☐ 3. I was not oriented or trained ..... ☐ 4. I do not have the supplies ..... ☐ 5. Other ..... ☐ If "Other" please specify: _____ _____ _____
8.	**Do you check for storage temperature before preparing and administering oxytocin to mothers during AMTSL?**	1. Yes…***(→ Skip to #10)*** ..... ☐ 2. No ..... ☐

Provider Questionnaire (cont.)

9. **What is your reason for not checking the storage temperature before preparing and administering oxytocin to mothers during AMTSL?**

(Mark all that apply)

1. This is not a practice in my facility ..... ☐
2. This is not part of my job responsibilities .. ☐
3. I am not oriented or trained ..... ☐
4. Our facility does not have a refrigerator ... ☐
5. Other..... ☐

If 'Other' please specify: _____

_____

10. **How easy or difficult would you say it is to <u>prepare</u> the injection of oxytocin for women during AMTSL?**

1. Very easy ***(→ Skip to #12)***..... ☐
2. Somewhat easy ***(→ Skip to #12)*** ..... ☐
3. Somewhat difficult ..... ☐
4. Very difficult..... ☐

11. **Please describe any difficulties you have experienced <u>preparing</u> the injection of oxytocin during AMTSL before the start of this pilot:**

_____

_____

_____

12. **How easy or difficult would you say it is to <u>administer</u> the injection of oxytocin for women for their dose during AMTSL?**

1. Very easy***(→ Skip to # 14)***..... ☐
2. Somewhat easy ***(→ Skip to #14)*** ..... ☐
3. Somewhat difficult ..... ☐
4. Very difficult..... ☐

13. **Please describe any difficulties you have experienced <u>administering</u> oxytocin to mothers during AMTSL before the start of this pilot:**

_____

_____

_____

_____

_____

_____

14. **Additional comments:**

_____

_____

_____

_____

_____

Facility Manager Questionnaire

Background questions on the use of oxytocin as a component of active management of the third stage of labor (AMTSL)

Data Entry Record # :_____

1.	**Date**	_ _/_ _/_ _ _ _ **(month/day/year)**
2.	**Facility code**	
3.	**Does your facility provide the required maternal dose of oxytocin to women during the third stage of labor?**	1. Yes ..... ☐ 2. No ***(→ Skip to #5)*** ..... ☐ 3. Sometimes..... ☐
4.	**Describe the process (from preparation to administration) that your facility uses to provide the dose of oxytocin to women during active management of the third stage of labor (AMTSL).** _____ _____ _____ ***(→ Skip to #6)***	
5.	**What are the reasons your facility does not provide oxytocin to mothers during AMTSL?** *(Mark all that apply)*	1. This is not the practice in our facility..... ☐ 2. Staff are not oriented or trained..... ☐ 3. The facility does not have the supplies..... ☐ 4. Other..... ☐ If "Other," please specify: _____ _____ _____
6.	**Does your facility store oxytocin between 2°–8°C?**	1. Yes ***(→ Skip to # 8)***..... ☐ 2. No ..... ☐
7.	**If no, what are the reasons your facility does not store oxytocin within this temperature range?**	1. This is not the practice in the facility..... ☐ 2. Staff are not oriented or trained..... ☐ 3. Our facility does not have a refrigerator.... ☐ 4. Other..... ☐ If "Other," please specify: _____ _____ _____

Facility Manager Questionnaire (cont.)

8. **Does your facility have regular supply of oxytocin for AMTSL?**

1. Yes ***(→ Skip to #11)*** ..... ☐
2. No ..... ☐

9. **If your facility does not have a regular supply of oxytocin for AMTSL, please explain why not:**

_____
_____
_____
_____

10. **What does your facility do in the case of a stock-out of oxytocin for AMTSL?**

_____
_____
_____
_____

11. **How often does your facility receive supplies of oxytocin?**

_____
_____
_____
_____

12. **What do you think can be done within AMTSL services to ensure all women receive the dose of oxytocin for prevention of postpartum hemorrhage?**

_____
_____
_____
_____

13. **Additional comments:**

_____
_____
_____
_____

Annex 5. Post-intervention questionnaire for providers

Post-intervention questionnaire for providers

Data Entry Record # :_____

1.	**Date and name of interviewer**	_ _/_ _/_ _ _ _ (month/day/year) **Interviewer:**_____
2.	**Facility code**	
3.	**What is your designation?**	1. Auxiliary nurse..... ☐ 2. Registered nurse..... ☐ 3. AECAMN..... ☐ 4. Medical doctor (General Practitioner) ..... ☐ 5. OBGYN ..... ☐ 5. Other ..... ☐ (If "Other," please specify): _____
4.	**How many years have you been attending births?**	1. <5 ..... ☐ 2. 5-9 ..... ☐ 3. 10-29..... ☐ 4. 30+ ..... ☐
	Questions on the use of Uniject	
5.	**During this pilot, how many births did your attend in the 3-month period?** _____	
6.	**How many Uniject devices did you use during the pilot period?** _____	
7.	**Given your experience since you started using the oxytocin in Uniject, how easy or difficult would you say it was to prepare the oxytocin in Uniject?**	1. Very easy ***(→ Skip to #9)***..... ☐ 2. Somewhat easy ***(→ Skip to #9)*** ..... ☐ 3. Somewhat difficult ..... ☐ 4. Very difficult..... ☐
8.	**Please describe any difficulties you experienced <u>preparing</u> the oxytocin in Uniject** _____ _____ _____	
9.	**Given your experience since you started using the oxytocin in Uniject, how easy or difficult would you say it was to <u>activate</u> the oxytocin in Uniject?**	1. Very easy ***(→ Skip to #11)***..... ☐ 2. Somewhat easy ***(→ Skip to #11)*** ... ☐ 3. Somewhat difficult ..... ☐ 4. Very difficult..... ☐

10.	**Please describe any difficulties your experienced activating the oxytocin in Uniject** _____ _____ _____	
11.	**Given your experiences since you started using the oxytocin in Uniject, how easy or difficult would you say it was to <u>administer</u> the oxytocin in Uniject?**	1. Very easy ***(→ Skip to # 13)*** .....☐ 2. Somewhat easy ***(→ Skip to # 13)*** ...☐ 3. Somewhat difficult.....☐ 4. Very difficult.....☐
12.	**Please describe any difficulties you experienced administering the oxytocin in Uniject** _____ _____ _____	
13.	**Did the Uniject change the amount of time you needed to prepare the oxytocin during AMTSL compared to your previous practices?**	1. Took more time with Uniject.....☐ 2. Took same amount of time.....☐ 3. Took less time with Uniject.....☐
14.	**Overall, do you feel the Uniject has made any change in the quality of AMTSL services you provide to patients?**	1. Large increase in quality ..... ☐ 2. Small increase in quality ..... ☐ 3. Decrease in quality..... ☐ 4. No change..... ☐
15.	**How did the disposal of Uniject compare to discarding standard disposable syringes?**	1. More difficult ..... ☐ 2. No difference ..... ☐ 3. Easier ..... ☐ 4. No previous experience using standard disposable syringes..... ☐
16.	**What suggestions, if any, do you have for improving the instructions for use of the oxytocin in Uniject?** _____ _____ _____	
17.	**Do you have any other comments or concerns you would like to share about packaging oxytocin in Uniject for AMTSL?** _____ _____	

	_____	
18.	**Would you use oxytocin in Uniject after the pilot introduction is over?**	1. Yes ***(→ Skip to # 20*** ....☐ 2. No..... ....☐
19.	**If not, why would you not consider using oxytocin in Uniject after the pilot introduction?** _____ _____ _____	
20.	**Additional comments from the provider:** _____ _____ _____ _____ _____ _____	
	Questions on using the time-temperature indicator (TTI)	
21.	**Given your experience since the start of the pilot, how would you describe your experience using the TTI?**	1. Very easy ***(→ Skip to #23)*** .....☐ 2. Somewhat easy ***(→ Skip to #23)*** ....☐ 3. Somewhat difficult.....☐ 4. Very difficult.....☐
22.	**Please describe any difficulties you experienced using the TTI:** _____ _____ _____	
23.	**Did the TTI change the amount of time you needed to prepare and administer the oxytocin compared to your previous practices?**	1. Took more time with TTI .....☐ 2. Took same amount of time.....☐ 3. Took less time with TTI .....☐
24.	**During this pilot, did you have oxytocin in Uniject that were not usable according to the TTIs?**	1. Yes .....☐ 2. No ***(→ Skip to #26)*** .....☐
25.	**If yes, what did you do with the Uniject devices that were not usable?**	1. Discarded them ..... ☐ 2. Used them..... ☐ 3. Reported them to my supervisor .... ☐ 4. Other ..... ☐ If "Other," please specify: _____ _____

26.	**Overall, do you feel the TTI has made any change in the quality of AMTSL services you provide to patients?**	1. Large increase in quality ..... ☐ 2. Small increase in quality ..... ☐ 3. Decrease in quality..... ☐ 4. No change..... ☐
27.	**Please tell me your suggestions (if any) for improving the instructions for use of the TTI:** _____ _____ _____ _____ _____	
	Interviewer's notes: _____ _____ _____ _____ _____ _____ _____	

Annex 6. Post-intervention questionnaire for managers

Post-intervention questionnaire for managers		
		Data Entry Record #_____
1.	**Date and name of interviewer**	_ _/_ _/_ _ _ _ (month/day/year) **Interviewer:**_____
2.	**Facility code**	
3.	**What is your designation?**	1. Medical officer ..... ☐ 2. Medical Superintendent..... ☐ 3. Clinical officer ..... ☐ 4. Nursing officer ..... ☐ 5. Business manager..... ☐ 6. Other..... ☐ If "Other," please specify:_____
	Questions about the Uniject device	
4.	**During this pilot, how many births did your facility attend in the 3-month period?**_____	
5.	**How many oxytocin in Uniject did your facility use during the pilot period?**_____	
6.	**Did any Uniject devices have leaks, cracks, punctures, dents, lost or damaged labels, cap missing, or other defects?**	1.Yes ..... ☐ 2. No ***(→ Skip to #8)*** ..... ☐
7.	**If yes, approximately how many had:**	____ Leaks/cracks ____ Lost/damaged labels ____ Puncture/dents ____ Cap missing ____ Other defects If "Other," please specify:_____
8.	**Did you have a regular supply of oxytocin in Uniject during the pilot introduction?**	1.Yes ***(→ Skip to #10)*** ..... ☐ 2. No ..... ☐
9.	**If no, why didn't your facility have regular supply of oxytocin in Uniject during the pilot introduction?** _____ _____ _____ _____	

10.	**Did your facility experience any challenges storing oxytocin in Uniject?**	1.Yes ..... ☐ 2. No***(→ Skip to #12)*** ..... ☐
11.	**If yes, please explain what storage challenges your facility experienced.** _____ _____ _____	
13.	**Do you feel that packaging the oxytocin in the Uniject device has made the work of your staff easier or more difficult?**	1. Easier with Uniject ..... ☐ 2. More difficult with Uniject ..... ☐ 3. No change ..... ☐ 4. Don't know ..... ☐ Please explain : _____ _____ _____ _____
14.	**Overall, do you feel the Uniject has made any change in the quality of the active management of the third stag of labor (AMTSL) services your facility provides to clients?**	1. Large increase in quality ..... ☐ 2. Small increase in quality ..... ☐ 3. Decrease in quality ..... ☐ 4. No change ..... … ☐ Please explain : _____ _____ _____
15.	**How did your facility dispose of used Uniject devices before this pilot?** _____	
16.	**Did your facility have any difficulties with disposal of Uniject devices?**	1. Yes ..... ☐ 2. No ***(→ Skip to # 18)*** ..... ☐ 3. No change ***(→ Skip to 18)*** ..... ☐
17.	**Please describe any difficulties your facility experienced with disposal of Uniject devices** _____ _____	
18.	**How did the disposal of Uniject compare to the disposal of standard disposable syringes and ampoules?**	1. More difficult ..... ☐ 2. No difference ..... ☐ 3. Easier ..... ☐

19.	**After this pilot is completed, would you like to continue using oxytocin in Uniject in your facility?**	1. Yes ..... ☐ 2. No ..... ☐ Please explain _____ _____ _____ _____
20.	**What other comments or concerns would you like to share about packaging oxytocin in Uniject for prevention of PPH in the context of AMTSL?** _____ _____ _____ _____	
21.	**Additional comments from the facility manager:** _____ _____ _____ _____ _____ _____ _____	
	Questions about the time-temperature indicator (TTI)	
22.	**Given your facility's experiences since the start of the pilot, how would you describe your experience using the TTI?**	1. Very easy ***(→ Skip to #24)*** ..... ☐ 2. Somewhat easy ***(→ Skip to #24)*** .... ☐ 3. Somewhat difficult ..... ☐ 4. Very difficult ..... ☐
23.	**Please describe any difficulties your staff experienced using the TTI.** _____ _____	
24.	**During this pilot, did your facility have any oxytocin in Uniject that were not usable according to the TTI?**	1. Yes ..... ☐ 2. No **(→ *Skip to #26)*** ..... ☐
25.	**If yes, how many oxytocin in Uniject were unusable during this pilot according to the TTI guidelines?**_____	

26.	**Oxytocin in Uniject is available with or without a TTI. After this pilot is completed, would you like to continue to use the TTI on oxytocin in Uniject in your facility?**	1. Yes..... ☐ 2. No ..... ☐ Please explain : _____ _____ _____ _____
27.	**What other comments or concerns would you like to share about the TTI?** _____ _____ _____ _____	
	Interviewer's notes: _____ _____ _____ _____ _____ _____	
	Thank you very much for completing this questionnaire!	

Annex 7. Years of experience attending births by provider type

Years of experience attending births by provider type				
Years of experience attending births	**Auxiliary nurses**	**Nurses**	**Physicians (General practitioners)**	**Total (%)**
< 5 years	45	5	1	51 (66%)
5-9 years	8	3	1	12 (16%)
10-29 years	7	0	0	7 (9%)
30+ years	0	0	3	3 (4%)
No response	2	1	1	4 (5%)
	62	8	6	77 (100%)

Annex 8. Breakdown of births and utilization of oxytocin in Uniject in health facilities

Breakdown of births and utilization of oxytocin in Uniject in health facilities during time of the pilot				
	Vaginal births	**Number of C-sections**	**Total births**	**Used Uniject/Utilization rate (%)**
Coban *Regional hospital*	1217 (52%)	593 (73 %)	1810 (57 %)	1236 (68 %)
Fray Bartolomé *District hospital*	281 (12%)	137 (17%)	418 (13 %)	377 (90 %)
La Tinta *District hospital*	334 (14%)	83 (10%)	417 (13 %)	376 (90 %)
Chisec *CAP*	197 (8%)	0 (0%)	197 (6 %)	189 (96 %)
San Cristobal *CAIMI*	165 (7%)	3 (0%)	168 (5 %)	165 (98 %)
Carcha *CAP*	144 (6%)	0 (0%)	144 (6 %)	144 (100)
Total	**2338**	**816**	**3154**	2487

Notes:

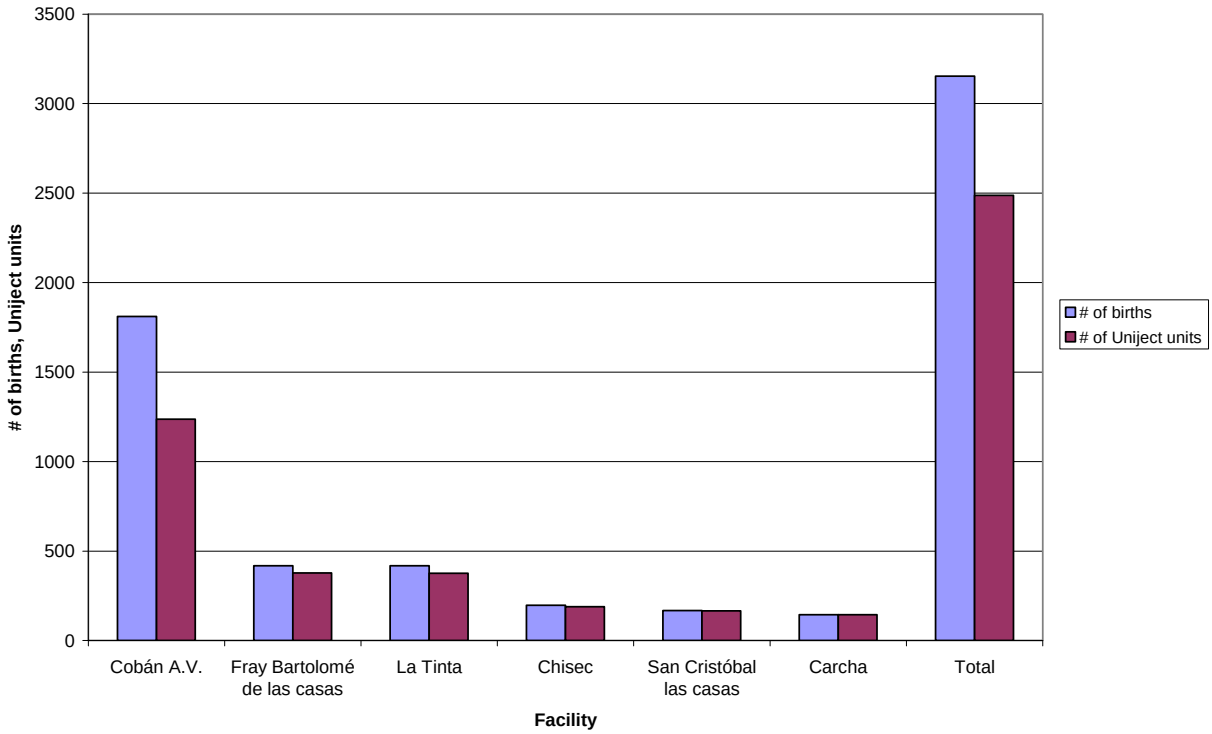
- The utilization rate of oxytocin in Uniject was low at the hospital of Coban, the hospital of La Tinta, and the CAIMI of San Cristobal. This can be due to the fact that these facilities did not use the product for cesarean sections. This is especially true at Coban, where the number of cesarean sections is high.
- There are also instances at the hospital of Fray Bartolome, CAP of Chisec, and CAP of Carcha where oxytocin in Uniject was not used at every birth. A possible explanation is that some women arrived at the facility after giving birth. It is not uncommon that women in Alta Verapaz come to the hospital late as it can take hours to transfer a patient to a health facility.

Annex 9. Utilization rate of oxytocin in Uniject by providers

Utilization rate of oxytocin in Uniject by providers			
	# of providers trained *(n=216)*	**# of providers that used oxytocin in Uniject**	**Utilization rate of oxytocin in Uniject by providers**
Coban	73	32	44 %
Fray Bartolomé	41	30	73 %
La Tinta	15	12	80 %
Chisec	28	19	68 %
San Cristobal	31	24	77 %
Carchá	28	13	46 %
Total	**216**	**130**	**60%**

Note: All providers who attend births at these facilities were trained, but some of them did not attend births during the study because they rotated to different departments.

Annex 10. Number of births and utilization rate of oxytocin in Uniject



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