

Oxytocin in the Uniject™¹ Injection System

Summary of Research: 1998–2011

Completed Studies						
Location	Date	Reference	Type of Study	Main Research Questions and Results	Types of Providers	Partner Organizations
Angola	1998–2000	Strand RT, Da Silva F, Jangsten E, Bergstrom S. Postpartum hemorrhage: A prospective, comparative study in Angola using a new disposable device for oxytocin administration. <i>Acta Obstetrica et Gynecologica Scandinavica</i> . 2005;84(3):260–265.	Acceptability, clinical effectiveness	1. Active management of the third stage of labor (AMTSL) using Uniject™ significantly reduced blood loss during the first 2 hours postpartum compared to expectant management. It also demonstrated that the duration of the third stage of labor was significantly reduced using this management. 2. The midwives had no difficulties in learning the administration technique of Uniject™ and were satisfied with the decreased prevalence of hemorrhage complications among their patients.	Midwives and physicians at facility level	Karolinska Institute, Stockholm, Sweden and Agostinho Neto University, Luanda, Angola
Indonesia	1999–2000	Tsu VD, Sutanto A, Vaidya K, Coffey P, Widjaya A. Oxytocin in prefilled Uniject injection devices for managing third-stage labor in Indonesia. <i>International Journal of Gynaecology & Obstetrics</i> . 2003;83(1):103–111.	Operational research assessing acceptability of oxytocin in Uniject as part of AMTSL and for initial treatment of PPH	1. High acceptability by midwives compared to needle and syringes. 2. Providers found Uniject to be more practical, safer, and easier to use. 3. Client reaction to the use of Uniject was satisfactory. 4. No significance difference in the rate of postpartum hemorrhage (PPH) in baseline and intervention period. 5. The provision of oxytocin in Uniject did not change the availability or use of oxytocin as much as had been expected, primarily because the majority of midwives were already using oxytocin on a regular basis during normal deliveries. The introduction of oxytocin Uniject did, however, increase the accuracy of dosing and the safety of injections.	Midwives (bidan di desa) attending home births	PATH, United States Agency for International Development (USAID), Ministry of Health (MOH) of Indonesia, and World Health Organization-Indonesia
Vietnam	2005	Tsu VD, Mai TTP, Nguyen YH, and Luu HTT. Reducing postpartum hemorrhage in Vietnam: Assessing the effectiveness of active management of third-stage labor. <i>Journal of Obstetrics & Gynaecology Research</i> . 2006; 32:489–496. AND [Report] Seattle; March 2005. Available at: http://www.path.org/files/CP_vietnam_pph_oxytocin.pdf .	Comparative study assessing effectiveness of AMTSL and acceptability of oxytocin in Uniject	1. AMTSL was associated with reduced risks for prolonged third stage beyond 30 minutes. 2. AMTSL leads to measurable reduction in the rate of PPH, even when underlying rates are already low, and reduces the need for extra treatment such as bimanual compression, with its attendant risk of infection. 3. Midwives reported Uniject decreased time of preparation of oxytocin and was easier to use than ampoules and syringes. 4. Use of Uniject devices overcomes many of the barriers cited by midwives with regard to the use of oxytocin in ampoules and will be less expensive than ampoules if prices at the lower end of the likely range become available.	Midwives attending births at home and in health facilities	Bill & Melinda Gates Foundation, PATH, USAID, and MOH of Vietnam

¹ Uniject is a trademark of BD.

Completed Studies (Cont.)						
Location	Date	Reference	Type of Study	Main Research Questions and Results	Types of Providers	Partner Organizations
Vietnam	2005	Tsu VD, Levine C, Mai TTP, et al. Cost-effectiveness analysis of active management of third-stage labour in Vietnam. <i>Health Policy Plan.</i> 2009; 24(6):438–444.	Cost-effectiveness analysis	The low net incremental cost of AMTSL suggests that the introduction of AMTSL in primary-level facilities in Vietnam can reduce the incidence of PPH and benefit women's health without adding much to national health care costs. In countries with scarce health care resources, where levels of PPH are generally much higher, AMTSL by either ampoule or Uniject device would likely be cost neutral, if not cost saving.	N/A	Bill & Melinda Gates Foundation, PATH, USAID, and MOH of Vietnam
Guatemala	2009	PATH. Pilot introduction of oxytocin in Uniject™ during active management of the third stage of labor at the institutional level in Guatemala: A report evaluating the acceptability and feasibility of introducing oxytocin in the Uniject™ device for AMTSL. [Report] Seattle; March 2010.	Operational Research evaluating acceptability and feasibility of introducing oxytocin in Uniject™ for AMTSL	<ol style="list-style-type: none"> 1. Decrease in time to prepare medicine. 2. Improved quality of AMTSL services. 3. Increased safety for health workers. 4. Easier to track use. 5. No significant difference in ease of preparation and administration between oxytocin in ampoules and oxytocin in Uniject. 	Nurses and physicians in health facilities (reference hospitals to primary health clinics)	PATH, USAID, MOH of Guatemala, and Obstetrics and Gynaecology Association of Guatemala
Argentina	2009	Althabe F, Mazzoni A, Armbruster D, et al. Using Uniject to increase the use of prophylactic oxytocin for management of the third stage of labor in Latin America. <i>International Journal of Gynecology & Obstetrics.</i> August 2011; 114(2):184–189.	Quasi-experimental study	<ol style="list-style-type: none"> 1. Uniject facilitated the administration of oxytocin during the third stage of labor. 2. Uniject increased use of prophylactic oxytocin during AMTSL. 3. The study showed that an intervention consisting of providing oxytocin in Uniject, training birth attendants working in maternity hospitals in AMTSL, and using posters as reminders to birth attendants may increase the use of prophylactic oxytocin, with no increase in maternal complications. It also showed birth attendants' high level of use and acceptance of oxytocin in Uniject, and their opinion that it is a valuable device for facilitating the use of prophylactic oxytocin. 	Midwives, nurses, physicians at hospital level	PATH, Institute for Clinical Effectiveness and Health Policy, and Tulane School of Health and Tropical Medicine
Mali	2008	POPHI. Pilot use of oxytocin in a Uniject™ device for AMTSL in Mali: Evaluation of the safety and feasibility of a new delivery technology. [Report] Seattle; December 2008. Available at: http://www.path.org/publications/detail.php?i=1740 .	Operational Research evaluating the safety and feasibility of a new delivery technology	<ol style="list-style-type: none"> 1. High AMTSL coverage before survey. Not significant change with introduction of oxytocin in Uniject™. 2. TTI allowed providers to easily assess quality of oxytocin. 3. Provider quickly learned how to use the Uniject™ device and interpret TTI. 4. Providers preferred Uniject with TTI to standard or autodisposable syringe. 5. No significant difference in rates of retained placenta or PPH between oxytocin in Uniject™ and oxytocin in ampoules. 	Matrones (midwife assistants) at regional hospitals, reference and community health centers	PATH and USAID

Completed Studies (Cont.)						
Location	Date	Title	Type of Study	Main Research Questions and Results	Types of Providers	Partner Organizations
Ghana	2010	Exploring use of uterotonic substances at or around birth in three regions in Ghana.	Landscape Review (qualitative research + simulated client/ uterotonic quality testing)	1. Among midwives, knowledge of risks associated with uterotonics and appropriate dosages is inconsistent. 2. TBAs and new mothers are unaware of risks associated with use of traditional substances during pregnancy and birth. 3. Majority of available pharmaceutical uterotonics (oxytocin and ergometrine) at the peripheral level are of poor quality.	Various	PATH and The Bill & Melinda Gates Foundation
Indonesia	2011	PATH. Assessment of willingness to pay for oxytocin in the Uniject™ injection system among private midwives in Indonesia. [Report] Seattle; September 2011.	Market Assessment	The results of this assessment showed that the majority of private midwives prefer oxytocin in Uniject for AMTSL, and believe a TTI will provide a large increase in the quality of AMTSL. Another important finding is that most private midwives reported that the cost of oxytocin is not an important part of the overall costs they paid to assist with a delivery, since it is only a small portion of private midwives' total costs to deliver a child.	Private midwives at community level	PATH, USAID, Maternal and Child Health Integrated Program (MCHIP), and Indonesian Midwife Association

Studies Planned or Under Way						
Location	Date	Title	Type of Study	Main Research Questions and Results	Types of Providers	Partner Organizations
Honduras	2011	Pilot introduction of oxytocin in Uniject™ during AMTSL at the institutional level in Honduras.	Operational Research linked to pilot introduction	Evaluation of acceptability and feasibility of introduction of oxytocin in Uniject at facility level.	Nurses and physicians in health facilities	PATH, USAID, MOH of Honduras, and ChildFund
Indonesia	2011	Assessment of the quality of existing oxytocin in ampoules in Indonesia.	Drug sampling and testing	Chemical potency testing of sampled oxytocin.	Various	PATH, USAID, MCHIP, and MOH of Indonesia
Ghana	2011–2012	Determining the effect of prophylactic administration of oxytocin in Uniject™ on PPH at the community level in four districts in Ghana.	Randomized controlled community-based trial	Primary research question: To determine if IM administration of 10 IU of oxytocin in Uniject™ during the third stage of labor by a community health officer in 4 districts in Ghana will reduce risk of PPH, defined as blood loss of ≥ 500 ml within 2 hours of delivery, by 50% relative to deliveries attended by the same type of provider who does not provide the intervention.	Community health officer at home deliveries	PATH and The Bill & Melinda Gates Foundation

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Location	Date	Title	Type of Study	Main Research Questions and Results	Types of Providers	Partner Organizations
India	2011	Exploring use of uterotonic substances at or around birth in two states in India.	Landscape Review (qualitative research + observation of delivery study + simulated client/ uterotonic quality testing)	1. Document provider knowledge of and attitudes toward uterotonic use during labor and delivery at the district facility level and all subsequent levels of the public health system, as well as the private health system. 2. Document community knowledge of and attitudes toward uterotonic use during labor and delivery. 3. Observe clinical practices during labor and delivery with an emphasis on AMTSL and uterotonic use at the district facility level and all subsequent levels of the public health system, as well as the private health system. 4. Attempt to purchase uterotonic drugs and/or traditional preparations believed to have uterotonic properties from various sources, and to test the chemical potency of pharmaceutical uterotonics purchased.	Various	PATH and The Bill & Melinda Gates Foundation
Nicaragua	2011	Nicaragua changing AMTSL behavior in obstetrics (CAMBIO) intervention.	Operational Research linked to CAMBIO and pilot introduction in facilities	Research linked to interventions to improve quality of delivery care to reduce the incidence of PPH and unnecessary episiotomies.	Physicians and midwives at hospitals	PATH, USAID, Institute for Clinical Effectiveness and Health Policy, MOH of Nicaragua, and MCHIP
Vietnam	2011–2012	Preventing postpartum hemorrhage: Examining two strategies for prevention of PPH in community settings—misoprostol and oxytocin in Uniject™.	Randomized community-based trial	Primary research question: Are misoprostol and oxytocin in Uniject™ both effective in preventing PPH when administered by providers at primary health centers?	Nurse-midwives at primary health centers	Gynuity and The Bill & Melinda Gates Foundation
India	2011–2012	Preventing postpartum hemorrhage: Examining two strategies for prevention of PPH in community settings—misoprostol and oxytocin in Uniject™.	Randomized community-based trial	Primary research question: Are misoprostol and oxytocin in Uniject™ both effective in preventing PPH when administered by providers at primary health centers?	TBD	Gynuity and The Bill & Melinda Gates Foundation
Mali	2011–2012	Preventing postpartum hemorrhage: Examining two strategies for prevention of PPH in community settings—misoprostol and oxytocin in Uniject™.	Randomized community-based trial	Primary research question: Are misoprostol and oxytocin in Uniject™ both effective in preventing PPH when administered by providers at primary health centers?	TBD	Gynuity and The Bill & Melinda Gates Foundation
Senegal	2011–2012	Preventing postpartum hemorrhage: Examining two strategies for prevention of PPH in community settings—misoprostol and oxytocin in Uniject™.	Randomized community-based trial	Primary research question: Are misoprostol and oxytocin in Uniject™ both effective in preventing PPH when administered by providers at primary health centers?	TBD	Gynuity and The Bill & Melinda Gates Foundation
Global + Kenya, Ethiopia, Mali	2011	Comparative analysis of costs, risks, and benefits of different approaches to the delivery of oxytocin for prevention of postpartum hemorrhage.	Comparative analysis	1. Comparative cost/benefit analysis of 3 oxytocin formulations (ampoule, Uniject™, lyophilized) to assess which formulations could help to expand coverage. 2. Provider and policymaker perception survey—effectiveness of introducing different formulations at different levels of the health care system.	Global + country studies	Swiss Tropical and Public Health Institute and Netherlands' Directorate-General for International Cooperation