A HealthTech Report

Technical Assistance Visit to Guatemala for Pilot Introduction of Oxytocin in the Uniject® Device

November 4, 2009

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Technical Assistance Visit to Guatemala for Pilot Introduction of Oxytocin in the Uniject[®] Device

Country visited: Guatemala

Date of visit: October 25, 2009, to November 4, 2009

Technical assistance providers:

Gloria Metcalfe (POPPHI) Erica Jacoby (HealthTech) Shirley V. Carter (HealthTech) Mark Guy (HealthTech)

I. Objectives:

- 1. Perform monitoring visits for pilot implementation of oxytocin in the Uniject^{®*} device (oxytocin in Uniject) in Alta Verapaz.
- 2. Collect cost data related to introduction of oxytocin in Uniject in Guatemala.
- 3. Develop an understanding of the logistics related to scale-up (i.e., storage, transport, and procurement).
- 4. Work with the Ministry of Health of Guatemala (MOH) and other stakeholders to determine next steps related to national scale-up of oxytocin in Uniject in Guatemala.

II. Background information

A pilot introduction study of oxytocin in Uniject as a component of active management of the third stage of labor (AMTSL) at the institutional level was initiated in September 2009 in the state of Alta Verapaz. Health providers, personnel from the pharmacy, as well as supervisors of facilities were trained in the use of oxytocin in Uniject as a component of AMTSL. The study is being implemented by the MOH, Health Care Improvement (HCI) and Asociacion de Ginecologia y Obstetricia de Guatemala (AGOG). PATH is assisting the implementation team with the evaluation component of the study, the supply of product needed during the pilot project, and the collection of cost data related to scale-up of oxytocin in Uniject.

III. Summary of findings

Monitoring visits for pilot implementation of oxytocin in Uniject in Alta Verapaz

The group visited all six facilities that are participating in the pilot project. The objectives of the visit to the facilities were:

- Evaluate the use of oxytocin in Uniject as a component of AMTSL.
- Assess practical use of AMTSL.
- Collect cost information related to oxytocin in Uniject and oxytocin in ampoules.

^{*} Uniject is a registered trademark of BD.

Understand the logistics pertaining to scale-up.

Information collected during the monitoring visit to Alta Verapaz is summarized in Annex 1.

Observations

Storage

- Oxytocin in Uniject was stored in the cold chain (between 2°C and 8°C) in all facilities visited.
- In general, oxytocin in Uniject was stored with other medications that also require cold chain storage. We observed that even the laboratory and delivery room has either a refrigerator or a cold box to temporarily store the oxytocin required to attend births.
- The hospitals of Fray Bartolome and Coban have utilized their maximum cold chain storage space and see capacity as a challenging issue if oxytocin in Uniject were to replace ampoules.





Storage of oxytocin in Uniject at the Hospital of Coban

There is a cold chain crisis at the regional coordinating office. This office does procurement of medicines and supplies for Centros de Atencion Permanente (CAPs), Centros de Atencion Inmediata Materno (CAIMIs), and health posts. Employees at this office mentioned that when they receive vaccines there is not sufficient space to store any other medication that requires the cold chain.

Training

The majority of people attending births at the six health facilities are trained in the use of oxytocin in Uniject in the context of AMTSL. However, in most institutions, there were still people that could not be trained due to conflicts in their schedules. Most of these personnel are physicians that work only during nights at the facilities or new staff (rotation is high).

Use of oxytocin in Uniject

The auxiliary nurses and the nurses that were interviewed are using oxytocin in Uniject according to the instructions. In only two facilities (Hospital of La Tinta and Hospital of Coban) we observed that the oxytocin in Uniject is being recapped, which is contraindicated. We provided refresher training in biosafety measures at these facilities.





Waste management and recapping of oxytocin in Uniject at the Hospital of Coban

- Oxytocin in Uniject is being used exclusively for prevention of postpartum hemorrhage (PPH) in all vaginal births at the participating health facilities. Even though the protocol for the pilot project specifies that during the three-month pilot introduction health facilities would use oxytocin in Uniject for both vaginal births and C-sections, the Hospital of Coban and Hospital of La Tinta are not using the prevention dose for Csections. Reasons for this change of plans are:
 - o *Low stock*. This is the case at Hospital of La Tinta where the number of births has increased in the past year. The amount of doses calculated for the pilot were not enough to cover the increased demand; therefore the hospital administration decided to use the oxytocin only for vaginal births.
 - Logistics. This is the case at the Hospital of Coban where there is no place to store the oxytocin in the cold chain in the surgery room. Also, they use oxytocin in the IV fluids and consider this to be easier than to provide an IM injection (as is specified in the protocol) at the time of the surgery.
- Nurses, auxiliary nurses, and physicians also provided their opinions about oxytocin in Uniject. In general, they see the following benefits for oxytocin in Uniject in comparison to oxytocin in ampoules:
 - o Easier to use than oxytocin in ampoules.
 - Less preparation time. Nurses said that it saves them the normal one to two
 minutes of preparation time for the PPH-prevention dose of oxytocin in
 ampoules.
 - Less wastage of medication. Some nurses and auxiliary nurses said that with oxytocin in ampoules there was more risk to waste product when opening the ampoules.

- Safer. Some nurses said that they had experienced cuts when trying to open oxytocin in ampoules. This risk is completely eliminated with oxytocin in Uniject.
- Easier to account for. Oxytocin is a controlled product in Guatemala.
 Therefore, nurses have to account for every product used. In the past, they had to show the empty glass ampoules to the pharmacy, but with oxytocin in Uniject, they can show the empty envelope, which decreases the risk of biohazard accidents with sharp objects.

Practice and use of AMTSL

- During the visits, no births occurred to allow for direct observation of administration of oxytocin in Uniject. Information about the use of AMTSL with oxytocin in Uniject was obtained by interviews with auxiliary nurses, nurses, and physicians.
- According to their description of how they are practicing AMTSL, only one health facility (Chisec) is practicing it correctly. The use and momentum of the administration of oxytocin in Uniject was well described. Three locations mentioned the uterus massage previous to the delivery of the placenta; none of them (except Chisec) mentioned that they have to wait for a contraction to start the Controlled Cord Traction (CCT). Most of them mentioned that they wait five minutes, and one of them said that the CCT is immediately after the administration of oxytocin in Uniject. The massage of the uterus immediately after the delivery of the placenta was mentioned and recognized as a key action. However, the follow-up required every 15 minutes during the two hours following delivery is not always done due to lack of time or staff.
- We provided refresher training in AMTSL to the nurses, auxiliary nurses, and physicians that were available during the time of the visit. In addition, we reinforced the immediate newborn care, particularly the skin-to-skin practice and principles of infection prevention, which were very poorly practiced.

Stock of oxytocin in Uniject and oxytocin in ampoules

- In general, the number of institutional births in Guatemala has increased due to a new social program created by the government called "Mi Familia Progresa." This program provides a stipend to pregnant women who go to the clinic for prenatal care, who give birth at an institution, and who bring their children in for regular checkups. This increase in demand for services related to births was not estimated during the planning of the pilot project. Therefore some institutions do not have enough stock for the three-month pilot introduction. However, extra doses are still remaining at the regional coordinating office and will be distributed to the institutions that have the low stock.
- There was no supply of oxytocin in ampoules at the three smaller facilities visited (CAPs and CAIMIs). In these institutions, we found a small stock of donated oxytocin (ampoules of 10 IU) that expired October 30, 2009. Reasons for this irregular supply are:
 - A fiscal deficit at the central and district level is impacting provision of required medications for smaller health facilities (there is a 50 percent shortage of medications at these facilities, so the issue does not only pertain to oxytocin).

- Increased demand for services. Government policies to increase the number of hours at CAPs in addition to programs such "Mi Familia Progresa" have increased demand for services at these health facilities.
- o The same budget is allocated to the regional offices despite the increased demand for services.
- Slow procurement processes at the central level. Some of the purchase orders have been at the central level for six months without being processed.

After the visit to Alta Verapaz, we had meetings with the MOH and AGOG to share the results of the visit and to provide guidance for the next monitoring visits in November and December as well as for the final interview. We created a guide document for the interview process (See Annex 2).

Preliminary findings of cost study

Currently, oxytocin in ampoules is not under open contract with the MOH. Thus, under the direct purchase system, health facilities have been quoted various prices per 5-IU ampoule depending on the size and date of their orders. Prices quoted range from Q3.15 to Q5 per 5-IU ampoule. In 2008, oxytocin in ampoules was under open contract and prices ranged from Q1.09 to Q1.24.

Prices for 3-ml syringes (currently under open contract) were found to be either Q0.338 or Q0.64.

The weighted average price per 5-IU ampoule of oxytocin under the current direct purchase system for the MOH is Q3.38. The weighted average price per 3-mL syringe under the current open contract for the MOH is Q0.42. Thus, the MOH is paying a weighted average of Q7.18 per administered dose of oxytocin in ampoules (approximately US\$0.87 per administered dose which consists of two 5-IU ampoules plus one 3-ml disposable syringe).

As mentioned above, only the hospitals appear to have issues with cold chain constraints at the facility level. While the regional coordinating office also had issues with cold chain storage, the full cost model will assume that the time-temperature indicator (TTI) will allow for out-of-cold-chain storage since it is in that office only short-term. The model will factor in three different scenarios to address potential cold chain needs at the hospital level only upon scale-up:

- 1. Optimistic Model: No additional cold chain costs. The model will assume that hospitals will find ways to incorporate storage of oxytocin in Uniject into their current cold chain capacity. For example, the MOH may be able to utilize the vaccine cold chain.
- 2. <u>Likely Model</u>: Partial additional cold chain costs. The model will assume that one-third of the hospitals will have to incur the cost of an additional storage unit (refrigerator) for storage of oxytocin in Uniject.
- 3. <u>Conservative Model</u>: Major additional cold chain costs. The model will assume that every hospital will incur the cost of an additional storage unit (refrigerator) for storage of oxytocin in Uniject.

None of the facilities accounted for cold chain maintenance costs in their budgets. Only one facility had purchased a new refrigerator (at Q2,700) to expand their cold chain capacity, however this new unit was not being used to store oxytocin in Uniject.

The only recurrent costs within the model will be for supplies (although there may be additional recurrent costs associated with specific cold chain scenarios that are still being assessed). For transport, the model will assume that oxytocin in Uniject can either travel safely outside the cold chain with other supply deliveries or that there is currently sufficient capacity to transport oxytocin in Uniject with vaccine deliveries in the cold chain from the health coordination offices to CAPs and CAIMIs.

Summary of logistics/information to consider regarding potential planning for scale-up

- The MOH confirmed that if they roll out oxytocin in Uniject it would be on a national basis for equity reasons.
- The MOH would like to see oxytocin in Uniject introduced within the context of AMTSL, so refresher training in AMTSL along with training on oxytocin in Uniject would need to be planned.
- Scale-up will likely need to done in a phased fashion, as the MOH has 15 trainers and these trainers do all of the training directly (there is no training-of-trainer process). Rollout needs to match training capacity.
- As described above, cold chain is an issue that needs to be further analyzed. Likely some investments will need to be made. However, the MOH mentioned exploring opportunities to share vaccine cold chain space.
- Financing will be an issue that needs to be considered, as the MOH can not even pay for current basic medications, including oxytocin in ampoules.

Meetings with stakeholders to identify next steps

Highlights of meetings with the MOH

- The MOH expressed interest in continuing the use of oxytocin in Uniject in the context of AMTSL beyond the pilot program. The MOH suggested that once the pilot introduction and cost data is analyzed and available that they can make a decision fairly quickly regarding scale-up. This decision is estimated to happen in March of 2010.
- The Sexual and Reproductive Health Program (SRHP) at the MOH considers that oxytocin in Uniject would be an ideal medication to be included in the United Nations Population Fund (UNFPA) channel like contraceptives.
- The MOH reiterated that maternal health continues to be a high priority for Guatemala and that the government is committed to maintain interventions that have proven effective to address maternal mortality.
- The MOH was receptive to PATH donating an additional three months of supply so that there is continuity of supply of oxytocin in Uniject (assuming the MOH wants to scale up the technology).
- PATH and the MOH discussed the best way forward to explore potential donors. Beyond PATH's three-month donation, an additional donation will likely be needed to fill the gap before the MOH can purchase and roll out the product. Ideally the second donation would be larger than PATH's donation so the phased process of scale-up can begin.

- The MOH will take the lead on writing a proposal for this donation. The proposal will be shared with potential donors, including UNFPA.
- The MOH mentioned that potential donors to support the continuation of this project are Canadian International Development Agency (CIDA), the Government of Spain, Banco Interamericano de Desarrollo (IDB), and the Government of Holland.
- The MOH will review options on how to solve the shortage of oxytocin at the facilities.
- Dr. Walter Linares (AGOG) and Dr. Carlos Morales (MOH) were the only monitors attending this meeting, despite that all of the monitors were requested to participate in order to analyze the results of the visit and discuss the providers' interview process for the end of the pilot in December 2009. We strongly emphasized the need to do a follow-up of the refresher training and to ensure the correct and standardized performance of AMTSL practices for all providers attending births during the next two supervision visits to the pilot facilities.

Highlights of meetings with UNFPA

- UNFPA in Guatemala has two main projects:
 - 1. Strengthening institutional capacities to reduce maternal mortality. This program provides training to traditional birth attendants (TBAs) and health workers on techniques to reduce maternal mortality.
 - 2. Procurement of contraceptives, birth kits, C-section kits, and emergency care birth kits. The reusable birth kits are donated to train TBAs, and the other kits are for disaster situations and other emergencies.
- UNFPA works in 7 of the 22 states; these 7 states have the highest mortality rates in the country.
- For a medical product to be part of UNFPA channels, it has to go through a qualification process similar to the WHO prequalification process. UNFPA Copenhagen usually calls for a specific product to be part of the process and the qualification is done there. It is easier to get UNFPA qualification if the product has been WHO prequalified. It was unclear whether the process of obtaining UNFPA qualification could be expedited if the process is initiated in parallel (or staggered) with the WHO prequalification process.
- It takes six months from ordering the product to receive it in country via UNFPA.
- Since oxytocin in Uniject is not on the UNFPA list and because the timing for qualification can take several months, UNFPA proposed some different approaches:
 - OUNFPA Guatemala can decide to be the purchasing agent and can request a tendering for the product. This process can occur even if the product is not UNFPA qualified. In this case, UNFPA can be just an intermediary. This process takes more than six months depending on the quantity and dollar value.
 - O UNFPA can also be a temporary donor of the product if the government of Guatemala decides oxytocin in Uniject is a high priority for the country. To start this process, Guatemala has to submit a proposal to UNFPA outlining the need. In general donors for maternal mortality programs are not open to buying supplies because they want to invest more in institutional capacity. However, if this is considered a priority, it is worth submitting a proposal. The donation process can take approximately 6 months, and it is important to

- consider that UNFPA does not have cold chain capacity and that they do not do local distribution.
- o A combination of the two approaches: Guatemala can submit a proposal for a donation for a couple of months until a tendering process can be put in place.
- Contacts for the UNFPA proposal:

Nadine Gasman (Guatemala country representative of UNFPA) Dr. Alejandro Silva (Reproductive Health Officer of UNFPA) Monica Lay (UNFPA Copenhagen)

Highlights of meetings with USAID Guatemala

- USAID Guatemala maintains its commitment to the project and to envision next steps to ensure that the work continues.
- USAID suggests we connect with some other stakeholders in collaboration with the MOH to seek out opportunities for wide-scale introduction of oxytocin in Uniject in Guatemala. These stakeholders are:
 - o Population Services International (PSI). PSI currently has a large amount of funding directed to improve maternal mortality.
 - o International community. USAID suggested we present the results of the pilot study to the international community in our next visit. This group has resources and is willing to invest in the country. USAID can help to make the link with the international community.
 - o Asociación Pro Bienestar de la Familia de Guatemala (APROFAM). This organization is actively working on maternal health in Guatemala.
 - o Sistema Integrado Atención de Salud. This national institution can help with ideas to strengthen aspects related to the practice of AMTSL in Guatemala.

IV. Recommendations and next steps

Recommendations

- 1. Ensure that all health personnel attending births at the participating health facilities are proficiently trained in AMTSL. To that end:
 - The monitors should provide refresher training in AMTSL every time they visit the health facilities in Alta Verapaz.
 - MOH and AGOG monitors must follow a standardized and competence-based methodology with a checklist and support the practice with real clients as much as feasible or using an anatomic model if needed.
 - o MOH and AGOG monitors should support the providers in the field by implementing an on-the-job training system to ensure that new staff are trained before starting work.
- 2. Continue the dialogue with the MOH to plan for future activities related to introduction of oxytocin in Uniject in the country.
- 3. Provide the facilities that are participating in the pilot project with enough oxytocin in Uniject for three additional months while the government makes a decision and sets up a process for introduction of oxytocin in Uniject in Guatemala.

Next steps

- 1. PATH will follow up with monitors after the next monitoring visit (November 2009) to track improvement of performance of AMTSL practices in the six health facilities.
- 2. PATH will provide a report with preliminary results of the pilot study to the MOH and USAID by mid-November. This report will help the MOH connect with UNFPA in regards to a potential donation of oxytocin in Uniject; it will also help USAID have information when connecting with the international donor community.
- 3. The SRHP at the MOH will put together a proposal for UNFPA for a temporary donation of oxytocin in Uniject.
- 4. PATH, in collaboration with the MOH and USAID Guatemala, will establish links with PSI and APROFAM. Ideally, we will meet with these stakeholders during our next visit.
- 5. PATH will provide a report of the cost study at the end of December.

V. Acknowledgments

We would like to express our sincere appreciation to Dr. Hector Chaclan and Dr. Luigi Jaramillo from HCI for helping us arrange all of the details related to our visit to Alta Verapaz. In addition, we want to thank the research team from the MOH (Dr. Jacqueline Lavidalie, Dr. Carlos Morales, and Dr. Gustavo Batres) for their time and commitment to the project. We would also like to thank Dr. Walter Linares from AGOG and Dr. Fidel Arevalo and Dr. Baudilio Lopez from USAID for their dedicated effort to ensure that our visit was a success.

VI. Annexes

Annex 1: Summary of data collected during monitoring visits to Alta Verapaz.

Annex 2: Guidance document for final interviews (In Spanish)

Annex 3: Trip itinerary

Annex 1: Summary of data collected during monitoring visits to Alta Verapaz.

Institution	Pilot start date	Date of visit	# of people trained	# of births attended since start of the pilot	# of dispensed doses of oxytocin in Uniject	# of doses used since start of the pilot
CAIMI de	Sept 16	Oct 27	31	VB: 63	119	64
San Cristobal				CST: 1		
CAP de	Sept 18	Oct 30	28	VB: 66	184	66
Carcha				CST: N/A		
CAP de	Sept 11	Oct 29	28	VB:93	113	93
Chisec				CST: N/A		
Hospital	Sept 14	Oct 28	15	VB:	260	Info pending
de la Tinta				Pending		
				CST*:		
Hospital	Sept 19	Oct 29	41	VB:109	666	168
de Fray				CST: 59		
Bartolome				CS1. 37		
Hospital	Sept 10	Oct 30	73	VB: 595	1500	595
de Coban				CST: 310*		
Total	-	_	216	VB: 926	2842	986
				CST: 370		

VB: Vaginal Births, CST: Cesarean

^{*} Hospital of Coban and Hospital of La Tinta are not utilizing oxytocin in Uniject for cesarean

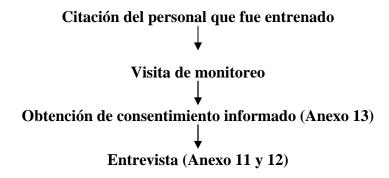
Consejos para la entrevista final

Elementos generales de la entrevista

- Objetivo: Obtener información precisa de la aceptabilidad de la oxitocina en Uniject por parte de los proveedores y administradores
- *Tipo de entrevista:* Entrevista estructurada cara a cara
- *A quien:* Directores de establecimiento y usuarios (no solo los que utilizaron el Uniject, pero también los que asistieron al entrenamiento)
- Cuando: Al final del piloto de introducción y luego de la ultima visita de monitoreo

Secuencia de eventos

- Citar a la mayor parte del personal con anticipación para estar presente en la entrevista
- Visita de monitoreo
- Obtención de consentimiento informado escrito (Anexo 13)
- Entrevista (Anexo 11 y 12)



Estrategias para eliminar sesgo

- Intercambio de monitores (Monitores del ministerio entrevistando los sitios de la AGOG y viceversa)
- Actitud del entrevistador. Lo ideal es no interferir en la opinión del entrevistado
- Preguntar las preguntas en orden
- Preguntar todas las preguntas a todos los entrevistados
- Tener tiempo suficiente para realizar toda la entrevista- no apurar al responderte
- Explorar áreas que requieran mas información sin imponer nuestra opinión

Itinerary for TA Visit to Guatemala Oct 25-Nov 4, 2009

Date	Activity	Responsible
Oct 25	Arrival	
Octubre26	Meeting with MOH designated person for cost study	Dr. Batres + MOH designated person Mark Guy, Shirley Carter, Erica Jacoby Gloria Metcalfe (optional)
	Gathering of cost data at the central level	Mark Guy, Erica Jacoby MOH designated person Shirley Carter
	Meeting with research team	Research team
Oct 27	Transportation to Alta Verapaz	Mark Guy, Gloria Metcalfe Shirley V. Carter, Erica Jacoby Dr. Héctor Chaclan
Oct 27	Visit to CAP of Carcha and CAIMI of San Cristobal (depending on time)	Mark Guy, Gloria Metcalfe Shirley V. Carter, Erica Jacoby Dr. Héctor Chaclan
Oct 28	Visit to Chisec and Hospital of Fray Bartolome	Mark Guy, Gloria Metcalfe Shirley V. Carter, Erica Jacoby Dr. Héctor Chaclan
Oct 29	Visit to Hospital of La Tinta	Mark Guy, Gloria Metcalfe Shirley V. Carter, Erica Jacoby Dr. Héctor Chaclan
Oct 30	Visit to Hospital of Coban and return to Guatemala	Mark Guy, Gloria Metcalfe Shirley V. Carter, Erica Jacoby Dr. Héctor Chaclan
Nov 2	Meeting with research team	
Nov 3	Meeting with Minister of health (Dr. Ovalle), Dra Lavidalie Dr. Batres and other members of the research team Goal: Share progress of the Project and lessons learned up to date.	Shirley Carter, Gloria Metcalfe, Erica Jacobi
Nov 3	Meeting with USAID	Gloria Metcalfe, Shirley V. Carter Erica Jacobi
Nov 4	Meeting with ANGEFISA (BIOL distributor in Guatemala)	Gloria Metcalfe, Shirley V Carter Erica Jacobi
Nov 4	Meeting with other potential organizations	Erica Jacobi, Shirley Carter, Gloria Metcalfe

POPPHI

Summary of the Nicaragua's Grant activities December 14, 2009

POPPHI issued a grant to the Nicaraguan OB/Gyn Association (SONIGOG) that supported the MOH training plan to prevent PPH. SONIGOG collaborated also with HCI, the USAID bilateral project for maternal health.

The objective was to improve the skills of the providers who assist births in prevention and management of PPH. Participants were doctors and nurses midwives who lead pre and in service trainings in three hospitals: the National Hospital of Women in Managua, which is the national referral hospital; Maternal and Children Hospital in Managua; and the Training Hospital in Leon.

SONIGOG and the MOH selected thirteen trainers to conduct two workshops. They came from the MOH, HCI, the Medical School of Leon, the Director of the hospital, and SONIGOG. The workshops included two days to review the evidence and practice on anatomic models, and three days of practical training in the labor and birthing rooms. A total of 146 providers were trained: 45 OBs, 34 OB Residents, 19 General practitioners, 18 nurse midwives, 23 nurses, and 7 medical students.

The Hospital in Leon is the only one that is coordinated with the primary level of care network, and it is the referral centre for maternal complications.

Before the SONIOGOG intervention, the National Hospital knew almost nothing about AMSTL, and AMTSL was incorrectly performed in the other two hospitals,

According to the Dr Flor Marin's report from SONIGOG, the objectives of the grant were totally accomplished. These included skills training to implement and reinforce the use of AMTSL and to improve life-saving skills to management PPH. Because of time and money limitations, they did not include quantitative information, evaluation or follow up.

The SONIGOG final report includes the following results after the workshops:

- The participants agreed to implement and improve AMTSL.
- MOH declared it mandatory to register the three steps of AMSTL in both, normal birth and caesarean. HCI supported this move with a stamp, which was included in the forms.
- MOH guarantees to provide the basics supplies to perform AMTSL to every woman during birth.
- AMTSL was approved as a norm in the birthing rooms.
- AMTSL was included in the pre-service training of Medicine and Nursing, OB and nurse midwives residents.
- A workshop for continue education in prevention and management of PPH were planned in the National Referral Hospital in Managua.

Recommendations: Follow up with the hospitals at 3, 6 and 12 months, and replicate the workshop in the regions where the maternal mortality is high. This would include the north and some areas in the Atlántico.