

A HealthTech Report

Rapid Assessment: The Programmatic Landscape of Uterotonic and Postpartum Hemorrhage Policies in Eleven Countries

November 2011

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Market Landscape Analysis for Oxytocin in the Uniject™ Injection System

In December 2010, the United States Agency for International Development (USAID) asked PATH to support an external analysis of the viability of supporting oxytocin in the Uniject™¹ injection system (OiU) as a niche product in both the public and private sectors. A major component of this analysis was to conduct separate market analyses in a subset of countries identified by USAID as priority countries for maternal health interventions. In consultation with USAID, PATH engaged a market analyst consultant in February 2011 to conduct an initial market landscape analysis across USAID's 30 priority countries using readily available data. The scope of the work included:

- A high-level analysis of the potential and relative need for OiU.
- The estimated potential demand for OiU under different scenarios.
- The development of a country opportunity assessment tool to score countries based on the relative market opportunity for OiU.

To complete the analysis, the consultant developed the country opportunity assessment tool (based on the business-focused stop light tool). Public health need, market size, and other enabling factors were considered in identifying the relative OiU market opportunity among 27 priority countries (Afghanistan, Sudan, and Tajikistan were excluded from the analysis due to data constraints). Countries were scored and ranked on each variable relative to the other countries in the dataset, with the goal of identifying a subset of countries that scored higher for need, market size, and enabling factors.

One of the key findings of the market landscape analysis was identification of 11 high-scoring countries: Bangladesh, Benin, Cambodia, Democratic Republic of Congo, Ethiopia, Ghana, India, Kenya, Malawi, Nigeria, and Uganda. PATH's report summarizing the results of the analysis, *Oxytocin in Uniject™: Market Landscape Analysis* was delivered to USAID in June 2011 and is available upon request.

Assessing the Policy and Programmatic Landscape

As follow-on to the market landscape analysis, PATH conducted a rapid assessment of national policies on prevention of postpartum hemorrhage (PPH) and uterotonic use in the 11 high-scoring countries (see Appendix 1). With the understanding that policy-level support is critical and can facilitate a more rapid uptake of a newer technology like OiU, a primary purpose of this rapid policy landscape was to help prioritize two or three of the high-scoring countries as lead candidates for a more in-depth, in-country market analysis of OiU's potential niche and viability. The information collected on this assessment is based on desk research and analysis of secondary data from the Maternal and Child Health Integrated Program (MCHIP) survey published in

¹ Uniject is a trademark of BD.

Prevention and Management of Postpartum Hemorrhage and Pre-Eclampsia/Eclampsia: National Programs in Selected USAID Program-Supported Countries.

OiU will likely serve as a niche product in many settings; therefore, identifying potential factors that may be catalytic to facilitating uptake is critical. These include not only political will, policy support, registration status, and current practices for uterotonics, but ongoing program opportunities as well. OiU is one of a handful of options that programs/countries should consider as they develop a strategy to increase access to uterotonics. The assessment includes information on the regulatory status of misoprostol, oxytocin, and OiU as considerations for the landscape. The rationale for each of the factors examined in this assessment is further expanded upon below. Note that this is not an exhaustive list of considerations for the market niche and viability of OiU, but is intended to provide a brief snapshot of the policy and programmatic landscape.

- **Level of prioritization for maternal health by the government and the Ministry of Health (MOH):** In many countries, maternal health is often a lower priority for the government and the MOH. However, in countries where there is strong political will and support to improve maternal health outcomes, governments may be interested in trying new tools to expand the reach of services, including the use of OiU. A key policy consideration that needs further exploration is the balance between country efforts to increase the number of births in facilities and efforts to increase community access to active management of the third stage of labor (AMTSL) and other interventions for preventing PPH.
- **Current registration status and policies around use of oxytocin and misoprostol for PPH prevention:** The World Health Organization recommends oxytocin as the drug of choice for prevention of PPH. However, in many countries, misoprostol use has increased as availability and well-funded efforts have expanded to increase access to the drug. In October 2011, MCHIP published the uterotonic selection tool to help countries make decisions around their needs for prevention and treatment of PPH. With the case being made for both misoprostol and OiU as potential tools to increase access at the periphery and community levels, there are multiple perspectives to consider when determining where the greatest opportunities are for OiU. In countries where there is strong political pressure against use of misoprostol, there may be stronger opportunities for OiU. Fears of misuse of both oxytocin and misoprostol play into these policy decisions. At the same time, countries that are willing to extend the use of misoprostol to the community may also be willing to extend use of OiU to the community.

In countries where misoprostol and OiU are registered for PPH prevention and treatment indications, introduction activities and broader uptake can happen more quickly, including expanding use to lower-level health care workers in periphery and community settings.

- **Cadres allowed to administer injections:** In countries where current policies allow lower-level health care workers and less-skilled birth attendants to give injections, use of OiU in the community is likely to be taken up more rapidly. Where policy change needs

to happen to allow additional cadres to give injections, use of OiU in the periphery and community beyond a pilot stage is likely to be limited and take additional resources.

- **Ongoing efforts that support increasing access to AMTSL and/or uterotonics at the community level:** The level of programmatic efforts underway with a focus on increasing access to AMTSL and/or uterotonics at the community level is an indication of the current status of policy-level and donor support for these types of interventions. There is also the opportunity to leverage funding and relationships that have been developed as part of these efforts.

Conclusions

The next logical step would be in-depth, in-country market analysis of OiU's potential niche and viability in perhaps two or three of the 11 high-scoring countries. While it is useful to now have the prevention of PPH policy and program landscape for the 11 countries summarized in the attached table, the policy and program landscape data itself does not, on its own, clearly suggest to PATH major differences in OiU opportunity or viability among these countries. PATH welcomes additional input and insight from USAID on potential OiU niche and viability in any of these countries.

In terms of identifying two or three countries for a next step of more detailed in-country market analysis, PATH recommends prioritizing the following countries:

India

- India is a large potential market and has seen a recent policy shift that now emphasizes oxytocin as the drug of choice.
- Gland Pharma has Indian drug regulatory approval (registration) for its OiU
- Identifying a viable market niche for OiU in India (if one exists) could help influence Gland Pharma to invest in additional (and more efficient) production capacity.

Ghana

- OiU is currently being used in a community-based trial in Ghana with results due in late 2012. Pending positive results, the MOH has expressed interest in expanding use of OiU.
- BIOL has submitted its application for registration of its OiU to the Ghana Food and Drugs Board.

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Acknowledgement

This work was made possible by generous support of the American people through the United States Agency for International Development (USAID) under the terms of HealthTech Cooperative Agreement #GPH-A-00-01-00005-00. The content of these materials are the responsibility of PATH and do not necessarily reflect the views of USAID or the US Government.

Appendix 1. Matrix on Programmatic Landscape of Uterotonic and Postpartum Hemorrhage Policies in Eleven Countries

Country	Level of prioritization for maternal health by the government and the MOH	Current registration status and policies around use of oxytocin and misoprostol for PPH prevention	Cadres allowed to administer injections	Ongoing efforts that support increasing access to AMTSL and/or uterotonics at the community level
Bangladesh	<ul style="list-style-type: none"> Data from the Bangladesh Maternal Mortality and Health Service Survey conducted in 2010 found that maternal deaths in Bangladesh fell from 322 per 100,000 in 2001 to 194 in 2010, a 40 percent decline in nine years. The decline is most likely the consequence of better care-seeking practices and improved access to and use of higher-level referral care, as well as a decline in the total fertility rate, which has reduced exposure to high-risk pregnancies. 	<ul style="list-style-type: none"> Oxytocin is in the national guidelines for PPH prevention and treatment. Misoprostol was approved for PPH prevention and added to the essential drugs list (EDL) in 2008. 	<ul style="list-style-type: none"> Skilled birth attendants (SBAs), doctors, nurses, and community-based SBAs and nurses are authorized to administer oxytocin. Still, 85 percent of births occur at home and skilled birth attendance during home births is only 26.5 percent. 	<ul style="list-style-type: none"> The Ministry of Health and Family Welfare is scaling up emergency obstetric care and AMTSL. The Ministry recently approved distribution of misoprostol tablets to all pregnant women shortly after delivery to prevent PPH.
Benin	<ul style="list-style-type: none"> The MOH is committed to a significant and lasting reduction in child and maternal mortality. Over the past decade, the MOH has reorganized its structure through the creation of health zones or <i>zones sanitaires</i> (often called districts in other African 	<ul style="list-style-type: none"> Oxytocin is in the national guidelines for PPH prevention and treatment. Misoprostol is not approved for PPH prevention. 	<ul style="list-style-type: none"> SBAs, doctors, and nurses are authorized to administer oxytocin. 	<ul style="list-style-type: none"> Maternal and child health is part of the integrated family health project, <i>Projet Intégré de Santé Familiale (PISAF)</i>.

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Benin (cont.)	<p>countries). These zones are designed to facilitate decentralized planning and management, as well as the efficiency of resource allocation and the rehabilitation of referral units.</p>			
Cambodia	<ul style="list-style-type: none"> • A new minister of health demanded that his staff and partners work together to develop a road map for maternal health and this was launched in mid-2010. • The first lady was recently appointed as the national champion for the United Nation's Action Plan for maternal and child health (focus on maternal health). • The MOH and Ministry of Economics and Finance introduced a midwife delivery incentive, whereby the government pays midwives US\$15 for every live baby they deliver. 	<ul style="list-style-type: none"> • Oxytocin is in the national guidelines for PPH prevention and treatment. • Misoprostol is not approved for PPH prevention or treatment. ACCESS advocated for a pilot study of misoprostol at the community level, but the MOH did not approve the study. The MOH cited concerns about potential misuse at the community level for medical abortion. 	<ul style="list-style-type: none"> • Doctors, nurses, and midwives are authorized to administer oxytocin. 	<ul style="list-style-type: none"> • In-service AMTSL training is being supported by multiple donors and organizations. • An emergency obstetric and newborn care (EMONC) assessment was implemented in 2009 and an EMONC improvement plan was developed in 2010.

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Congo, DRC	<ul style="list-style-type: none"> Unknown 	<ul style="list-style-type: none"> Oxytocin is in the national guidelines for PPH prevention and treatment as a first-line uterotonic, and metergrine as a second-line. Misoprostol is on the EDL for gastric ulcers. It is not authorized for PPH prevention. 	<ul style="list-style-type: none"> Doctors, nurses, and midwives. 	<ul style="list-style-type: none"> There are limited activities for prevention of PPH in USAID-supported zones.
Ethiopia	<ul style="list-style-type: none"> The government is working to ensure that in-service training integrates PPH prevention and management and is supportive of efforts to increase access to AMTSL. 	<ul style="list-style-type: none"> Oxytocin is the drug of choice for AMTSL at the facility level. Misoprostol is on the EDL and authorized for PPH prevention. It is currently being distributed to health extension workers on a pilot basis. 	<ul style="list-style-type: none"> Doctors, nurses, and midwives. 	<ul style="list-style-type: none"> The Population Council and Venture Strategies Innovations (VSI) are implementing community-based distribution of misoprostol. PATH visited Ethiopia in 2009 to assess the potential for an “Oxytocin Initiative.” The government was interested in OiU but not interested in pilots.
Ghana	<ul style="list-style-type: none"> Maternal health is a government priority, and they introduced the free delivery care policy in 2004 under the National Health Insurance Scheme, exempting women from user fees during deliveries with 	<ul style="list-style-type: none"> Oxytocin: The 2009 National Safe Motherhood Service Protocol specifies the use of oxytocin (10 IU intramuscularly) within one minute of delivery of the baby for PPH prevention within AMTSL. 	<ul style="list-style-type: none"> Doctors, nurses, and midwives. 	<ul style="list-style-type: none"> National Reproductive Health Service protocols clearly define AMTSL, and the National Safe Motherhood Service Protocol includes detailed instructions for AMTSL.

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Ghana (cont.)	public, private, and mission health providers.	<ul style="list-style-type: none"> • Misoprostol: In September 2008, the Food and Drugs Board registered misoprostol for obstetric use. The 2009 National Safe Motherhood Service Protocol allows the use of misoprostol for management of PPH by community-level providers. • BIOL, producer of OiU, initiated the drug registration process by submitting a regulatory dossier to the Ghana Food and Drugs Board. 		<ul style="list-style-type: none"> • Pre-service midwifery training is being supported by USAID. • VSI and the Ghana Health Service are undertaking pilots using misoprostol for PPH prevention at the community level in four districts. • PATH is currently undertaking a community-based randomized controlled trial looking at community health officers using OiU for prevention of PPH during home deliveries.
India	<ul style="list-style-type: none"> • Improving maternal health is prioritized by the government. A conditional cash transfer program, <i>Janani Suraksha Yojana</i>, was established in 2005 by the government to increase facility-based deliveries by women living below the poverty line. 	<ul style="list-style-type: none"> • Oxytocin: The 2010 Guidelines for Antenatal Care and Skilled Attendance at Birth specify the use of oxytocin for PPH prevention within AMTSL. The guidelines also include the use of oxytocin by workers at the periphery, where feasible. • Misoprostol: The 2010 Guidelines for Antenatal Care and Skilled Attendance at Birth allow the use of misoprostol for PPH prevention by workers at 	<ul style="list-style-type: none"> • Doctors, nurses, midwives, and auxiliary nurse midwives. 	<ul style="list-style-type: none"> • PATH is currently undertaking an assessment of practices/policies for PPH in India. Initial plans are being developed to evaluate OiU for treatment of PPH in 2012.

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India (cont.)		<p>the periphery <u>where oxytocin is not feasible</u>.</p> <ul style="list-style-type: none"> • Gland Pharma has Andhra Pradesh state-level drug regulatory approval to allow distribution and sale of its OiU throughout India. 		
Kenya	Unknown.	<ul style="list-style-type: none"> • Oxytocin is on the EDL, and is approved for prevention and treatment of PPH. • Misoprostol is on the EDL; however, it is not approved for PPH but has been piloted. 	<ul style="list-style-type: none"> • Doctors, nurses, and midwives. 	<ul style="list-style-type: none"> • A maternal health and nutrition technical working group is in place. • Broad health systems strengthening efforts are underway, and PPH training has been integrated into pre-service training.
Malawi	<ul style="list-style-type: none"> • The first lady is the coordinator for safe motherhood. 	<ul style="list-style-type: none"> • Oxytocin is approved for PPH prevention and treatment, and is on the EDL as part of the essential health package. • Misoprostol was approved for PPH prevention and treatment in 2010, and is on the EDL. It is also included in Malawi's national obstetric protocols for PPH. 	<ul style="list-style-type: none"> • Doctors, nurses, midwives, and SBAs in facilities. 	<ul style="list-style-type: none"> • MCHIP plans to pilot misoprostol for community-based distribution in three districts, although this has been delayed. • AMTSL has been integrated into pre-service training.

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Nigeria	<ul style="list-style-type: none"> The MOH has policies and programs for PPH prevention and treatment but needs support for program rollout. 	<ul style="list-style-type: none"> Oxytocin is approved for PPH prevention and treatment, and is on the EDL. Misoprostol is approved for PPH treatment and prevention, and has been piloted for home births. 	<ul style="list-style-type: none"> Doctors, nurses, midwives, and trained community health extension workers. 	<ul style="list-style-type: none"> USAID-funded programs such as ACCESS, MCHIP, and the Targeted States High Impact Project are addressing PPH prevention and treatment.
Uganda	<ul style="list-style-type: none"> The MOH policy is in place, but needs support for rollout. 	<ul style="list-style-type: none"> Oxytocin is approved for PPH prevention and treatment. Misoprostol is approved as a second-line drug. It is not policy to distribute it at the community level. 	<ul style="list-style-type: none"> Doctors, nurses, and midwives. 	<ul style="list-style-type: none"> University Research Co., LLC is supporting PPH activities.