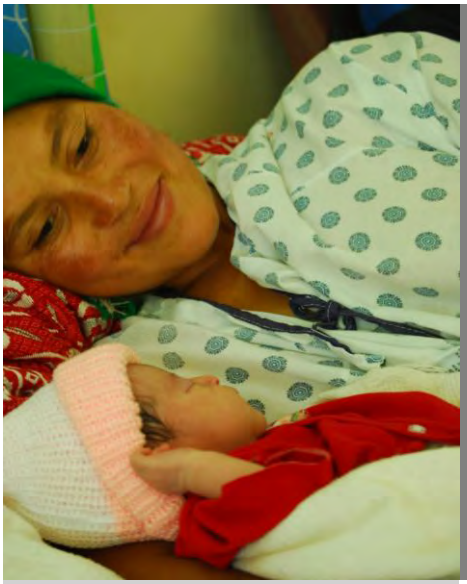

Oxytocin in the Uniject® Prefilled Injection Device: Guatemala Pilot Introduction

Cost Analysis of Replacing Oxytocin in Ampoules with Oxytocin in the Uniject® Prefilled Injection Device for Active Management of the Third Stage of Labor at the Institutional Level in Guatemala

March 2010

GOBIERNO DE ÁLVARO COLOM
GUATEMALA
MINISTERIO DE SALUD PÚBLICA Y ASISTENCIA SOCIAL
USAID
FROM THE AMERICAN PEOPLE
PATH

Acknowledgements

A special thanks to all the facility managers and procurement personnel who shared data and their perspectives with the research team. Without them none of this work would have been possible.

Thanks also to the research team from the Ministry of Health and Social Welfare (MSPAS) and to the Health Care Improvement Project (HCI), who ensured that all of the details of the data collection visit were arranged. We would especially like to thank Billy Aragón of the Vice Ministry of Hospitals, who patiently provided answers to our numerous questions on the logistics of Guatemala's procurement and distribution system.

Research team:
Dr. Gustavo Batres, Vice Ministry of Hospitals, MSPAS Guatemala
Billy Aragón, Vice Ministry of Hospitals, MSPAS, Guatemala
Mark Guy, Health Economist, PATH
Erica Jacoby, Commercialization Officer, PATH

Technical reviewers:
Carol Levin, Senior Health Economist, PATH
Steve Brooke, Team Leader, Oxytocin in Uniject project, PATH
Susheela Engelbrecht, Senior Program Officer, PATH
Dr. Shirley Villadiego, Senior Program Associate, PATH
Adriane Berman, Senior Program Associate, PATH

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

Table of contents

Attachments

Acronyms

AGOG	Association of Gynecology and Obstetrics of Guatemala
AMTSL	Active management of the third-stage of labor
BIOL	Instituto Biologio Argentino
CAIMI	Center for Integral Attention of Maternal and Child Health. CAIMIS are a type of maternal and child health clinic. They focus only on women and children.
CAP	Center for Permanent Attention. CAPs are a type of health facility that attends primary care services, but that also attend births and have beds for short hospitalization of non complicated diseases.
IU	International units
MSPAS	Ministerio de Salud Pública y Asistencia Social (Ministry of Public Health and Social Assistence)
PATH	Program for Appropriate Technology in Health
POPPHI	Postpartum Hemorrhage Prevention Initiative
PPH	Postpartum hemorrhage
TTI	Time-temperature indicator
USAID	United States Agency for International Development

Executive Summary

A pilot introduction study of oxytocin in the Uniject®* prefilled injection device (hereafter referred to as oxytocin in Uniject) during active management of the third stage of labor (AMTSL)† at the institutional level was initiated in September 2009 in the state of Alta Verapaz in Guatemala. The purpose of the pilot introduction was to evaluate user's acceptability and feasibility of using oxytocin in Uniject for AMTSL at the institutional level in Guatemala. Health providers and facility managers were trained in the use of oxytocin in Uniject as a component of AMTSL. The pilot introduction aimed only to replace oxytocin in ampoules with oxytocin in Uniject in facilities. The Ministerio de Salud Pública y Asistencia Social (MSPAS) in collaboration with PATH, the Prevention of Postpartum Hemorrhage Initiative (POPPHI), the United States Agency for International Development (USAID) and the Association of Gynecology and Obstetrics of Guatemala (AGOG) conducted the three-month pilot introduction of oxytocin in Uniject as part of Guatemala's ongoing postpartum hemorrhage (PPH) prevention initiative that included AMTSL. After the pilot introduction, MSPAS with assistance from PATH, POPPHI, USAID, and AGOG, evaluated the acceptability of oxytocin in Uniject by providers and managers as well as the feasibility and fit with the system.

The pilot introduction was complemented by a cost analysis to determine the costs of replacing the existing delivery method (two 5-IU ampoules of oxytocin and one syringe) with oxytocin in Uniject (one prefilled Uniject device with 10 IU of oxytocin) for the prevention of postpartum hemorrhage. This study was only intended to evaluate introduction costs, not to be a cost effectiveness study. Results from this cost study will support MSPAS of Guatemala in its decision-making process regarding broader introduction of oxytocin in Uniject in the context of a PPH-prevention strategy.

The cost analysis was conducted at six health facilities in six different districts of Alta Verapaz, the same facilities where the pilot introduction study was implemented. The facilities in the study represent different levels within the health system; three were district hospitals, one was an intermediate second-level facility, and two were primary-level facilities. Data on resources and direct costs were collected from these facilities. In addition to cost data, qualitative data were also collected at each facility and from a regional health office to evaluate broader acceptability and logistics related to wide scale introduction of oxytocin in Uniject.

Based on the costs modeled for this study, oxytocin in Uniject will increase the cost of a preventive dose of oxytocin during AMTSL at all facility levels in Guatemala. Depending on the supply price of oxytocin in Uniject and investments needed in the cold chain, the per-dose cost ranges in Guatemalan quetzales (Q) from Q9.69 to Q13.08 (US$1.17 to US$1.59). The incremental per-dose increase in cost compared to current practice (looking at both 2009 and 2010 costs) could range from Q2.09 to Q10.53 (US$0.25 to US$1.28). The estimated increase in cost per dose as compared to ampoule and syringe will vary depending on different scenarios. The price of oxytocin in Uniject varied from Q8.25 to Q11.55 (US$1.00 to US$1.40), and the

* Uniject is a trademark of BD.

† The components of AMTSL are: (1) administration of a uterotonic drug within one minute after the baby is born (oxytocin is the uterotonic of choice), (2) controlled cord traction with counter traction to support the uterus; and (3) uterine massage immediately after delivery of the placenta.

cold chain investments varied from no cold chain investments to every hospital needing a new refrigerator.

While oxytocin in Uniject is more expensive than current practice, the decision to move forward with introduction should include consideration of the value obtained from the device—especially for certain scenarios of use or within the context of increased government efforts aimed at reducing the prevalence of postpartum hemorrhage. Oxytocin in Uniject is a simple, easy-to-use, prefilled injection device that facilitates the administration of the prophylactic dose of oxytocin for PPH prevention in the context of AMTSL where facilities are often working with few staff to attend to both the mothers and the babies.

The benefits of oxytocin in Uniject could also facilitate additional future scenarios of use in communities, expanding an important health intervention (administration of prophylactic oxytocin) that is not otherwise reaching these populations. Successfully reaching even a portion of the 58 percent of women[‡] who currently deliver in communities would be a significant step forward in addressing maternal mortality in Guatemala.

Background

Oxytocin in Uniject

The oxytocin in Uniject prefilled injection device comes with 10 IU of oxytocin for the prevention of postpartum hemorrhage, which is an important component of AMTSL. The injection-ready format of oxytocin in Uniject offers some advantages over a standard ampoule and needle-syringe delivery format for the administration of oxytocin for PPH prevention. The main benefits of oxytocin in Uniject already proven by several research studies include:

- **Single dose**—to facilitate outreach to individual patients.
- **Prefilled**—to ensure that the correct dose is given and to simplify 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.

In addition, the oxytocin in Uniject used for the pilot introduction in Guatemala has a time-temperature indicator (TTI). TTIs are similar to vaccine vial monitors used in immunization programs. Because oxytocin is a heat-sensitive drug, a TTI was added to the packaging of each oxytocin in Uniject dose to allow precise monitoring of cumulative temperature exposure.

Oxytocin in Uniject (10 IU) is manufactured by Instituto Biologio Argentino (BIOL), an Argentine pharmaceutical company. BIOL has completed product registration necessary to make oxytocin in Uniject commercially available in Guatemala. The locally appointed distributor is Agefinsa.

[‡] Moccia, P, ed . The State of the World's Children, 2009: Maternal and Newborn Health. New York, NY: United Nations Children's Fund (UNICEF); December 2008. Available at: http://www.unicef.org/sowc09/docs/SOWC09-FullReport-EN.pdf.

Country context

General context:

- Guatemala uses two (5 IU) ampoules of oxytocin for a preventative dose. The cost of the drug itself is fairly inexpensive so typically one 5-IU ampoule and one 10-IU ampoule are similar in cost since most of the cost is in the packaging (glass ampoule).
- The 2006 POPPHI study in Guatemala on the practice of AMTSL found that 87 percent of the facility-based deliveries received a uterotonic drug (oxytocin) during the third or fourth stages of labor. The results of the study showed that 7 percent to 12 percent of deliveries met the definition of AMTSL use.

Procurement:

- The Guatemalan system for procurement of drugs and medical supplies is almost completely decentralized. Purchasing is done by 58 different entities. Thirty-six of these are hospitals, and the remaining 22 are regional health offices that purchase on behalf of smaller facilities. Each hospital as well as regional health office has their own procurement staff and has an annual budgeting plan that is approved by the national government, and there are specific allocations by drug.
- There are two general procurement mechanisms for supplies and drugs purchased for the public sector—open contract and outside of contract. For a drug to be on open contract a supplier must have an agreement with the national government. A drug on open contract is preferable, as the prices are much lower and each procuring entity can go straight to the supplier that is on contract. The process is more extensive if a product is outside of contract, and there are different processes according to the amount purchased. These include: less than Q90,000 (US$10,909) is a direct purchase, between Q90,000 to Q900,000 (US$10,900 and US$109,090) requires a quotation, and anything above Q900,000 (US$109,090) requires competitive bidding.
- Regardless of the type of contract (open contract or outside of contract) each of the 58 procuring entities issue their own tenders and prices among entities can vary.

Logistics:

- In-country distributors are responsible for delivering supplies/drugs directly to each hospital and to each regional health office. Each regional health office has their own storage facilities and then delivers supplies/drugs to each lower-level facility on a monthly basis. This is the only transportation and storage that is undertaken by MSPAS.
- Because supplies and drugs are delivered directly from the private in-country distributor to the hospitals and regional health offices, they must have their own storage capacity, as they receive fairly large shipments at a time (i.e., for one year or six months). This means that the oxytocin in Uniject will likely need to be stored for some time, making cold chain storage more pertinent because of the necessary shelf life.

- The POPPHI study, referenced above, found that there is substantial variation in the storage recommendations for oxytocin in ampoules (including room temperature), actual storage conditions also varied, with 13 percent of facilities storing oxytocin at room temperature. Recommended storage practices vary by manufacturer and are specified on the product label.

Training:

- Health care workers are commonly rotated among departments at all facility levels so training on the Uniject device would be required as part of standard refresher training.

Objectives of the study

The specific objectives of this cost analysis were to estimate the program costs of introducing oxytocin in Uniject as compared to the current delivery system using ampoules and syringes for the prevention of postpartum hemorrhage. The components of the analysis include:

1. Estimating the incremental costs to the system, as well as incremental cost per dose delivered.
2. Performing a cost profile that provides a summary of the program costs of introducing oxytocin in Uniject by cost category and type of input. Specifically, the analysis will present costs allocated to: (1) start-up costs, such as planning and training; and (2) recurrent costs associated with each delivery method, including breakdowns for supplies, personnel, transport and storage.
3. Providing projections for wider introduction needs based on average annual procurement for a typical-size regional hospital, a typical-size district hospital, and a typical-size health center to estimate overall facility costs.

In addition, this analysis estimates the up-front financial costs needed for introduction, including training and cold chain costs.

Study design

Study sites:

The study team visited six health facilities and one regional health office participating in the pilot introduction study in the state of Alta Verapaz. Costs were obtained from three hospitals and one regional health office. Quantitative data were collected from the six facilities and one office. The costs collected, infrastructure and logistics, as well as procurement processes of these facilities are considered representative of other facilities in Guatemala.

Table 1: Health facilities that participated in the pilot study.

Health facility	Type of health facility
Centro de Atención Permanente/Center for Permanent Attention (CAP) of Chisec	Primary-level health center
CAP of Carchá	Primary-level health center
Centro de Atención Integrada Materno Infantil/Center for Integral Attention of Maternal and Child Health (CAIMI) de San Cristobal	Secondary-level health center
Hospital of Coban	District level hospital
Hospital of La Tinta	District level hospital
Hospital of Fray Bartolomé	District level hospital
Total	**6 health facilities**

Ethical approval

The protocol for this cost analysis was submitted to the Research Determination Committee at PATH that determined it was not considered a research activity requiring ethics review.

Methods

The cost models use costs collected from the facilities participating in the pilot introduction study to estimate the per-dose and national-scale introduction costs for one year. The model evaluated incremental costs, assessing only cost categories that will change as a result of introduction of oxytocin in Uniject.

The costs collected were extrapolated to reflect country-wide costs. At each facility, the following costs were collected:

- Cost of oxytocin in ampoules in 2009 and projected cost for 2010.
- Cost of needles and syringes used to deliver oxytocin (standard disposable 3-ml syringes and 22- to 25-gauge needles).
- Cost of any cold chain equipment recently purchased for the storage of oxytocin.
- Costs of any cold chain maintenance incurred in the last five years.
- Costs for transportation of drugs and supplies related to the delivery of oxytocin for the prevention of PPH.

When relevant costs were not incurred at the facility level, the study team worked with the national MSPAS team to determine either direct national MSPAS costs or the best proxy. For example, since MSPAS training costs were not readily available, the costs associated specifically with training for the pilot introduction study were used. The model estimates that there would be one training session with three trainers for each hospital (36 sessions of three days each) and one training session with two trainers that would cover the CAPs and CAIMIs under each health

coordination office (22 sessions, three days each). Additionally, because oxytocin in Uniject is likely to be introduced within the context of refresher AMTSL training, of which only a small portion (30 percent) of each training session is dedicated specifically to training in use of the oxytocin in Uniject device. The model assumes that the benefit of the training is spread out over five years. Any recurrent training needed is incorporated into the existing system and does not incur additional costs.

To reflect the opportunity costs of committing resources for capital items, the cost of cold chain equipment were annualized over ten years using a 3 percent discount rate.

The exchange rate used was US$1 to Q8.25.

Input on use and cost data were collected through interviews with responsible personnel from each facility using data collection tools that were previously developed. A procurement officer from MSPAS participated in the interviews at each level and facilitated in the study team's understanding of procurement and distribution processes in Guatemala. In addition to asking targeted questions about costs, the study team also posed broader questions on potential impact of introduction and related processes and recorded observations of cold chain storage at the facilities.

In addition, to estimate the feasibility and logistical impact related to wide-scale introduction of oxytocin in Uniject, data and information were collected from each facility and regional health office on:

- Procurement, distribution, and storage of drugs and supplies including associated costs and responsibilities of each (i.e. national MOH vs. facility vs. private sector distributor, for example).
- Occurrence of stock-outs of drugs and supplies and the processes for procuring additional supplies, as well as associated costs.
- Infrastructure of facilities related to cold chain capacity.
- Evaluation of current scenario of storage and use of oxytocin in ampoules.
- Potential considerations or issues related to scale-up of oxytocin in Uniject.

The health output used in the cost analysis is the number of women with vaginal deliveries taking place at health facilities (Table 2). The model assumes that all women who deliver vaginally in facilities would be given one dose of 10 IU of oxytocin in Uniject for PPH prevention. The denominator used to estimate cost per dose is the MSPAS number of public-sector facility-based vaginal births for 2008. Women who received a cesarean operation were excluded from this number (a known 31 percent of hospital births and an estimated 5 percent of smaller facility births). An additional 5 percent was added per year (2009 and 2010) to account for national population growth and the trend of increasing facility based births because of the new government social program "Mi Familia Progresa" to encourage facility rather than community-based births with the goal of reducing the country's maternal mortality rate.

Table 2: Number of vaginal births in public sector facilities.

Vaginal births by year in public-sector facilities	
2008	107,077
2009	112,431
2010	118,052

Scenario analysis:
To estimate the future costs of introducing oxytocin in Uniject, PATH used scenario analysis to vary the price of oxytocin in Uniject. In addition, to accommodate different scenarios for cold chain capacity, costs were estimated for three potential scenarios of cold chain capacity, reflecting the potential variations needed once a wider-scale review is conducted and MSPAS determines the feasibility of using existing systems.

Data from the cost study was entered and analyzed in MS Excel.

Findings

Costs within the current system

Drugs and supplies:
Although the country of Guatemala has made an effort to increase resources to address maternal mortality, some of the smaller health facilities visited had stock-outs of oxytocin for an entire year. No problems with stock outs of syringes were reported. Some reasons for the stock-outs of oxytocin include:

- Limited resources allocated to the purchase of essential medicines.
- An unplanned increase in the number of births attended at public health facilities because of government initiatives to encourage women to deliver in facilities.
- A relatively complicated procurement system that can result in delays in the purchase of medicines.

In 2009 oxytocin in ampoules was not under open contract with MSPAS. Thus, under the direct-purchase system, health facilities visited were quoted various prices per 5-IU ampoule depending on the size and date of their orders. Prices quoted by facility personnel range from Q3.15 to Q5 per 5-IU ampoule. In 2010, oxytocin reverted to open contract status with a price of Q 1.03.

The weighted average price per 5-IU ampoule of oxytocin under the out of contract, direct purchase system for MSPAS hospitals in the pilot study is Q3.16 (Table 3). The weighted average price per 5IU ampoule of oxytocin under the direct purchase system for the MSPAS coordination office visited in the pilot study is Q3.63. The weighted average price per 5IU ampoule of oxytocin across all health facilities visited is Q3.38.

Similarly, the weighted average price per 3-mL syringe under the open contract for MSPAS hospitals and coordination office is Q0.49 and Q0.34, respectively. The weighted average price per 3-mL syringe across all health facilities visited is Q0.42. Oxytocin in ampoules with needle

and syringe in 2009 was Q7.60 per dose in health centers and Q6.81 per dose in hospitals. The cost in 2010 is estimated at Q2.40 in health centers and Q2.55 in hospitals (Table 3).

For a national estimate of the drug and supply costs, we estimated the costs for 36 hospitals across the country where births occur and 22 regional health coordination offices that place all orders for drugs and supplies for the smaller health facilities that attend births (CAPs and CAIMIs). Using the unit cost data for hospitals and facilities shown in Table 4, the 2009 total drug and supply cost estimate for all MSPAS facilities in Guatemala attending births is Q775,351 to deliver 112,431 prophylactic oxytocin doses (consisting of two 5-IU ampoules and 1 3-mL disposable syringe).

Table 3. Weighted average cost per dose of oxytocin in ampoules and syringe (amounts shown in Guatemalan quetzales).

Cost category	2009		2010	
	CAPs / CAIMIs	Hospitals	CAPs / CAIMIs	Hospitals
Ampoule (5 IU)	3.63	3.16	1.03	1.03
Syringe (3 mL)	0.34	0.49	0.34	0.49
Total cost per dose (2 5-IU ampoules + 1 3-mL syringe)	7.60	6.81	2.40	2.55

Table 4. Estimated unit and total costs for oxytocin in ampoules in 2009.

	Hospitals	CAPs/CAIMIs	TOTAL (MSPAS)
Unit cost per dose (Q)	6.81	7.60	
Quantity	100,001	12,430	112,431
Total cost (Q)	681,007	94,344	775,351

Cold chain and transport:

None of the facilities visited reported any cold chain maintenance costs in their budgets over the last five years. In addition, only one facility had purchased a new refrigerator (at Q2,700) in the past five years to expand their cold chain capacity. Monthly cold chain maintenance costs (e.g., electricity costs) were considered negligible as these were not a line item in facility budgets.

Transport costs for oxytocin in ampoules are also negligible as the hospitals currently receive drugs and supplies directly from the distributor, and the CAPs and CAIMIs receive oxytocin in ampoules and syringes within larger supply shipments provided by the health coordination offices. In most cases, oxytocin in ampoules is currently transported and stored outside the cold chain, and there are no plans within MSPAS to alter this delivery approach in the future.

In summary, cold chain or transport costs for oxytocin in ampoules were either not recorded or incurred by facilities so these costs were not estimated in the model.

Costs associated with the use of oxytocin in Uniject

This section presents the results for the baseline estimate for oxytocin in Uniject, along with alternate scenarios that allow for lower and higher prices for oxytocin in Uniject, and different scenarios for the cold chain capacity.

Estimated costs of oxytocin in Uniject:
Three cost estimates have been used in the model for the unit cost of oxytocin in Uniject: Q 8.25, Q9.90, and Q11.55 (Table 5). As of Q4 2009, the Argentine manufacturer indicated that their selling price would be under Q8.25. The range of Q8.25 to Q11.55 would include the additional costs of shipping, taxes, import duties and distributor margins. The baseline scenario taken was the middle cost of Q9.90.

Table 5. Oxytocin in Uniject cost scenarios.

	Quetzales	USD
Baseline	9.90	1.20
Scenario 1	8.25	1.00
Scenario 2	11.55	1.40

Future scenarios—cold chain costs:
All secondary- and primary-level facilities visited had sufficient cold chain capacity to store the oxytocin in Uniject while third-level facilities (hospitals) did not. The reasons for lack of cold chain storage space included: high service volume, procurement of enough drugs to cover extended periods of time (i.e., six months). Additionally, the hospitals visited were storing oxytocin in ampoules out of the cold chain. For these reasons, there would likely be cold chain storage constraints at the hospitals visited; this may require increased investment in cold chain equipment to accommodate scale-up of oxytocin in Uniject across all MSPAS facilities. Thus, the model factors in three different scenarios to address cold chain needs for a scale-up at the hospital level:

1. Baseline. Partial additional cold chain costs: The model assumes that one-third of hospitals will have to incur the cost of a single additional storage unit (refrigerator) for storage of oxytocin in Uniject.
2. Optimistic. No additional cold chain costs: The model assumes that hospitals will find ways to incorporate storage of oxytocin in Uniject into their current cold chain capacity. For example, MSPAS may be able to use the vaccine cold chain system.
3. Conservative. Significant additional cold chain costs: The model assumes that all hospitals will have to incur the cost of a single additional storage unit (refrigerator) for storage of oxytocin in Uniject.

The model uses the price paid by the Coban Regional Hospital for a new, 400-L, standard upright refrigerator in 2009 (Q2,700) as an average cost and assumes a useful lifespan of ten years for a new refrigerator. For the baseline scenario, MSPAS would need to purchase 12 new refrigerators for a total additional cold chain storage cost of Q32,400 and an annualized financial cost of Q3,240. The resulting additional cost per dose of administered oxytocin in hospitals is approximately Q0.03 (Table 6). These costs would rise to Q97,200 up front, or an annualized

financial cost of Q9,720 in the conservative scenario 3 in which all 36 hospitals would require one additional refrigerator unit. The additional cost per dose would then be Q0.09.

Table 6. Estimated cold chain costs and additional cost per dose for 2010.

	# of hospitals needing additional cold chain capacity	Estimated additional units required per hospital	2009 Estimated unit price of new 400-L refrigerator (Q)	Total costs for cold chain (Q)	Additional cost per dose (Q)
Baseline	12	1	2,700	**32,400**	**0.03**
Optimistic	0	0	2,700	**0**	**0**
Conservative	36	1	2,700	**97,200**	**0.09**

Transport costs:
In the model, no costs were added for the transportation of oxytocin in Uniject from regional health offices to the CAPs and CAIMIs. Personnel from the regional health office felt that there was sufficient transportation capacity for oxytocin in Uniject to be delivered with vaccines. Alternatively, oxytocin in Uniject could be delivered out of the cold chain because the TTI offers more flexibility in transportation as it registers cumulative heat exposure.

Given the current method of transporting oxytocin in ampoules outside the cold chain, the inclusion of a TTI on the packaging of oxytocin in Uniject, and the relatively short periods of time for transport between facilities, it was determined that there would likely not be any significant scale-up costs incurred by MSPAS around the cold chain for transport of oxytocin in Uniject.

Training costs for oxytocin in Uniject:
The MSPAS training system does not use a "train the trainer" type system. Rather, there is a staff of 15 MSPAS trainers that travel to each hospital, CAP, or CAIMI and provide training directly to the health care workers. MSPAS has indicated that they foresee oxytocin in Uniject being scaled-up within the broader context of refresher AMTSL training, which is reflected in the cost per dose estimates below unless otherwise stated. Costs for the full AMTSL refresher training includes training on oxytocin in Uniject. Cost estimates around training for oxytocin in Uniject only are calculated as a percentage of the broader overall costs for AMTSL refresher training within MSPAS. The model assumes that no additional refresher training beyond what is planned for introduction would be needed, other than what is already taking place within MSPAS.

Total training costs for full AMTSL training including lodging, food, and per diem for trainers, all training materials, and transportation costs amount to approximately Q15,950 per large session (e.g., organized at hospitals) and Q12,500 per smaller session (e.g., organized at regional health coordination offices).

Since per diem, lodging, food, and transportation costs were not broken down by type of training facility, total training costs for the entire MSPAS were estimated assuming one larger training session per hospital and one smaller training session for CAPs and CAIMIs. Dividing this total cost by the estimated number of women giving birth vaginally through MSPAS facilities provided an average annualized training cost per woman of Q1.44 for the full AMTSL training,

including oxytocin in Uniject, or an incremental training cost of Q0.43 for the oxytocin in Uniject training portion only (Table 7).

Table 7. Estimated training costs for oxytocin in Uniject for 2010.

Estimated costs (2010)	Total cost (Q)	Number of women reached	Average annualized cost per woman reached (Q)
Cost of full AMTSL training across all facilities (includes cost of oxytocin in Uniject training).	849,200	118,052	1.44
Cost of training for oxytocin in Uniject alone (assumes no broader AMTSL refresher training).	254,760	118,052	0.43

Cost per dose analysis for oxytocin in Uniject:
The cost per dose for oxytocin in Uniject for AMTSL was estimated using the baseline cost of Q9.90 (US$1.20) and two different price levels. In addition, three cold chain scenarios were estimated for hospitals only, where cold chain requirements may be affected.

In the CAPs and CAIMIs, training for oxytocin in Uniject within the context of AMTSL adds Q1.44 per dose (if training were on oxytocin in Uniject only, costs would be 30 percent of the training costs of AMTSL, or Q0.43). Cold chain costs are negligible as there are no additional cold chain requirements for CAPs and CAIMIs. The result is an oxytocin in Uniject per-dose cost in the baseline scenario of Q11.34 (Table 8). The per dose price in hospitals is Q11.37, which reflects the cost of oxytocin in Uniject plus the cost of training and an additional Q0.03 per dose for cold chain costs.

Table 8. Cost per dose analysis—baseline.

Cost category	CAPs/CAIMIs (Q)	Hospitals (Q)
Full AMTSL Training	1.44	1.44
Oxytocin in Uniject portion only	*0.43*	*0.43*
Cold chain	0	0.03
Supplies (oxytocin in Uniject)	9.90	9.90
Total cost per dose	**11.34**	**11.37**

The cost per dose for the different price levels can range from as low as Q9.69 to as high as Q13.02. For further details refer to Appendices A and B containing Tables A1 and B1.

Comparative cost analysis between oxytocin in Uniject and oxytocin in ampoules and syringe:
The cost per dose of oxytocin in Uniject is compared to the 2009 and the 2010 cost per dose of oxytocin in ampoules with needle and syringe (as shown in table 3) because of the significant oxytocin price variations between 2009 and 2010 (as oxytocin in ampoules is under contract in 2010).

Table 9 presents the incremental costs of using oxytocin in Uniject compared to the current system with oxytocin in ampoules with needle and syringe. Providing full AMTSL training and using the baseline cold chain costs, the incremental cost for oxytocin in Uniject is Q3.74 for 2009 prices and Q8.94 for 2010 prices in CAPs and CAIMIs. The incremental cost of using oxytocin in Uniject over oxytocin in ampoules in hospitals is Q4.56 (2009) and Q8.82 (2010).

Table 9. Incremental cost analysis with baseline assumptions.

	2009 cost per dose (Q)		2010 cost per dose (Q)	
	CAPs / CAIMIs	Hospitals	CAPs / CAIMIs	Hospitals
Oxytocin in ampoules with needle and syringe	7.60	6.81	2.40	2.55
Oxytocin in Uniject	11.34	11.37	11.34	11.37
Incremental cost difference	+3.74	+4.56	+8.94	+8.82

With the different pricing levels and scenarios, the incremental cost per dose can range from as low as Q2.09 compared to 2009 prices in CAPs and CAIMIs, to as high as Q10.47 when compared to 2010 prices in hospitals. For additional details, refer to Appendix B and Tables B1 and B2.

Projections of number of units of oxytocin in Uniject for introduction needs:
Projections for the average procurement needs for a typical-size regional hospital, a typical-size district hospital and a typical-size health center are based on the annual projected number of vaginal births for the facilities that participated in the pilot (Table 10). Past procurement of oxytocin in ampoules was not used as a reference, since oxytocin can be used for augmentation, induction, and treatment, and thus is not reflective of the needs for a prophylactic dose for PPH prevention for vaginal births only.

Table 10. Projections for number of units of oxytocin in Uniject for 2010 annual procurement by facility type.

Type of facility	Average projection of vaginal births (2010)	Reserve units (10%)	Procurement needs per year
Regional Hospital	5540	554	6094 units
District Hospital	1393	139	1532 units
CAP/CAIMI	690	69	759 units

Projections of units for national scale-up:
Projections for national introduction in all facilities were calculated according to the estimated total number of women that will be reached in 2010; the estimated total number of women that will be reached in 2010 is 118,052 (Table 2). Therefore, MSPAS would need to procure a total of 129,857 units of oxytocin in Uniject (including a 10 percent reserve).

Upfront financial costs:
The total up-front financial costs for the baseline scenario (cost of Q9.90 for oxytocin in Uniject and one new refrigerator for every three hospitals) is Q2,167,191 for the full AMTSL training or Q1,572,751 for oxytocin in Uniject training only (Table 11).

Training costs were not separated by costs for hospitals and costs for smaller level health centers. Only recurrent costs specific to capital costs (cold chain equipment) and supplies were broken out according to facility type.

Table 11. Baseline scenario, up-front costs.

Baseline Scenario		
	CAPs and CAIMIs and hospitals (Q)	
Training		
Full AMTSL	849,200	
Oxytocin in Uniject only	254,760	
	CAPs and CAIMIs (Q)	**Hospital (Q)**
Capital		
Cold chain	0	32,400
Supplies		
Oxytocin in Uniject	142,134	1,143,456
Totals	**All Facilities**	
Full AMTSL training	**2,167,191**	
Oxytocin in Uniject only	**1,572,751**	

If oxytocin in Uniject were more economical, (Q8.25) then the total cost would be reduced by Q225,033. At a higher price (Q11.55) there would be an additional cost of Q214,265.

Limitations:
This cost analysis was meant primarily to provide a comparison of oxytocin in Uniject to the use of oxytocin in ampoules under the 2009 out of contract procurement status of oxytocin in ampoules. Given the complexity of the MSPAS procurement system and the return of oxytocin in ampoules to being on contract in 2010, the incremental costs vary widely.

In addition, certain costs and other factors (e.g., cold chain electricity costs, population growth, etc.) were not figured into the analysis for reasons of simplicity and lack of availability of data.

Disposal of Uniject devices is done in the same manner as disposal of used syringes, depending on the location. Despite Uniject devices being smaller in volume than traditional needles and syringes, no saving in waste disposal costs was assumed for the model due to low volumes.

Finally, some of the costs estimated across MSPAS are based upon incomplete information and/or from the limited number of facility visits conducted by the study team. Data collected from the study sites may or may not be reflective of other facilities of the same size throughout the country. While the study team attempted to use accurate and realistic methods and data for this analysis, it should be noted that this analysis is meant to provide more of a qualitative view of the incremental costs rather than a quantitative verification of current MSPAS cost differences.

Discussion

Oxytocin in Uniject was used at six MSPAS facilities in the state of Alta Verapaz for prevention of PPH during AMTSL. These same facilities served as sources of information for a cost analysis to estimate the program costs of introducing oxytocin in Uniject at a national scale compared to the current delivery system using ampoules and syringes for the prevention of PPH.

Based on the costs modeled for this study, oxytocin in Uniject will increase the cost of a preventative dose of oxytocin during AMTSL at all facility levels in Guatemala. Depending on the supply price of oxytocin in Uniject and investments needed in cold chain, the per-dose cost ranges from Q9.69 to Q13.08 (US$1.17 to US$1.59). The maximum incremental per-dose increase in cost compared to current practice (looking at both 2009 and 2010 costs) could range from Q2.09 to Q10.53 (US$0.25 to US$1.28), respectively. The estimated increase in cost per dose as compared to ampoule and syringe will vary depending on different scenarios that include the price of oxytocin in Uniject and cold chain capacity at the national level.

The price of oxytocin in Uniject is not yet established, and it is reasonable to expect that the price could decrease as market demand increases. Additionally, the incremental price attributed to cold chain costs could be reduced by using new cold chain equipment for other purposes such as storing other medications that also require controlled temperature. This can spread out the cost of adding additional equipment required for cold chain for reproductive health purposes.

Despite the increase in cost, oxytocin in Uniject offers benefits over ampoules and syringes that are not easily quantified. National-level decision-makers should consider these benefits as they weigh the trade-off with incremental costs of scaling up the use of oxytocin in Uniject. These include current benefits such as:

1. Ease of use by health providers and improved availability and quality of AMTSL services.
    - Decreased time to prepare medication. Oxytocin in Uniject eliminates the need to break open two ampoules and fill a syringe, saving time which is particularly important for facilities where birth attendants work alone. This ease of preparation can improve the chances that the provider administers the dose of oxytocin according to standard (i.e., within one minute after birth of the baby).
    - Exact dose administered to mothers. The Uniject syringe is prefilled with the recommended 10 IU for PPH prevention, which increases the chances that the

provider consistently and accurately administers the correct dose of oxytocin for AMTSL.

- Ability for lesser-trained community health volunteers to administer a prophylactic dose in communities, which could be a potential future scenario of use.
- Decreased injury to health workers from opening the ampoules.

2. Additional training to health providers on AMTSL. Introduction of oxytocin in Uniject in health facilities needs to be accompanied by a strategy to educate providers on proper use within the context of AMTSL. This training and capacity building of providers could evolve into better adherence to proper practices of AMTSL.
3. Ensures potency of oxytocin administered through the use of a TTI.
4. Eliminates the risk of needle reuse.

Recommendations

Oxytocin is the recommended uterotonic for PPH prevention by the World Health Organization. Oxytocin in Uniject is an alternative mechanism to deliver the dose of oxytocin for PPH prevention that is both effective and acceptable.

While oxytocin in Uniject is more expensive than current practice, the decision to move forward with introduction should consider the value obtained from the device—especially for certain scenarios of use or within the context of increased government efforts aimed at reducing the prevalence of postpartum hemorrhage. Oxytocin in Uniject is a simple, easy-to-use, prefilled injection device that facilitates the administration providing a prophylactic dose of oxytocin in the context of AMTSL where facilities are often working with few staff to attend to both the mothers and the babies.

The benefits of oxytocin in Uniject could also facilitate additional future scenarios of use in communities, expanding an important health intervention (administration of prophylactic oxytocin) that is not otherwise reaching these populations. Successfully reaching even a portion of the 58 percent of women that currently deliver in communities population would be a significant step forward in reducing maternal mortality in Guatemala.

In light of the study findings, we recommend that Guatemala consider the following:

- Review the budgeting and forecasting processes to reflect the increase in use of health services due to government efforts to increase institutional births and to avoid critical stock-outs of oxytocin.
- Consider developing a process that would enable regional health offices to make an emergency purchase of small amounts of life saving drugs when there is a stock-out of an essential medicine and they do not have the budget.
- Review the quality assurance process to ensure that heat-sensitive drugs imported and distributed into the country have proper labeling and that they adequately indicate storage requirements.

The follow next steps are suggested in the event that Guatemala decides to move forward with wide-scale introduction of oxytocin in Uniject:

- Engage with the stakeholder community to determine what support for introduction may be available, including financial, planning, and logistical support.
- Further assess the cold chain capacity at the hospital level to determine what cold chain investments would be required for introduction of oxytocin in Uniject (or if these additional costs could be offset by other means).

In conclusion, decisions about purchase and provision of oxytocin in Uniject for PPH prevention will depend on multiple factors in addition to cost. These factors include health impact, affordability, sustainability, programmatic capacity, and competing priorities. Based on the findings of this cost study as well as the pilot introduction study, we recommend that Guatemala considers national adoption of oxytocin in Uniject to further enhance the country's strategy on PPH prevention. New technology introduction always has an associated cost. International and local support from donors and cooperating agencies would be required to assist Guatemala in its efforts to introduce this technology in the context of the country's PPH-prevention strategy.

Appendix A: Results for cost per dose according to different oxytocin in Uniject price scenarios.

Scenario 1 assumes a supply price for oxytocin in Uniject of Q8.25. This would then mean an incremental cost per dose for CAPs and CAIMIs of Q9.69 and for hospitals of Q9.72. Scenario 2 assumes a supply price for oxytocin in Uniject of Q11.55, which results in an incremental cost per dose of Q12.99 and Q13.02 for CAPs and CAIMIs and hospitals respectively (Table A1).

Table A1. Oxytocin in Uniject price scenario analysis.

Scenario	Oxytocin in Uniject price assumption (Q)	Total cost per dose (Q)	
		CAPs and CAIMIs	Hospitals
Scenario 1	8.25	9.69	9.72
Scenario 2	11.55	12.99	13.02

The additional cold chain scenarios for hospitals would bring the cold chain costs down from Q0.03 in the baseline case to zero in the optimistic case, or raise the cold chain costs to Q0.09 per dose in the conservative case. The result is an oxytocin in Uniject total cost per dose in the baseline scenario that varies from Q11.34 to Q11.43, and in the two different oxytocin in Uniject price scenarios from Q9.69 to Q13.08 (Table A2).

Table A2. Additional cold chain scenario analysis—hospitals only.

Scenario	Oxytocin in Uniject price assumption (Q)	Total cost per dose (Q)	
		Optimistic	Conservative
Baseline	9.90	11.34	11.43
Scenario 1	8.25	9.69	9.78
Scenario 2	11.55	12.99	13.08

Appendix B: Results for cost comparison for different oxytocin in Uniject price scenarios compared to oxytocin in ampoules and syringes.

The cost per dose of oxytocin in Uniject was compared to the 2009 and the 2010 costs of oxytocin in ampoules (with needle and syringe) because of the significant cost variations between 2009 and 2010 (as oxytocin in ampoules is under contract in 2010). The cost for a dose of oxytocin in ampoules with needle and syringe in 2009 was Q7.60 for CAPs and CAIMIs (CAPs and CAIMIs) and Q6.81 for hospitals. The cost in 2010 is estimated at Q2.40 for CAPs and CAIMIs and Q2.55 for hospitals.

The comparative cost analysis presents a more promising picture under oxytocin in Uniject price Scenario 1 in which oxytocin in Uniject is estimated at a supply cost of Q8.25, and a less encouraging situation under Scenario 2 in which oxytocin in Uniject is estimated at a supply cost of Q11.55. At the lower price, the incremental cost is Q2.09 in 2009 and Q7.29 in 2010 for CAPs and CAIMIs, and Q2.91 in 2009 and Q7.17 in 2010 for hospitals. Scenario 2 results in an incremental cost of Q5.39 in 2009 and Q10.59 in 2010 for CAPs and CAIMIs, and Q6.21 in 2009 and Q10.47 in 2010 for hospitals (Table B1).

Table B1. Comparative cost analysis—Oxytocin in Uniject price sensitivity analysis compared to oxytocin in ampoules and syringes.

	2009 cost per dose (Q)		2010 cost per dose (Q)	
	CAPs and CAIMIs	**Hospitals**	**CAPs and CAIMIs**	**Hospitals**
Oxytocin in ampoules with needle and syringe	7.60	6.81	2.40	2.55
Oxytocin in Uniject price scenario 1				
Total cost per dose	9.69	9.72	9.69	9.72
Incremental cost difference	+2.09	+2.91	+7.29	+7.17
Oxytocin in Uniject price scenario 2				
Total cost per dose	12.99	13.02	12.99	13.02
Incremental cost difference	+5.39	+6.21	+10.59	+10.47

The additional cold chain scenarios for hospitals cause further variation in the incremental costs per dose. For the baseline case in 2009, the incremental cost per dose in the optimistic scenario drops to Q4.53. In the conservative scenario for 2009, the incremental cost per dose increases to Q4.62. For 2010, the incremental cost per dose equals Q8.79 for the optimistic scenario, and Q8.88 for the conservative scenario. Incremental costs per dose for the different oxytocin in Uniject price scenarios vary from Q2.88 in 2009 for the optimistic scenario to Q10.53 in 2010 for the conservative scenario (Table B2).

Table B2. Incremental cost analysis—cold chain scenarios, hospitals only.

	2009 cost per dose (Q)		2010 cost per dose (Q)	
Oxytocin in ampoules with needle and syringe	6.81		2.55	
	Optimistic	**Conservative**	**Optimistic**	**Conservative**
Oxytocin in Uniject price baseline				
Total cost per dose	11.34	11.43	11.34	11.43
Cost difference	+4.53	+4.62	+8.79	+8.88
Oxytocin in Uniject price scenario 1				
Total cost per dose	9.69	9.78	9.69	9.78
Cost difference	+2.88	+2.97	+7.14	+7.23
Oxytocin in Uniject price scenario 2				
Total cost per dose	12.99	13.08	12.99	13.08
Cost difference	+6.18	+6.27	+10.44	+10.53