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Private Sector Mobilization
for Family Health-Phase 2
(PRISM2) Project

TECHNICAL BRIEFER

Introduction of Oxytocin in the Uniject™ Injection System in the Philippines

Assessment of acceptability and feasibility of use among health workers and initial commercialization activities for market introduction

Although the Philippines has seen notable improvements in reproductive, maternal, and child health, progress on certain indicators has stagnated. The maternal mortality ratio, for example, remained essentially unchanged between 2006 and 2011. In addition, although 95% of pregnant women in the Philippines receive antenatal care, only 73% of deliveries occur with a skilled birth attendant.¹ Postpartum hemorrhage (PPH) remains a major contributor to maternal mortality, accounting for 17% of all maternal deaths.²



There are also large geographic inequities in service delivery. In rural areas only 51% of births occur in facilities. There is marked variation across regions: only 12% of births in the Autonomous Region in Muslim Mindanao occur in facilities, compared to more than 75% in the National Capital Region.³

A promising new option to help reduce maternal mortality

Oxytocin has been identified by the World Health Organization (WHO) as the gold standard drug for prevention and treatment of PPH.⁴ It is normally available in an ampoule-and-syringe format and forms a key component of active management of the third stage of labor (AMTSL) as recommended by WHO.

Ideally, an injection of oxytocin should be simple enough for to be administered at the lowest level of health care by a provider with little or no auxiliary support. Oxytocin in the Uniject injection system (OiU) fits this description: the medicine comes pre-packaged in a small bubble of plastic pre-filled with a single dose and attached to a short needle. Developed by PATH, an international non-profit organization, and now trademarked and produced by Becton Dickinson, the OiU is small, light, and easy to use. With a gentle squeeze, health care workers can quickly deliver an accurate, potentially lifesaving dose of oxytocin with minimal preparation and minimum waste.

In addition, a time-temperature indicator (TTI) — similar to the vaccine vial monitor used in immunization programs — can be placed on OiU packaging to indicate cumulative heat exposure, which allows for more flexible transportation and storage of the product. Health workers can also use the TTI to monitor the quality of the product before administration.

¹2013 National Demographic and Health Survey: Preliminary Report. Philippines Statistics Authority

²http://www.doh.gov.ph/kp/statistics/maternal_deaths.html#2010. Accessed July 14, 2014

³2013 National Demographic and Health Survey: Preliminary Report. Philippines Statistics Authority

⁴WHO. WHO recommendations for the prevention and treatment of postpartum haemorrhage. 2012.



PRISM2 project

USAID Philippines through the Private Sector Mobilization for Family Health-Phase 2 (PRISM2) project assessed the potential for introduction and widespread use of OiU in the Philippines. A field study was conducted on the acceptability and feasibility of using OiU for the prevention of PPH. The objective was to generate evidence to help policymakers and planners make informed decisions regarding the introduction and scale-up of the product in the Philippines. In tandem with field activities, a complete landscaping review was conducted to evaluate sustainable market opportunities and potential for local manufacturing was explored.

Methodologies

To evaluate commercialization prospects, supply and demand issues were explored and a target market profile created. As part of the market assessment, a validation study of birth attendants including obstetrician/gynecologists and midwives was conducted and a landscape assessment involving pharmaceutical groups was completed between March and June 2012. A total of 237 midwives and obstetricians from the private and public sectors participated in a willingness-to-pay study while a market landscape and potential production assessment of pharmaceutical groups was conducted to explore options for sustainability and scale-up.

The field research was conducted between December 2013 and May 2014 in the four main regions of the Philippines—National Capital Region, Visayas, Luzon and Mindanao. A total of 124 midwives, nurses, and doctors in 44 peripheral facilities (including lying-in clinics and midwife birthing clinics) participated in the study. Following a two-month baseline data collection period, when facilities and providers continued their regular practices according to established protocols, OiU was introduced for three months. At the end of this period, health care workers and facility managers were interviewed to assess their experiences and opinions related to OiU. The study also assessed the impact on provider practices.

Results

Health care worker perspectives

All health care workers who used OiU felt that it made practicing AMTSL easier. Among the beneficial features cited were no cutting of ampoule needed (91%), exact quantity of drug administration through the pre-filled syringe (80%) and no risk of broken glass (91%). Overall, 97% of health workers expressed a preference for OiU compared with oxytocin in ampoules administered with a needle and syringe. Providers also felt that it improved timing of oxytocin administration, especially for providers working alone.

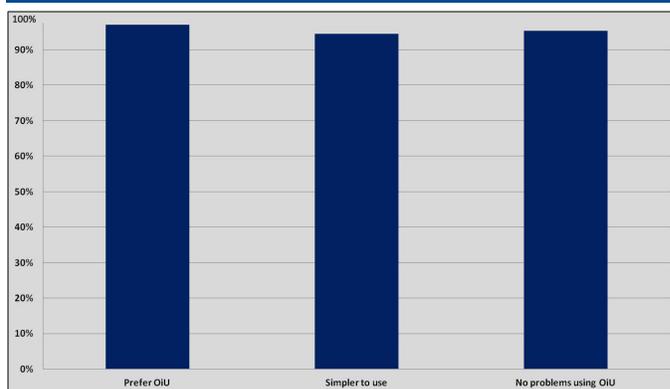
In addition, 85% of providers said they found the TTI very easy to interpret and another 14% said it was somewhat easy to interpret. Nearly 95% of providers suggested that a TTI be included on OiU or on both ampoules and OiU.

Asked about any specific concerns related to the use of OiU, a few providers expressed concern about the length of the needle – it was perceived as being much longer than a needle in a regular syringe – and the fact that they could not aspirate the drug in the OiU. Provider practices around AMSTL were similar at baseline and follow-up evaluation, with almost universal practice of the core AMSTL requirements.

Opinions of facility managers

More than half (54%) of all facility managers felt that the introduction of OiU had improved the quality of care at their facility. The vast majority stated that introduction of OiU did not result in any logistical challenges and that OiU was easy to introduce with current practices and workflows. About 83% reported that their staff did not encounter any problems using the device. The only area of potential concern was the price of OiU at market introduction (facilities in the study received free samples of the product).

Figure 1. Providers' views on use of oxytocin in Uniject relative to oxytocin with ampoule and syringe



“Using Uniject for me is simpler because we need not break an ampoule to get oxytocin. It is easy to use and danger free.” (Health Care Provider, Iloilo).

“Sometimes by using the traditional needle and ampoule I will accidentally prick myself and in addition it takes time to open the ampoule.” (Health Care Provider, General Santos City)

“For AMSTL you need to give oxytocin within one minute. With OiU, it is now easier to do this over the traditional way.” (Facility Manager, Manila)

Local demand and supply prospects

The average willingness-to-pay amongst all participants was Php92 (\$ 2.11) per 10 IU dose, much higher than the price of generic oxytocin, but Php70 (\$1.60) less per dose than Syntocinon, the highest priced oxytocin brand amongst study participants.

Fifty-four percent of the participants in the willingness-to-pay study selected OiU with a TTI as their first-choice product uterotonic for prevention and treatment of PPH, even at the highest, hypothetical price point. The potential cost of the product was however, a clearly expressed concern by most respondents, although the majority of participants indicated a preference to purchase oxytocin in Uniject over Syntocinon if both products were priced at Php170 (\$3.89) per dose.

The following supply options were considered by the project:

- Importation of the finished OiU;
- Importing filled OiU reels and providing secondary processing (labeling, sealing, and packaging) in the Philippines; and
- Undertaking both Uniject filling and secondary processing in the Philippines.

The project landscaped local generic drug manufacturers that could potentially process OiU as well as local drug importers and distributors that could transport OiU. Product marketing and distribution programs were also assessed. Although there are manufacturers in the Philippines who have the technical and market capacity to produce and market the product, facility preparation costs pose a major barrier to local manufacturing. There are, however, identified importers and distributors of drugs and medical devices who would have the capacity to import the filled Uniject devices in reels, and then perform the secondary processing (reel cutting, labeling and packaging) and distribution.

Conclusion

Both the research results and target market profiling indicate significant opportunity for use of OiU in the Philippines. OiU was very popular with providers, with most expressing a strong preference for OiU compared with syringe and ampoules, particularly in terms of making AMSTL easier and improved timing of oxytocin administration during AMSTL. Additionally, providers felt it was safer in terms of reducing risk from broken glass and needle sticks. Given that a significant proportion of births occur in midwife birthing homes or in small rural facilities and may be attended by a single provider, there is a strong public health case for introducing a product that streamlines the practice of AMSTL. The introduction of OiU in the Philippines is also supported by policy changes, including Administrative Order No. 2010-0014, which allows midwives to administer lifesaving drugs such as oxytocin. The final decision around use scenarios rests with local stakeholders, however OiU holds greatest promise where providers are logistically and otherwise minimally supported—those settings where its use will significantly improve delivery care.

Oxytocin in Uniject is relatively more expensive to produce than oxytocin in ampoules and the higher cost of the product produced outside of the Philippines may pose a challenge to early scale-up. However, at about Php62 (\$1.42), the current low-volume cost, OiU falls near the midpoint of the range of Php11 (\$.25) to Php169 (3.87) at which generic and brand-name oxytocin in ampoules is available in the Philippine market. A costing analysis to assess cost per PPH case averted is recommended to provide an objective assessment of cost-effectiveness in various use scenarios and volumes. The decision on introduction should also consider the added value and advantages offered by OiU in terms of safety, accurate dosing and improved AMSTL practices within the context of increased efforts aimed at reducing the prevalence of PPH and improvements in maternal health.

Challenges remain around ensuring a supply of the product. The issue is not access to a bulk supply of oxytocin or raw ingredients or the ability to perform secondary processing and distribution. The immediate issue is the absence of any existing OiU filling facility. It is the upfront costs for facility preparation and regulatory qualification, personnel training, and installation of equipment that are currently a major factor in ensuring supply. Any decision to introduce OiU will likely need to include a “pull” commitment to incentivize investment in production. This might include pre-purchase commitments for a specific volume of OiU devices, tax credits, funding support, and other commercial incentives.

The introduction of OiU in the Philippines is supported by policy changes which allows midwives to administer lifesaving drugs such as oxytocin. OiU holds greatest promise where providers are logistically and otherwise minimally supported — those settings where its use will significantly improve delivery care.