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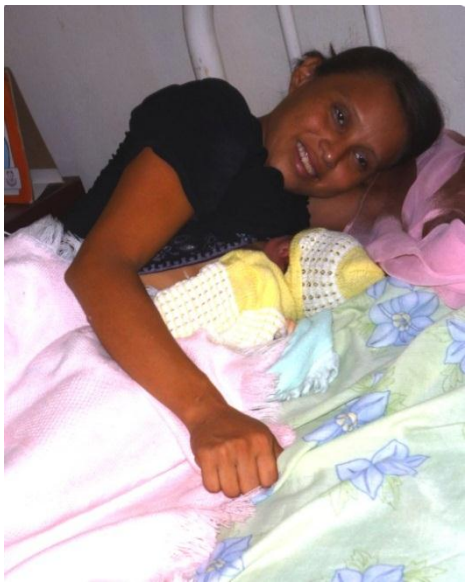

Pilot Introduction of Oxytocin in the Uniject™ Injection System During Active Management of the Third Stage of Labor (AMTSL) at the Institutional Level in Honduras

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

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MCHIP Maternal and Child Health Integrated Program

Secretaría de Salud Honduras

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PATH

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Research team and authors:
Dr. Ivo Flores Flores, Principal Investigator, Director, Program for Family and Comprehensive Care for Women, Ministry of Health of Honduras
Dr. Brenda Morales, Ministry of Health of Honduras
Ms. Laura Martinez, Ministry of Health of Honduras
Dr. Mauricio Ramirez, Country Director, ChildFund Honduras
Ms. Susheela Engelbrecht, Consultant, MCHIP, PATH
Ms. Gloria Metcalfe, Consultant, MCHIP, PATH
Dr. Shirley Villadiego, Public Health Specialist, PATH

Trainers and monitors:
Ms. Gloria Metcalfe, Consultant, MCHIP, PATH
Dr. Shirley Villadiego, Public Health Specialist, PATH
Dr. Rigoberto Castro, Hospital Suazo Córdova
Ms. Nelly Rueda, Hospital Suazo Córdova
Ms. Guadalupe Contreras, Hospital Suazo Córdova
Ms. Edil Santos, Clinica Materno Infantil de Márcala
(Maternal and Child Health Clinic of Márcala)
Ms. Aleida Meza, Clinica Materno Infantil de Márcala
(Maternal and Child Health Clinic of Márcala)
Ms. Suyapa Lopez, Clinica Materno Infantil de Márcala
(Maternal and Child Health Clinic of Márcala)
Ms. Maira Mejia, Clinica Materno Infantil de Reitoca
(Maternal and Child Health Clinic of Reitoca)
Ms. Indira Guzman, Clinica Materno Infantil de Reitoca
(Maternal and Child Health Clinic of Reitoca)
Lic. Gladys Arias, Program Manager, Atención a la Mujer de la Región Departamental de Salud de Francisco Morazán

Data analysts:
Dr. Ricardo Mena Aplícano
Mr. Pablo Sevilla

Technical reviewers:
Dr. Patricia Coffey, Senior Program Officer, PATH
Mr. Steve Brooke, Team Leader, Oxytocin in Uniject Project, PATH
Ms. Adriane Berman, Program Officer, PATH

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Abbreviations and Acronyms

AMTSL	Active management of the third stage of labor
ANMAT	Administración Nacional de Medicamentos, Alimentos y Tecnología Médica [National Administration of Medicine, Food, and Medical Technology]
BIOL	Instituto Biológico Argentino
CCT	Controlled cord traction
CI	Confidence interval
IM	Intramuscular
IU	International units
MCHIP	Maternal and Child Health Integrated Program
MOH	Ministry of Health, Honduras
PPH	Postpartum hemorrhage
RAMNI	Reducción Acelerada de la Mortalidad Materna y de la Niñez [Accelerated Reduction of Maternal and Child Mortality]
TTI	Time-temperature indicator
USAID	United States Agency for International Development
VVM	Vaccine vial monitor
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 low-resource countries. According to the World Health Organization (WHO), about 14 million women worldwide suffer severe postpartum blood loss each year. Of these women, more than 100,000 will die a few hours after childbirth. PPH is also responsible for approximately 25% of maternal deaths worldwide,[1] reaching as high as 60% in some countries, and can be a cause of long-term severe morbidity. Furthermore, an additional 12% of those who suffer from PPH survive with severe anemia.[2, 3] Data from 2010 revealed that the maternal mortality rate in Honduras is 100 per 100,000 live births. Dirección General de Vigilancia de la Salud data indicate that PPH is the leading cause of maternal death in the country.[4]

Application of the active management of the third stage of labor (AMTSL) during deliveries with a skilled provider prevents up to 60% of immediate PPH cases, and reduces total blood loss, incidence of retained placenta, and length of the third stage.[5,6,7] AMTSL consists of three specific steps: 1) administration of a uterotonic agent within one minute of birth, 2) controlled cord traction (CCT), and 3) uterine massage after delivery of the placenta. Oxytocin is the preferred uterotonic because it is fast-acting, inexpensive, and, in most cases, has no side effects or contraindications for use during the third stage of labor. Additionally, oxytocin is marginally more effective and more heat stable than ergometrine.

The Ministry of Health of Honduras (MOH) has a strong interest in reducing PPH. As a result, the MOH identified oxytocin in the Uniject™*injection system (oxytocin in Uniject) as a potential part of its strategy to address high mortality from PPH, due to the system's benefits of being single-dose, prefilled, non-reusable, and easy to use. As a way to evaluate the feasibility and acceptability of introducing oxytocin in Uniject into the health system, the MOH—in collaboration with the United States Agency for International Development (USAID) flagship Maternal and Child Health Integrated Program (MCHIP), PATH, ChildFund Honduras (ChildFund), and USAID Honduras—conducted a pilot introduction of oxytocin in Uniject for use during AMTSL at the institutional level as part of the ongoing PPH prevention initiative in Honduras.

The pilot study conducted research in three facilities: Hospital Suazo Córdova (municipality of La Paz), the Maternal and Child Health Clinic of Márcala (municipality of Márcala), and the Maternal and Child Health Clinic of Reitoca (municipality of Reitoca). The MOH selected these health facilities based on high maternal mortality due to PPH, number of providers previously trained in AMTSL at those facilities, and an adequate number of births per month to maximize the likelihood of having sufficient numbers of patients.

Health providers who attended births and facility managers participated in the pilot introduction and evaluation portion of the study. Specifically, the health workers and facility managers completed an inventory of current practices and a questionnaire before introduction and at the end of the pilot. During the pilot introduction, monitors visited the facilities once a month to collect data on the number of births, survey the stock and storage of oxytocin in Uniject, report any maternal deaths and problems that occurred with the use of oxytocin in Uniject, and reinforce the correct use of AMTSL as needed.

After the pilot introduction, PATH assisted the MOH, USAID, and ChildFund in evaluating the results. A total of 62 health care providers completed the pre-intervention questionnaire, 54

* Uniject is a trademark of BD.

health care providers responded to the post-intervention questionnaire, and seven facility managers participated in the study. A total of 960 women gave birth at the three health facilities during the pilot. Oxytocin in Uniject was used in all those births as part of AMTSL.

In general, providers and managers found oxytocin in Uniject to be acceptable for administering the dose of oxytocin during AMTSL. With regard to ease of use, providers found the preparation, activation, and administration of oxytocin in Uniject to be very easy. Additionally, a statistically significant difference was seen between ease of preparation and administration of oxytocin in ampoules and syringes and oxytocin in Uniject. A few key advantages described by providers about the acceptability and feasibility of oxytocin in Uniject are as follows:

- **Decreased time to prepare medication:** 92.6% 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 resources constraints reported by managers and various stakeholders in Honduras, this benefit offered by the product would be of interest to the country. In most cases, nurses and auxiliary nurses are alone when attending a birth. They must also attend to the needs of the mother and the baby, as well as perform AMTSL.
- **Improved quality of AMTSL services provided to patients:** 82.4% of providers and 100% of managers (n=7) 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 refresher training in AMTSL, the features of the product, and the stock of oxytocin available to provide to patients are possible reasons for this response.
- **Increased perception of efficacy of medication:** Health workers reported that they felt more confident in the efficacy of the oxytocin in Uniject, compared with that of the standard injectable oxytocin. This perception is attributed to the inclusion of the time-temperature indicator (TTI).† The efficacy of oxytocin is well-established; as such, this factor was not studied due to the prevalence of existing literature.
- **Increased awareness on proper use of AMTSL.**

The presence of a TTI on each Uniject package was also highly accepted by providers and facility managers. They found the TTI to be very easy to interpret.

Although the Uniject device consumes considerably more cold chain volume per dose than oxytocin in ampoules, facility managers did not consider this to be a major disadvantage. There were no issues reported on storage space for oxytocin in Uniject.

This pilot evaluation demonstrated high levels of acceptability of oxytocin in Uniject and relative ease in training health care providers in its use, indicating that its introduction for use by most cadres should be relatively easy. Given the particular challenges faced by the MOH in implementing the national PPH prevention strategy, it is possible that the benefits offered by oxytocin in Uniject would likely outweigh the disadvantages, such as cost and the larger volume that the product occupies in the cold chain. In addition, oxytocin in Uniject with the TTI may be used as an important tool to ensure the quality of the medication.

† 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.

LIMITATIONS OF THE STUDY

Several factors limited the significance of this study, including small sample size, short introduction period, and frequent monitoring visits during the introduction. Additionally, the oxytocin in Uniject devices were donated for the pilot; thus, cost of the device was not part of the evaluation. The results, however, give a reasonably accurate portrayal of the realities of using oxytocin in Uniject for the practice of AMTSL in Honduras.

RECOMMENDATIONS

Oxytocin in Uniject could potentially address some of the challenges that the country is facing in implementing its national PPH prevention program, as it simplifies the administration of oxytocin and ensures product quality using the TTI contained in each package. Ultimately, we recommend that the MOH consider including the devices in its mix of uterotonic drugs. We also believe that a selective introduction of oxytocin in Uniject has the potential to increase access to AMTSL and improve the impact of the carefully developed PPH prevention strategy.

Considering the number of births that still occur outside of health facilities and without PPH prevention, we recommend that the MOH consider conducting a demonstration project at the community level with traditional birth attendants using oxytocin in Uniject for PPH prevention during home births.

2. Introduction

Honduras has adopted international standards for the prevention of postpartum hemorrhage (PPH), including promoting the active management of the third stage of labor (AMTSL) for all facility-based births in the country. AMTSL includes the intramuscular (IM) administration of 10 IU of oxytocin after delivery of the placenta. Despite government efforts, AMTSL is not correctly practiced by all providers and PPH continues to be the leading cause of maternal mortality. In an effort to reduce the PPH burden, the Ministry of Health of Honduras (MOH) identified the oxytocin in Uniject™ injection system (oxytocin in Uniject) as a potential solution for increasing access to AMTSL and helping to address PPH.

As a way to determine whether oxytocin in Uniject is a viable solution for supporting AMTSL practices in the country, the MOH—in collaboration with the United States Agency for International Development (USAID) flagship Maternal and Child Health Integrated Program (MCHIP), PATH, ChildFund Honduras (ChildFund), and USAID Honduras—conducted a pilot introduction of oxytocin in Uniject for use during AMTSL at the institutional level as part of the ongoing PPH prevention initiative. After the pilot introduction, PATH assisted the MOH, USAID, and ChildFund in evaluating the results.

This pilot project garnered data on initial country-level experience with oxytocin in Uniject in three health care facilities, including feedback from providers and managers on the acceptability and feasibility of introduction into the health system. Data from this study will enable the MOH to consider inclusion of oxytocin in Uniject on the list of uterotonic drugs for health care facilities in Honduras.

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. Of these women, more than 100,000 die a few hours after childbirth. PPH is also responsible for around 25% of maternal mortalities worldwide,[8] reaching as high as 60% in some countries, and can be a cause of long-term severe morbidity. Furthermore, an additional 12% survive with severe anemia.[9, 10] Currently, the maternal mortality rate in Honduras is 100 per 100,000 live births, one of the highest in Latin America.[11]

The majority of PPH cases occur in the immediate postpartum period (within 24 hours after birth). Between 70% and 90% of these cases are due to uterine atony, a failure of the uterus to properly contract after the child is born,[12,13] with retained placenta and genital lacerations accounting for most of the remaining PPH cases. 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, particularly, where most births occur—at lower-level facilities such as community-level health centers or at home.

3.2 AMTSL TO PREVENT PPH

Research has shown that AMTSL, which includes routine use of 10 IU of oxytocin given intramuscularly (IM), decreases the incidence of PPH (by up to 60%), the length of third-stage labor, the percentage of third stages of labor lasting longer than 30 minutes, the need for blood transfusion, and the need for uterotonic drugs to manage PPH.[14,15] WHO, 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 for all vaginal births.‡ AMTSL includes the following steps:[16]

- **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 two to three 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 and with counter-traction to the uterus to prevent inversion of the uterus.
- **Uterine massage after delivery of the placenta.** Uterine massage stimulates uterine contractions and removes clots that may inhibit uterine contraction.

‡ WHO. *WHO Recommendations for the Prevention of Postpartum Haemorrhage*. 2006.

3.3 PRACTICE OF AMTSL AND USE OF OXYTOCIN IN HONDURAS

Honduras adopted international guidelines for the prevention of PPH with AMTSL to address maternal mortality and problems with accessibility of health care for women. Five of 20 districts in the country have already received training on and are providing AMTSL for the prevention of PPH for all institutional births. These five districts are actively using oxytocin as a component of AMTSL administered by a disposable syringe and needle, using two 1 mL doses of 5 IU each in glass ampoules. Oxytocin is stored in health facilities at 2°C to 8°C. However, not all facilities have access to a refrigerator, especially primary care clinics.

Honduras, as a signatory country of the 2000 Millennium Declaration and to ratify its commitment to the attainment of the Millennium Development Goals, established the goal of reducing maternal mortality by three-fourths, from 108 per 100,000 live births in 1990 to 46 per 100,000 live births by 2015. To accomplish this, Honduras is now planning the implementation of a national policy called Accelerated Reduction of Maternal and Child Mortality (Reducción Acelerada de la Mortalidad Materna y de la Niñez [RAMNI]). The focus of RAMNI will be to reduce maternal and infant mortality by increasing the number of institutional births, expanding family planning coverage, and improving the quality of health care. The policy will also promote the generation and use of evidence for decision-making.

The introduction of oxytocin in Uniject at the institutional level in Honduras is aligned with RAMNI and could potentially address specific needs of the country, such as:

- Providing managers of health facilities with an alternative way of distributing and storing oxytocin in more remote areas of the country and at the community level.

  NOTE: Oxytocin in Uniject is accompanied by a TTI that permits the user to determine over exposure to heat, facilitating storage and transport of the product. Also, based on previous studies in which the product has been outside the cold chain for months, its effectiveness is maintained as long as TTI monitoring is used.

- Allowing easy incorporation with the RAMNI strategy for reduction of maternal mortality, potentially increasing the coverage of uterotonic protection.

- Helping to improve the continuous practice and systematization of AMTSL, given that the process for the introduction of oxytocin in Uniject facilitated training and reinforcement of correct AMTSL practice for health workers.

3.4 OXYTOCIN IN UNIJECT

Oxytocin in Uniject is a non-reusable, disposable syringe that is 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 the standard ampoule and needle-syringe delivery format. The main benefits of oxytocin in Uniject are as follows:

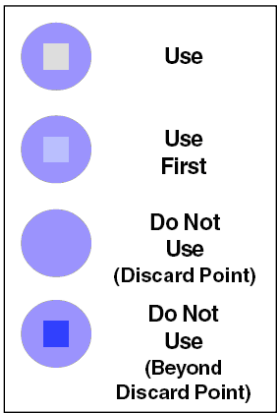
- **Single dose** to minimize wastage and facilitate outreach to individual patients.
- **Prefilled** to ensure that the correct dose is given and to simplify administration, procurement, and logistics.

Oxytocin in Uniject

- **Non-reusable** to minimize patient-to-patient transmission of blood-borne pathogens through needle reuse.
- **Easy to use** to allow proper use by health workers who do not normally give injections.
- **Compact size** for easy transport and disposal.

The needle on oxytocin in Uniject is permanently attached. The device is packaged in a foil pouch. 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 drug or vaccine product labels or adhered to the drug or vaccine packaging. 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 drug or vaccine was exposed to excessive heat. Important decisions on whether to use or discard the drug and which drug should be used first are now clear with the use of the TTI.[17,§] The TTI helps ensure that oxytocin given to a woman is potent, while allowing for more flexibility during field transport and storage and increasing access to facilities with limited or no cold chain.



Instructions for using the TTI

Instituto Biologico Argentino (BIOL) of Argentina completed the product development work to support initial registration of its formulation of oxytocin in Uniject in July 2007. In August 2007, BIOL submitted its registration application (dossier) to the National Administration of Medicine, Food, and Medical Technology (ANMAT), the regulatory drug authority in Argentina. By October 2008, BIOL received ANMAT approval to market oxytocin in Uniject in Argentina. In May 2010, BIOL received drug regulatory approval for oxytocin in Uniject in Honduras. BIOL has also registered the product in eight other Latin American countries. BIOL provided stability reports and certificates appropriate for this study, and submitted its Good Manufacturing Practice Certificate to health authorities in Honduras.

§ Pharmaceutical companies conduct stability studies to determine adequate conservation time, storage conditions, and the expiration date for secure storage of the uterotonic medicines they produce. A manufacturer recommends the conditions of storage based on the conditions in which it has conducted its stability studies and establishes the expiration date to be consistent with this. The TTI permits the exact monitoring of the accumulated temperature during transport and storage.

4. Methods

4.1 PURPOSE AND METHODOLOGY

The purpose of the study was to assess: 1) the acceptability of oxytocin in Uniject by providers and facility managers, and 2) the feasibility of introducing the device for delivering oxytocin within the existing health system.

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

1. **Pilot introduction of oxytocin in Uniject for PPH prevention in three facilities.** During pilot introduction, oxytocin in ampoules was replaced by the use of oxytocin in Uniject during the application of AMTSL.
2. **Evaluation of the pilot introduction of oxytocin in Uniject.** The evaluation sought to: 1) assess health worker and manager acceptability of oxytocin in Uniject, 2) assess fit with the system, and 3) identify sustainability issues resulting from introduction of oxytocin in Uniject.
3. **Evaluation of the feasibility of integrating oxytocin in Uniject with the current system.**

4.2 SETTING AND PARTICIPANTS

The pilot introduced oxytocin in Uniject in three facilities in the municipalities of Márcala, La Paz, and Reitoca located in the states of La Paz and Francisco de Morazán. The municipality of Márcala has a population of 21,460 and a poverty index of 31.2%, one of the highest in the country. Health services in this municipality are limited, mainly in the most remote areas. Maternal mortality in the municipality of Márcala is 108 per 100,000 live births.[18] The municipality of La Paz is the capital of the state of La Paz. It has a population of 29,027 and a human development index of 0.685.[19] The municipality of Reitoca has a population of 10,000 and a poverty index of 52.9 %.[20]

The MOH and ChildFund implemented the introduction. Specifically, the MOH implemented the introduction in the Hospital Suazo Córdova (municipality of La Paz) and the Maternal and Child Health Clinic of Márcala (municipality of Márcala), and ChildFund implemented the introduction in the Maternal and Child Health Clinic of Reitoca (municipality of Reitoca). In each of these institutions, health workers were trained in AMTSL before the introduction of oxytocin in Uniject. The MOH based the selection of these health facilities on rates of maternal mortality due to PPH, number of providers trained in AMTSL at those facilities, and number of births per month. See the **Table 1** for information on the type of health facility, number of health professionals attending births, and volume of births in each facility.

Table 1. Information on participants for introduction of oxytocin in Uniject

Health Facility	Number of Trained Health Professionals		Volume of Births Per Month
Hospital Suazo Córdova	Medical Doctors	11	242
	Nurse Practitioners	5	
	Auxiliary Nurses	31	
	Facility Managers	5	
	Total	**52**	
Maternal and Child Health Clinic of Márcala	Medical Doctors	6	59
	Nurse Practitioners	2	
	Auxiliary Nurses	11	
	Facility Managers	2	
	Total	**21**	
Maternal and Child Health Clinic of Reitoca	Medical Doctors	0	30
	Nurse Practitioners/Supervisor	0	
	Auxiliary Nurses	8	
	Facility Managers	1	
	Total	**9**	
Total		**82**	331

In addition to the health workers attending births, pharmacists and staff dedicated to managing the stock of uterotonics were included in the initial training. The only pharmacist who participated was from Hospital Suazo Córdova.

The study used a convenience sample to engage participants. Health providers who attend births and were trained in AMTSL and facility managers working at the selected health facilities were included. Women who went to the clinic to give birth were also included as part of the pilot introduction component of the project.

4.3 MATERIALS

A total of 1,500 doses of oxytocin in Uniject with TTI were provided to the MOH to carry out the three-month introduction at the facility level. Upon the arrival of the devices in country, the MOH used its existing procurement mechanisms to distribute oxytocin in Uniject from the central level to the province, district, and health facilities participating in the project. All challenges encountered during the distribution of oxytocin in Uniject were recorded and are included in this report. Health facilities were responsible for ensuring that cold storage requirements for oxytocin in Uniject were met (i.e., 2°C to 8°C).

Oxytocin in Uniject was used only for the PPH preventive dose during vaginal births. Health facilities were responsible for procuring oxytocin in ampoules for other purposes (e.g., treatment of PPH, induction, conduction, etc.). This supply also helped health facilities to return to their regular standard practice of using of oxytocin in ampoules for PPH prevention once the introduction was completed. Health facilities were also responsible for providing cold chain equipment (e.g., refrigerators, cool boxes) to store oxytocin in Uniject at the recommended temperature, as well as infection control equipment (e.g., alcohol wipes, safety boxes, etc.).

4.4 DATA COLLECTION AND ANALYSIS

Health care providers and facility managers completed a self-administered inventory of current practices before the introduction of oxytocin in Uniject. Three months after the initial introduction, in-depth interviews were conducted with facility managers and providers. 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.

During the pilot introduction, monitors from the MOH and ChildFund visited the facilities once a month. These monitors observed the providers' practices, provided any necessary supervision, and completed a form to document their observations, including information on the number of units of oxytocin in Uniject administered, the number of births attended at the facility during the preceding month, the number of women who had a vaginal birth and received oxytocin in Uniject, number of defective Uniject devices, the number of providers using oxytocin in Uniject, and the aggregate number and causes of maternal deaths.

Data were entered and analyzed with Epi Info™ version 3.5.1 using a univariate analysis. To evaluate feasibility and fit within the Honduran health system, researchers from PATH and the MOH met in Honduras from August 21 to August 26, 2011, 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 meeting was divided into two parts:

1. Stakeholder interviews at the central level to identify sustainability issues that may affect the potential introduction of oxytocin in Uniject for PPH prevention in Honduras.
2. Visits to health facilities that participated in the pilot introduction to observe practices and assess opportunities and challenges associated with the pilot introduction oxytocin in Uniject.

4.5 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 giving consent.

4.6 ETHICAL REVIEW

The study protocol was approved by PATH's Research Ethics Committee and the Human Research Subjects Committee of the Universidad Autonoma de Honduras.

The feasibility component of the project was deemed a non-research activity by the Research Determination Committee at PATH.

5. Results

5.1 INVENTORY OF CURRENT PRACTICES

Results from Providers

Of 82 providers trained, 62 consented to answer the questionnaire before training. Of these, 34 (55%) were from the Hospital Suazo Córdova, 19 (31%) from the Maternal and Child Health Clinic of Márcala, and nine (14%) from the Maternal and Child Health Clinic of Reitoca.

Practice of AMTSL at health facilities

All providers interviewed said they conduct AMTSL (n=62, 100%). However, when exploring the components of AMTSL in detail, not all providers performed all three. (See **Table 2** for the components of AMTSL practiced at each facility). Of the three components, CCT and uterine massage were the most commonly performed steps. Use of uterotonics was the least.

Table 2. Practice of AMTSL at participating health facilities (n=62)

Facility	Use of AMTSL at Health Facility	Use of Uterotonics	Controlled Cord Traction	Uterine Massage
Hospital Suazo Córdova	34 (100%)	26 (76.5%)	29 (85.3%)	32 (94.1%)
Márcala	19 (100%)	19 (100 %)	18 (94.7%)	18 (94.7%)
Reitoca	9 (100)	8 (94.1%)	9 (100 %)	9 (100 %)
Total	**62 (100.0%)**	**53 (85.5%)**	**56 (90.3%)**	**59 (95.1%)**

Preparation and administration of oxytocin

This inventory only obtained information about current practices and not the use of oxytocin in Uniject. The majority of providers answered that they administer the dose of oxytocin for AMTSL (see **Table 3**). All providers in health centers administer oxytocin in ampoules, while only 64.7% (22/34) of providers in the hospital administer oxytocin.

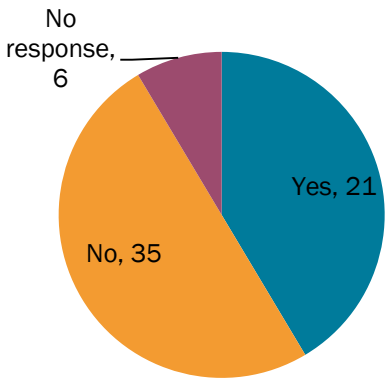
Table 3. Number of providers who use oxytocin in ampoules during AMTSL (n=62)

Facility	Yes	No	Sometimes	Total
Hospital Suazo Córdova	22 (64.7%)	10* (29.4%)	2 (5.9%)	34 (100%)
Márcala	19 (100%)	0	0	19 (100%)
Reitoca	8 (100%)	0	0	6 (100%)
Total	**49 (79.0%)**	**10 (16.1%)**	**2 (3.2%)**	**61 (98.4%)**

*Eight providers responded that it was not part of their responsibility and two said that they had not been trained in administering oxytocin in ampoules.

Of the 56 providers who answered the question on storage, only 21 stated that they checked the storage temperature before administering oxytocin as part of AMTSL (see **Figure 1**).

Figure 1. Number of providers who check the temperature of oxytocin at health facilities



The most frequent reasons for not checking temperature were: 1) the health facility does not have a refrigerator (n=5, 14.3%), 2) the provider did not have the skills (n=4, 11.4%), 3) the task was not part of his/her responsibilities (n=4, 11.4%), and 4) it is not standard practice in the health facility (n=3, 8.6%).

Responses about preparation and administration of oxytocin during AMTSL included the use of 3 mL syringes, alcohol, cotton, and oxytocin in ampoules of 10 units. Some providers referred to 10 mL ampoules rather than ampoules with 10 IU. Only 57 providers (91.9%) responded to the question about ease of preparing the oxytocin ampoules. Of those, 35 providers (61.4%) felt it was very easy to prepare the injection of oxytocin, 16 providers (28.1%) felt it was somewhat easy, five providers (8.8%) felt it was somewhat difficult, and one provider (1.5%) felt it was very difficult. The providers who found it difficult to prepare the injection had difficulty breaking the ampoules and/or manipulating the syringe.

All providers administered the dose intramuscularly in the deltoid region. There was no standardization on the timing of administration—some providers administered the dose three minutes after birth of the baby, while others did so one minute after birth. Some of the providers interviewed responded that the doctor decided on dosage and administration.

Of 62 providers, 57 (91.9%) responded to the question about ease of administering oxytocin in ampoules. Thirty-four providers (59.6%) felt it was very easy to administer the injection of oxytocin, five providers (8.8%) felt it was somewhat easy, 15 providers (23.1%) felt it was somewhat difficult, and three providers (5.3%) felt it was very difficult. Providers who found it difficult to administer the injection said they had difficulty breaking the glass ampoules.

Results from Managers

Eleven facility managers answered the question on inventory of current practices. Most managers said their health facilities provide the preventive dose of oxytocin during AMTSL—except for the three managers from the Hospital Suazo Córdova who said that the facility does not provide the dose of oxytocin for all women during AMTSL. The reasons provided for not having the dose of oxytocin available for all women were:

- It is not a practice in the facility.
- Personnel are not all trained.
- The facility does not have a regular supply.

Managers also provided opinions on how to improve access to oxytocin for women. Their responses included:

- Guarantee stock of the product from central level to the facilities.
- Store the product according to specifications to ensure quality.
- Properly forecast demand for product.

5.2 EVALUATION OF ACCEPTABILITY AND EASE OF USE BY PROVIDERS

The study evaluated acceptability by providers after the three-month pilot introduction. A post-intervention questionnaire was used to gather information on providers' experience using oxytocin in Uniject as a component of AMTSL. Of the 62 providers who participated in the study, 54 (73%) responded to the post-intervention questionnaire, which was complemented by observations made by monitors during monthly visits to the health facilities.

Description of Participants

Of the 54 providers who participated in the questionnaire, the majority were auxiliary nurses (n=37, 68.5%) followed by physicians completing their mandatory social service year (n=6, 11.1%), nurse practitioners (n=4, 7.4%), general physicians (n=5, 9.3%), and obstetricians/gynecologists (n=2, 3.7%). See **Table 4** for more information on providers.

Table 4. Description of providers

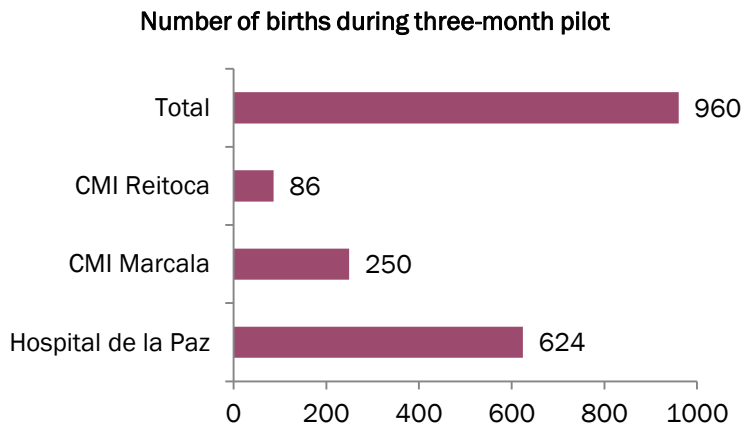
Facility	Auxiliary Nurses	Nurse Practitioners	Physicians in Social Service	General Physicians	Ob/Gyns	Total (%)
Hospital Suazo Córdova	21	1	0	5	1	28 (51.9%)
Márcala	9	1	6	0	1	17 (31.5)
Reitoca	7	2	0	0	0	9 (16.7%)
Total	**37 (68.5%)**	**4 (7.4%)**	**6 (11.1%)**	**5 (9.3%)**	**2 (3.7%)**	**54 (100%)**

In regard to number of years attending births, of the 54 providers interviewed, 30 (55.6%) had less than five years of experience attending births, 12 (22.1%) had five to nine years of experience, and 12 (22.1%) had between 10 and 29 years of experience.

Births Attended during the Pilot Introduction of Oxytocin in Uniject

During the three-month pilot introduction of oxytocin in Uniject, there were 960 vaginal births. Of these births, 65% (n=626) were attended at Hospital Suazo Córdova, 26% (n=251) at Maternal and Child Health Clinic of Márcala, and 8% (n=83) at Maternal and Child Health Clinic of Reitoca. See **Figure 2** for details of births by facility.

Figure 2. Number of births during pilot introduction of oxytocin in Uniject



Usage of Oxytocin in Uniject

A total of 970 oxytocin in Uniject devices were used during the three-month introduction—this is in contrast to the 960 reported births at the three facilities. Differences between number of oxytocin in Uniject devices used and vaginal births was explained either by the fact that a woman gave birth in the community and was then transferred to the facility or because there were defective Uniject devices.

Ease of Use

Of the providers who responded to the questions about the preparation and administration of oxytocin during AMTSL:

- The majority (92.6%, n=50) felt that the preparation of oxytocin in Uniject was very easy, while 5.6% (n=3) felt it was somewhat easy, and only 1.8% (n=1) felt it was somewhat difficult. In other words, 98.2% (n=53) of providers felt that use of the oxytocin in Uniject device was either very easy or somewhat easy.
- Fifty-two providers (96.3%) felt that the activation of oxytocin in Uniject was very easy and two providers (3.7%) felt that is was somewhat easy.
- Fifty-one providers (94.4%) felt that is was very easy to administer the injection of oxytocin and three providers (5.6%) felt that it was somewhat easy.

The one provider who felt it was somewhat difficult to activate the oxytocin in Uniject device was a physician in social service at the Maternal and Child Health Clinic of Márcala. This professional stated that there was some spill of the product when the oxytocin in Uniject device was activated. See **Table 5** for summary information on ease of use of oxytocin in Uniject by providers.

Table 5. Ease of use of oxytocin in Uniject by providers (n=54)

Categories	Ease of Preparing Oxytocin in Uniject	Ease of Activating Oxytocin in Uniject	Ease of Administering Oxytocin in Uniject
Very easy	50 (92.6%)	52 (96.3%)	51 (94.4%)
Somewhat easy	3 (4.9%)	2 (3.7%)	3 (5.6%)
Somewhat difficult	1 (1.8%)	0	0
Very difficult	0	0	0
No response given	0	0	0
Total	**54 (100%)**	**54 (100%)**	**54 (100%)**

The percentage values for ease of preparation and administration of oxytocin in Uniject were higher, compared with oxytocin in ampoules. There was also a statistically significant difference between ease of preparation and ease of administration with oxytocin in Uniject, as compared with oxytocin in ampoules. See **Table 6**.

Table 6. Comparison of ease of use of oxytocin in Uniject versus oxytocin in ampoules

	Categories	Oxytocin in Uniject		Oxytocin in Ampoules	
		n (%)	95% CI (%)	n (%)	95% CI (%)
Ease of preparation	Very easy	50 (92.6)	83.00–97.06	35 (61.4)	43.95–68.36
	Somewhat easy	3 (4.96)	1.43–14.38	16 (28.1)	16.09–37.64
	Somewhat difficult	1 (1.8)	0.09–8.79	5 (8.8)	3.01–16.97
	Very difficult	0	-	1 (1.8)	0.08–7.69
	No response	0	-	5 (8.8)	-
	Total	**54 (100)**	**-**	**62 (100)**	**-**
Ease of administration	Very easy	51 (94.4)	85.62–98.67	34 (59.6)	42.36–66.86
	Somewhat easy	3 (5.6)	1.43–14.38	5 (8.8)	3.01–16.97
	Somewhat difficult	0	-	15 (25.3)	14.77–35.98
	Very difficult	0	-	3 (5.3)	1.24–12.6
	No response	0	-	5 (8.8)	-
	Total	**54 (100)**	**-**	**62 (100)**	**-**

Time Required to Prepare the Dose of Oxytocin for AMTSL

When asked about time needed to prepare oxytocin for AMTSL, 88.9% of providers (n=48) said that it took them less time to prepare the oxytocin in Uniject device than oxytocin in ampoules, while 11.1% (n=6) said it took more time with oxytocin in Uniject than with ampoules. Of the six providers who thought it took more time to prepare the oxytocin in Uniject than oxytocin in ampoules, three were general physicians, two were auxiliary nurses, and one was a nurse practitioner. Five of the six providers had been attending births for less than five years and one had between five and nine years of experience.

Experience with the TTI

Most providers (96.3%, n=52) felt that interpretation of the TTI was very easy, and 3.7% (n=2) felt it was somewhat easy.

Only 7.4% (n=4) of providers had oxytocin in Uniject devices with changes in the TTI indicating that the device should be discarded; one of these providers was from the Hospital Suazo Córdova and three were from the Maternal and Child Health Clinic of Retoica.

With regard to change in the quality of care secondary to use of the TTI, 96.3% (n=52) of providers felt that the TTI was associated with a large increase in the quality of care, and 3.7% (n=2) felt there was no change in quality of care. **Table 7** summarizes the data collected on provider acceptability of the TTI.

Table 7. Acceptability of TTI by providers

Experience Using the TTI during the Pilot (n=54)	
Very easy	52 (96.3%)
Somewhat easy	2 (3.7%)
Somewhat difficult	0 (0%)
Very difficult	0 (0%)
No response	0 (0%)
Total	**54 (100%)**
Unusable Oxytocin in Uniject According to TTI (n=54)	
Yes	4 (7.4%)
No	50 (92.6)%
Total	**54 (100%)**
Changes the TTI Made in Quality of AMTSL Services (n=54)	
Large increase in quality	52 (96.3%)
Small increase in quality	0 (0%)
Decrease in quality	0 (0%)
No change	2 (3.7%)
No response	0 (0%)
Total	**54 (100%)**

Quality of Services

A total of 82.4% (n=42) of providers felt there was a large improvement in the quality of AMTSL services provided to patients when oxytocin in Uniject was used, 5.9% (n=3) reported a small improvement in quality, 3.9% (n=2) reported a decline in quality, and 7.8% (n=4) reported no change in quality.

Waste Disposal

Providers reported on how disposal of Uniject compared with disposal of standard disposable syringes and ampoules. A total of 33.3% (n=18) said it was easier to dispose of the Uniject device, 53.7% (n=29) said there was no difference, and 13% (n=7) said it was more difficult to dispose of the Uniject than disposable syringes. Of the seven providers who felt that disposal of oxytocin in Uniject was more difficult than disposal of oxytocin in ampoules, five were auxiliary nurses and two were nurse practitioners.

No specific reasons were given by providers who reported more difficulty in disposing the oxytocin in Uniject devices. Guidelines for disposal of Uniject were the same as traditional syringes.

Defective Units of Oxytocin in Uniject

The pilot introduction of oxytocin in Uniject used 970 devices. Of these, 10 devices were reported to have leaked liquid due to a lost needle cap or perforation.

Interest in Continuing to Use Oxytocin in Uniject

Of the providers interviewed, 92.6% (n=50) indicated they would use oxytocin in Uniject after the pilot ended, and 7.4% (n=4) said they would not use the device after the pilot. Only one of the general physicians reported to have observed more bleeding postpartum with use of the oxytocin in Uniject device, which was a reason for not wanting to continue using oxytocin in Uniject.

The majority of comments from providers focused on advantages of oxytocin in Uniject (including not needing to use syringes), decrease in preparation and administration time, and use of the TTI to guarantee that the product was still active.

5.3 EVALUATION OF ACCEPTABILITY AND EASE OF USE BY FACILITY MANAGERS

Evaluation of acceptability by facility managers was conducted after the three-month pilot introduction. Of the eight facility managers, seven responded to the post-intervention questionnaire including three nursing managers, a pharmacy manager, a warehouse manager, a medical director, and an administrative manager.

Regular Supply

None of the facilities reported a stock-out of oxytocin in Uniject during the time of the pilot. This finding was reinforced by the monitors who indicated that all facilities had sufficient stocks of oxytocin in Uniject at the time of their visit.

Storage of Oxytocin in Uniject

Six (85.7%) of the managers did not report any challenges in storing oxytocin in Uniject at the recommended temperature. One manager (14.3%) reported that s/he either did not have cold chain equipment (i.e., refrigerators) or did not have batteries for the cold chain equipment.

All monitors reported that they found oxytocin in Uniject devices to be consistently stored correctly during monitoring visits.

Acceptability of the TTI

All seven managers who responded (100%) felt that interpretation of the TTI was very easy. None of the managers described any difficulties that staff experienced using the TTI. All seven managers who responded also believed that the TTI was important because it ensured the quality of the administered oxytocin.

In addition, 100% (n=7) of managers responded that they would like to continue using the TTI after completion of the pilot.

Use of Oxytocin in Uniject

During monitoring visits, all monitors found that the oxytocin in Uniject devices were stored according to the manufacturer's recommendations. During 100% of observations, providers

interpreted the TTI before administering the dose and correctly administered the dose of oxytocin in the Uniject device.

Monitors noted that it was necessary to provide refresher training for staff in the Maternal and Child Health Clinics of Márcala and Reitoca during monitoring visits, which included providing an update on application of AMTSL on three occasions, use of the oxytocin in Uniject device on two occasions, and interpretation of the TTI on one occasion.

Quality of Services

Of the seven facility managers, six (86%) reported a change in the provision of AMTSL after introduction of the oxytocin in Uniject devices, believing that this change had greatly improved the quality of AMTSL services provided at their facilities.

Waste Disposal

Most managers (57%, n=4) felt that elimination of the oxytocin in Uniject devices was easier, while 28.5% (n=2) felt there was no difference between the elimination of oxytocin ampoules and syringes and elimination of the oxytocin in Uniject device. One manager (14.3%) did not give a response.

Interest in Continuing Use of Oxytocin in Uniject

The seven (100%) facility managers interviewed said they are interested in continuing to use oxytocin in Uniject after the pilot. Managers commented on acceptance of the product for its ease of use and ability to safely administer oxytocin, as well as the fact that hemorrhage was prevented in patients during the third stage of labor. Other comments were related to satisfaction regarding the type of packaging, as well as concern for the ability to have a constant supply from the central level.

Instructions for Use

Monitors recommended that the TTI be printed on the packaging and water resistant to preserve it when stored in the refrigerator. This recommendation was drawn from the particular case of the Maternal and Child Health Clinic of Reitoca, where the oxytocin in Uniject was stored in a portable cold box with ice packs. After direct contact with ice packs, the package labels became wet, making it difficult to read the label's legend. This issue was corrected during a monitoring visit.

Maternal Deaths during the Pilot

There were no reported maternal deaths during the pilot introduction.

5.4 FEASIBILITY AND FIT WITHIN THE SYSTEM

To evaluate feasibility and fit within the Honduran health system, researchers from the MOH and PATH visited Honduras from August 21 to August 26, 2011. 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 two parts: site visits and interviews with key stakeholders.

During visits to all three health facilities, researchers observed practices of AMTSL and logistical issues related to the use and storage of oxytocin in Uniject for AMTSL. They also held interviews with key stakeholders at the central and state levels. The main findings from the

visits and informal interviews with key stakeholders were 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 visits to health facilities, no births occurred; as such, there was no opportunity to observe how providers were practicing AMTSL. In two of the three facilities visited, the practice of AMTSL was correctly described by providers. The use and timing of the administration of oxytocin in Uniject were well-described. One location mentioned uterine massage before the delivery of the placenta; two of them (the Maternal and Child Health Clinic of Márcala being the exception) mentioned that they have to wait for the uterotonic to take effect in the form of a contraction before starting CCT.

Uterine massage immediately after the delivery of the placenta was reported and recognized as a key action when applying AMTSL. All facilities recommend performing uterine massage every 15 minutes during the two hours following birth. However, the follow-up required every 15 minutes during the first two hours after delivery was not always done due to lack of time or staff. In response, health workers are teaching mothers and family members to perform their own uterine massage and participate in their own care.

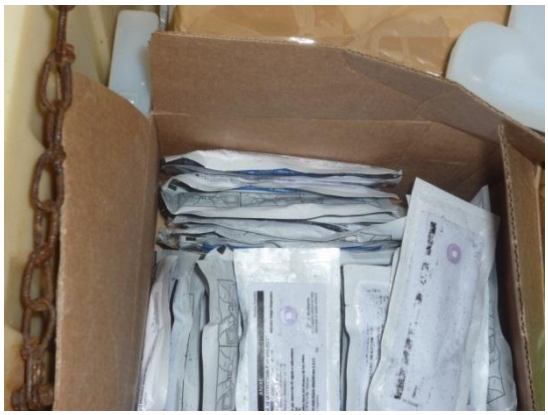
Storage of Oxytocin in Uniject

Oxytocin in Uniject was stored in the cold chain between 2°C and 8°C in all facilities visited. At the Maternal and Child Health Clinics of Reitoca and Márcala, oxytocin in Uniject was stored by itself in a cold box and refrigerator, respectively. The Hospital Suazo Córdova stored oxytocin in Uniject in a refrigerator along with other medications. Only Márcala had a refrigerator or cold boxes inside the delivery room. Health workers in the other two facilities used a carrier with ice packs to transport and store oxytocin in Uniject in the delivery room. The stock in the carrier was rotated every day based on demand.

Oxytocin in Uniject stored in the cold chain.

The team did not observe issues related to storage capacity in any of the facilities. However, it is important to note that the Maternal and Child Health Clinic of Reitoca received a cold box donated by the central store for the exclusive purpose of storing oxytocin, as there was no cold chain equipment in the facility before the pilot. At the Maternal and Child Health Clinic of Reitoca, the product was stored in cold boxes with ice packs. Nurses changed the ice packs every 72 hours. Reitoca also obtained a freezer as a donation from a private organization. The freezer is used to conserve and rotate the ice packs. At the Maternal and Child Health Clinic of Reitoca, the team noticed that some of the units were discolored by contact with the ice packs.

Storage conditions at Hospital Suazo Córdova and the Maternal and Child Health Clinic of Márcala.



Oxytocin in Uniject at the Maternal and Child Health Clinic of Márcala.

The team also visited the central medical storage warehouse in Tegucigalpa. The warehouse received 2,500 doses for the project and distributed them door-to-door to all participating health facilities. The product was stored in the cold chain (2°C to 8°C) while at the warehouse. No problems or issues related to the storage and transportation of oxytocin in Uniject were reported.

Use of Oxytocin in Uniject

Based on observations from the visit, providers used oxytocin in Uniject according to the instructions for use.

Oxytocin in Uniject was used exclusively for prevention of PPH in all vaginal births at the participating health facilities.

Providers shared their opinions about oxytocin in Uniject during the feasibility visit. They noted the following benefits of oxytocin in Uniject in comparison with oxytocin in ampoules:

- **Increased confidence in the efficacy of medication:** Health workers said they feel more confident in the efficacy of oxytocin in Uniject than the efficacy of standard injectable oxytocin. They attributed this perception to the use of the TTI.

- **Reduced wastage of medication:** Health workers interviewed said that less medication is wasted with oxytocin in Uniject because the product comes with the exact dose.
- **Increased awareness of importance of AMTSL:** Health workers said that both the training provided for the pilot and the use of oxytocin in Uniject have helped remind them of the importance of AMTSL in preventing PPH.
- **Increased ease of use, compared with oxytocin in ampoules**.

Stock of Oxytocin in Uniject and Oxytocin in Ampoules

All facilities had sufficient stock of oxytocin in Uniject during the pilot. All of them also had remaining doses that they can use for a few months after the pilot ended.

The visiting team did not identify any issues with supplies. In general, nurses and personnel from the pharmacy have a good recording system for registering the number of doses used and discarded due to malfunction or human error. All facilities reported that a few oxytocin in Uniject devices were discarded due to damage during the activation process (human error) or problems with the needle (two discarded syringes per facility).

6. Limitations of the Study

Several factors limited this study. Since the study was designed to operate within routine health services, randomization was not considered feasible. As such, the study used a convenience sample and not a randomized sample. There was also no comparison between practice of AMTSL pre- and post-intervention. We cannot, therefore, conclude that the use of oxytocin in Uniject increased the willingness of providers to perform AMTSL or improved the quality of how AMTSL was practiced. If this variable was included in the study, the results may have increased the value of the intervention.

Though outside the scope of the project, it would have also been useful to compare AMTSL practices pre-intervention with practices during the introduction of oxytocin in Uniject, or to compare AMTSL practices in the facilities where oxytocin in Uniject was introduced with facilities using oxytocin in ampoules. A study with a longer duration would have been useful, as well, to allow for more health workers in the designated areas to use the product. Although these limitations must be considered when reviewing data and conclusions, we believe that the study results give a reasonably accurate portrayal of the realities of using oxytocin in Uniject devices for the practice of AMTSL in Honduras.

The cultural diversity of Honduras is a factor that limits our ability to generalize findings from the pilot to the entire country. Specifically, Fransisco de Morazán and Márcala have unique geographical and accessibility situations that make them different from other areas in the country. While some inferences can be made from the results, data from this study are applicable only to the participating health facilities; it is not possible to generalize this information to the rest of the country.

All units of oxytocin in Uniject were donated for use in this project. Although this factor is not necessarily a limitation, the real cost of oxytocin in Uniject should be considered when making decisions about its inclusion on the national list of medicine for the prevention of PPH in Honduras. A study of costs—not only the product, but costs associated with the introduction of the product (e.g., training, storage, etc.)—would have been ideal. However, this was not undertaken due to the limited resources available.

Ultimately, since this project was a pilot demonstration, the lessons learned 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 trained birth attendants for AMTSL as part of an effective PPH prevention program at the facility level. The acceptability of oxytocin in Uniject reported by providers and managers during this pilot study was high and is similar to those reported in other studies.[21,22,23]

In general, providers and managers found oxytocin in Uniject to be an acceptable mechanism to deliver the preventive dose of oxytocin for AMTSL. In regard to ease of use and administration, most providers found the preparation, activation, and administration of oxytocin in Uniject to be very easy. There was a statistically significant difference between ease of use and ease of administration of oxytocin in Uniject, compared with oxytocin in ampoules. In addition, the TTI offers the advantage of storing the product under more flexible conditions.

Providers reported the following advantages associated with the use of oxytocin in Uniject:

- **Decreased time to prepare medication:** 92.6% 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 resources constraints reported by managers and various stakeholders in Honduras, this benefit offered by the product would be of interest to the country. In most cases, nurses and auxiliary nurses are alone when attending a birth. They must also attend to the needs of the mother and the baby, and perform AMTSL.
- **Improved quality of AMTSL services provided to patients:** 82.4% of providers and 100% of managers (n=7) 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 and having a stock of oxytocin available to provide to patients are two possible reasons for this response.
- **Increased perception of efficacy of medication by providers:** Health workers reported that they felt more confident in the efficacy of the oxytocin in Uniject, compared with that of the standard injectable oxytocin. This perception is attributed to the inclusion of the TTI. The efficacy of oxytocin is well-established; as such, this factor was not studied due to prevalence of existing literature.
- **Increased awareness on proper use of AMTSL.**

Apart from the high acceptance levels reported for oxytocin in Uniject, providers and managers also reported high levels of acceptance for the TTI. All providers (n=54) and managers (n=7) found that interpreting the TTI was either very easy or somewhat easy.

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. There were no issues reported in regard to storage space of oxytocin in Uniject. In addition, the TTI offers storage flexibility 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:

- **Storage outside the cold chain at delivery points.** In situations when a hospital or clinic are without sufficient cold chain capacity, the oxytocin in Uniject devices can be stored without refrigeration before use due to the inclusion of the TTI, which registers the accumulation of excessive heat and alerts the provider regarding the efficacy of the device when it changes color. 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.

- **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, there are tremendous opportunities to simplify logistics and improve accessibility to AMTSL through a more flexible cold chain for oxytocin in Uniject.

A logical next step in the process is to initiate discussions at the government level around the introduction of oxytocin in Uniject as part of a comprehensive national 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. If the MOH decides to introduce oxytocin in Uniject on a national level, it will need to create a strategy and implementation plan for incorporating the use of the device with 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 benefit most 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. Cost of oxytocin in Uniject.
4. Development of protocols for storage in hospitals and maternal and child health clinics.
5. Training of providers on how to use the Uniject when conducting AMTSL.
6. Monitoring of data on the impact of using oxytocin in Uniject.

Honduras adopted international standards for PPH prevention and introduced AMTSL as part of routine care for all births. Providers in all states in the country have been trained to apply AMTSL. However, there is still a need to standardize the procedure among health care providers and ensure the availability of oxytocin at every birth.

Additionally, it is necessary to guarantee the maintenance of the cold chain at an institutional level. In Honduras, the specification of oxytocin in ampoules stored in the public sector is varied. Two products exist with different specifications (between 2°C–8°C and between 12°C–25°C) that can create confusion on an institutional level. The introduction of oxytocin in Uniject, a new device, could serve as a tool to raise awareness about PPH and the use of AMTSL in prevention. In addition, the use of the TTI in oxytocin in Uniject could allow health workers to improve the impact of AMTSL practices to prevent PPH, given support to ensure pharmacological activity of each dose.

Considering the high number of births that still occur outside of facilities, oxytocin in Uniject could potentially increase access to uterotonics in a population that would not normally get it. Also, considering that studies exist that have used oxytocin in Uniject outside of the cold chain at the community level, we recommend that Honduras consider conducting a demonstration project with traditional birth attendants using oxytocin in Uniject for PPH prevention. This strategy has the potential of decreasing high rates of PPH at the community level.

Ultimately, oxytocin in Uniject has the potential to address some of the challenges that Honduras is facing in implementing its national PPH prevention program. We recommend that the MOH consider the national introduction of oxytocin in Uniject to increase access to AMTSL and improve the impact of its PPH prevention strategy.

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