

Conference Report: PQM Presentation at the Asia Regional Meeting on Interventions for Impact in Essential Obstetric and Newborn Care

Dhaka, Bangladesh

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Trip Report

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Promoting the Quality of Medicines

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PROMOTING THE QUALITY OF MEDICINES

Executive Summary

The “Asia Regional Meeting on Interventions for Impact in Essential Obstetric and Newborn Care” was convened in Dhaka, Bangladesh, May 2-5, 2012. By gathering national and international stakeholders and experts associated with maternal and newborn care, the meeting aimed to support the accelerated implementation and expansion of maternal and newborn health programs in Asian and Middle Eastern countries.

PQM was invited to present the results of a case study performed in Indonesia on the quality of oxytocin. The presentation was received with great interest by the audience.

Additional meetings were held with representatives from USAID/Bangladesh and other organizations working in the country to provide information on PQM’s mandate, capabilities, and activities in Asia and other regions of the world.

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About PQM

The Promoting the Quality of Medicines (PQM) program, funded by the U.S. Agency for International Development (USAID), is the successor of the Drug Quality and Information (DQI) program implemented by the United States Pharmacopeia (USP). PQM is USAID’s response to the growing challenge posed by the proliferation of counterfeit and substandard medicines. By providing technical assistance to developing countries, PQM helps build local capacity in medicine quality assurance systems, increase the supply of quality medicines to priority USAID health programs, and ensure the quality and safety of medicines globally. This document does not necessarily represent the views or opinions of USAID or the United States Government. It may be reproduced if credit is given to PQM and USP.

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- Dr. Yogesh Rajkotia, from the Institute for Collaborative Development, for meeting with PQM regarding potential areas of collaboration.
- Dr. Sadaf Khan, from PATH, for the invitation to present at the meeting.
- Dr. Patrick Lukulay and Dr. Souly Phanouvong, from PQM, for their assistance and advice in preparing the presentation.
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ACRONYMS

DQI	Drug Quality and Information Program
FIGO	International Federation of Gynecology and Obstetrics
ICM	International Confederation of Midwives
MCHIP	Maternal, Newborn and Child Health Integrated Program
MoH	Ministry of Health
NIHRD	National Institute of Health Research and Development
NQCL-DF	National Quality Control Laboratory of Drug and Food
PATH	Program for Appropriate Technology in Health
PE/E	Preeclampsia/Eclampsia
PPH	Post Partum Hemorrhage
PQM	Promoting the Quality of Medicines Program
USAID	United States Agency for International Development
USP	United States Pharmacopeia
VSI	Venture Strategies Innovations

Background

Oxytocin is the medicine of choice in many countries for the treatment of Post Partum Hemorrhage (PPH). Evidence of reduced efficacy in certain developing countries raised the concern that this could be due to quality problems, particularly under the inadequate storage conditions that are frequently encountered in rural and decentralized areas. Several studies confirm the existence of poor quality medicines for the treatment of PPH, including oxytocin. The Program for Appropriate Technology in Health (PATH) performed a survey in 2010 in Indonesia which uncovered that oxytocin in remote health facilities is not stored according to manufacturer's labeling and instruction; that in some districts, health personnel are not aware of the requirements for storage; and that in a district health office warehouse and some private midwife clinics in Jakarta, there was no quality assurance or quality control in place for the acquisition, distribution, and storage of oxytocin injections. These findings raised the concern that oxytocin injections stocked in these areas may not be potent enough to prevent PPH. Consequently, the Ministry of Health (MoH) of Indonesia and United States Agency for International Development/Indonesia (USAID/Indonesia) expressed a strong interest in assessing the quality of existing oxytocin injection in ampoules in remote areas of the country.

PATH, in collaboration with the National Institute of Health Research and Development (NIHRD), National Quality Control Laboratory of Drug and Food (NQCL-DF), and the United States Pharmacopeia (USP) Promoting the Quality of Medicines (PQM) Program, conducted a study to assess the quality of existing oxytocin injection in ampoules in five selected regions in Indonesia. The study was conducted March-July 2011.

PQM was invited to participate at a panel on Drug and Commodities for PPH at the "Asia Regional Meeting on Interventions for Impact in Essential Obstetric and Newborn Care" held in Dhaka, Bangladesh, and to present the results of the study in Indonesia.

Purpose of Trip

PQM attended the meeting to give a presentation on the Indonesian case study (See *Annex 1* for the Meeting Agenda). While in the country, PQM also met with USAID/Bangladesh and other organizations working in Bangladesh to provide information on PQM's capabilities and activities in Asia and other regions of the world. (See *Annex 2* for details on these meetings).

Source of Funding

This trip was supported with USAID Core funds for Common Agenda.

Overall Objectives of the Meeting

- Present and discuss global scientific and technical information on prevention, early detection, and management of PPH and pre-eclampsia/eclampsia (PE/E), and special care for newborns
- Review and discuss programmatic experiences and progress in the implementation of newborn care and PPH prevention and management programs in Asia and the Middle East
- Review and consider an appropriate programmatic platform for the scale-up of PPH reduction and newborn care programs and the initiation or expansion of PE/E reduction programs that can be implemented at multiple levels of the health system
- Develop knowledge and greater understanding of selected interventions in maternal and newborn health

Conference Proceedings

The three presentations at the Drugs and Commodities session addressing the quality of existing treatments for PPH (methyl ergometrine, misoprostols and oxytocin), clearly indicated that quality is a matter of serious concern for these products. PQM's presentation emphasized in particular that other considerations, besides storage temperature, need to be taken into account to ensure the sustained quality of oxytocin. A similar conclusion was supported by the presentation on the quality of misoprostol given by Concept Foundation.

Conclusion

PQM's presentation was received with great interest and elicited numerous questions. In particular, it was noted that assessments conducted at various stages of the supply chain are an important approach that need to be implemented in other similar studies.

The meetings with USAID and other organizations in Bangladesh were very productive and may lead to the identification of areas in which PQM could support Bangladesh to ensure the quality of the medicines distributed in this country.

Additional Meetings

Dr. Pribluda held three separate meetings at the Ruposhi Bangla Hotel on May 4, 2012.

Meeting I

Participants:

- USAID: Dr. Sukumar Sarker; Senior Clinical Officer, Population, Health, Nutrition, and Education Office; Dr. Mahommad Shaidul Islam. Education Team Leader, Office of Population, Health, Nutrition, and Education
- EngenderHealth: Dr. Abu Jamil Faisel, Project Director, Mayer Hashi and Country Representative

PQM had sent printed material in advance, including Public Service Announcements (PSAs) and videos. During the meeting, Dr. Pribluda provided a brief summary on PQM's mandate and capabilities, as well as its activities in various regions on the world, emphasizing Southeast Asia in particular. USAID representatives agreed that the quality of medicines is an area of concern and of utmost importance for the authorities in Bangladesh. It was agreed that USAID will provide to PQM a list of contacts in various institutions in Bangladesh, to discuss and identify areas in which PQM could provide support.

Meeting II

Participants:

- USAID: Dr. Mahommad Shaidul Islam. Education Team Leader, Office of Population, Health, Nutrition, and Education
- Institute for Collaborative Development: Dr. Yogesh Rajkotia, Managing Director

After a brief summary on PQM, Dr. Rajkotia explained that his organization is currently conducting an assessment for the MoH on health capabilities and needs in several districts in Bangladesh. He indicated that evaluation of quality assurance and quality control systems for medicines was not included as one of the indicators. Since it was agreed that those aspects are crucial health components that need to be incorporated in the assessment, both parties will explore potential funding sources to allow for PQM participation in this initial assessment.

Meeting III

Participants:

- Bill & Melinda Gates Foundation: Mr. Joel Segrè, Contractor, Product Development and Family Health

Mr. Segrè was very interested in the approach utilized for the PQM Indonesia study, in which product quality was assessed at various levels of the supply chain. He requested a copy of the presentation and expressed his interest in having support from PQM for a study that is planned in India. Dr. Pribluda mentioned that he will send the presentation and will ask Dr. Phanouvong, Manager for Asian Programs at PQM, to follow up with him.