

Rational Pharmaceutical Management Plus International Congress on Evidence Based Interventions to Prevent Post Partum Hemorrhage: Translating Research into Practice, Goa, India July 7-16, 2006: Trip Report

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About RPM Plus

RPM Plus works in more than 20 developing and transitional countries to provide technical assistance to strengthen drug and health commodity management systems. The program offers technical guidance and assists in strategy development and program implementation both in improving the availability of health commodities—pharmaceuticals, vaccines, supplies, and basic medical equipment—of assured quality for maternal and child health, HIV/AIDS, infectious diseases, and family planning and in promoting the appropriate use of health commodities in the public and private sectors.

Abstract

Severe bleeding after childbirth is the largest cause of maternal death, accounting for at least one-quarter of maternal deaths worldwide. More women in India die from PPH than in any other country in the world. In the Africa region postpartum hemorrhage (PPH) contributes to an even higher proportion of maternal mortality. The International Federation of Gynecology and Obstetrics (FIGO) and the International Confederation of Midwives (ICM), in collaboration with USAID since November 2003, launched efforts targeting the prevention of post partum hemorrhage (PPH). This Asian regional conference was to build on the knowledge available about best practices to prevent PPH and to adopt a concerted action to reduce the occurrence of the mortality from PPH.

Partners and Collaborators

The conference was organized by the Jawaharlal Nehru Medical College, Belgaum, and the University of Missouri –Kansas City School of Medicine in collaboration with the USAID, Dept of Health and Human Services (NIH, NICHD), ACCESS project, JHPIEGO, MOH/ Government of India and the POPPHI project. Other partners present were WHO and UNICEF.

The conference brought together leading experts, program managers and safe motherhood professionals.

Activities at the Conference

At the conference, Bannet Ndyabangi represented MSH/RPM Plus and made a poster presentation on management of uterotonics for prevention of PPH. He also facilitated discussions on policy recommendations for essential medicines for the prevention of PPH.

He also participated in the following plenary sessions:

- Epidemiology of postpartum in Africa
- The status of PPH prevention in Africa: results of a survey in Tanzania and Ethiopia
- Challenges in introducing Active Management of Third Stage Labor (AMTSL).
- PPH prevention in home births
- Promoting Community interventions to prevent PPH

Key Messages from the conference

- AMSTL should be provided by a skilled birth attendant to every woman at every birth
- Oxytocin is the recommended first-line medicine for prevention of post partum hemorrhage and for use in AMTSL. It is preferred because it is effective in two to three minutes after injection, has minimal side effects, and can be used in all women.
- There is an urgent need for community involvement in efforts to prevent PPH

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Acronyms

ACCESS program	USAID's global program to improve maternal and newborn health
AMTSL	Active Management of Third Stage Labor
CA	Contracting Agency
FIGO	Federation of Gynecology and Obstetrics
ICM	International Confederation of Midwives
IM	Intramuscular
IV	Intravenous
MSH	Management Sciences for Health
JHPIEGO	Affiliate of the Johns Hopkins University
NICHD	National institute of Child Health and Human Development
NIH	National institute of Health
PATH	Program for Appropriate Technology in Health
POPHI	Prevention of Postpartum Hemorrhage Initiative
PPH	Prevention of Postpartum Hemorrhage
RH	Reproductive Health
RPM Plus	Rational Pharmaceutical Management Plus Program
STGs	Standard Treatment Guidelines
TBA	Traditional Birth Attendant
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development,
WHO	World Health Organization

Background

Globally, Postpartum Hemorrhage (PPH) is the leading cause of maternal mortality. More than 125,000 women die each year due to postpartum hemorrhage, particularly in rural areas of underdeveloped countries. To address this critical issue, the World Health Organization (WHO), International Federation of Gynecology and Obstetrics (FIGO) and the International Confederation of Midwives (ICM), in collaboration with the U.S. Agency for International Development office of health, infectious diseases and nutrition (USAID/HIDM), have collaborated in encouraging nations to pursue evidence based PPH prevention practices. USAID and POPPHI launched a PPH Global Initiative in November 2003. More women in India die from PPH than in any other country. The goal of the Congress was to disseminate research findings and to effectively advance programs to prevent and treat PPH in health facilities in resource-poor communities thus supporting the Millennium Development Goal (MDG) of reducing maternal mortality by 75 y 2015. In July, 2006, Congress provided opportunities to hear and discuss updated, novel, cost effective, evidence-based interventions, explore innovative approaches, discuss challenges in low resource settings, participate in skill enhancement sessions, debate program approaches, and help develop country and community action plans. The meeting assembled leading researchers, clinical experts, program managers and reproductive health professionals to highlight critical issues associated with the major cause of maternal death and to propose solutions that can be integrated within existing maternal health programs.

Objectives of the Congress:

1. Assemble international experts and policy makers to share new data and assist translation of research findings into policy recommendations
2. Review new evidence and provide a framework that supports strategies for prevention and treatment of PPH in health care facilities and home settings by skilled providers as well as by community health workers and family members
3. Develop action plans for implementing large-scale programs to prevent and treat PPH
4. Forge Public-Private Partnerships for developing and implementing programs to reduce the burden of mortality from PPH

RPM Plus participated in the conference and made a poster presentation on management of Uterotonics. The presentation also included findings from a review of AMSTL policies and guidelines from six West African countries. In addition, RPM Plus facilitated group work sessions on essential medicines for the prevention and treatment of PPH.

Congress highlights included presentations on the following topics:

- The Worldwide Burden of Postpartum Hemorrhage
- A Critical Review of Literature on Prevention and Treatment approaches to PPH

- Results of a Randomized Controlled Trial of Oral Misoprostol for Prevention of PPH in rural India
- Reports of other Misoprostol trials in Community and Hospital Based Settings
- Pharmaceuticals for prevention/treatment of PPH –Importation, Registration, Storage, Distribution and Availability
- Novel Approaches to Assess Postpartum Blood Loss – “BRASSS-V Drape”
- Redefining Postpartum Hemorrhage in the Developing World
- Training of Rural Health Workers for Prevention and Treatment of PPH
- New low-cost technologies in the management of PPH – Uniject, BRASSS-V Drape, Uterine Tamponade, and Non-inflatable anti-Shock Garment
- Evaluating PPH programs in the field
- Translating Research into Practice
- Role of USAID, MOH & NGO's supporting PPH initiatives

Purpose of Trip

At the conference, Bannet Ndyabangi represented MSH/RPM Plus and made a poster presentation on management of uterotonics for prevention of PPH. He also facilitated discussions on policy recommendations for essential medicines for the prevention of PPH.

Scope of Work

Scope of work for Bannet Ndyabangi

- Make a poster presentation on management of uterotonics
- Participate in and facilitate group work sessions on management of medicines

Activities

Participate in the workshop and provide facilitation

RPM Plus participated in the five-day International congress. Bannet Ndyabangi facilitated group work sessions on management of medicines and made a poster presentation on management of uterotonics. He also participated in the congress plenary sessions.

Key pharmaceutical management recommendations for improving availability of uterotonics emanating from the International congress: (Essential Medicines working group)

Draft Policy Recommendations on Essential Medicines for Prevention and Treatment of Postpartum hemorrhage (PPH)

Which medications should be included in essential medicines listing for PPH?

- Oxytocin, in ampoule or single dose pre-filled syringe (including Uniject)
- Misoprostol
- 15 methyl F2 Alpha (brand name Carboprost)
- Ergometrine

Levels of availability

Tertiary level with doctors, nurses, midwives: Use AMTSL with oxytocin IM-IV

Health Centre level: Use AMTSL with oxytocin in ampoule or pre-filled single use syringe, or AMSTL with misoprostol. Keep ergometrine available for treatment in addition to oxytocin and misoprostol

Community level:

Prevention

OIf birth is not attended: In advance of birth a clinician or trained birth attendant can give misoprostol to a TBA for woman's use.

OIf attended: Use AMTSL with oxytocin (in ampoule or pre-filled syringe) or misoprostol.

Treatment: Refer to health center.

Dosage

•Oxytocin, 10 units prevention; 10 or 20 units IV in normal saline or ringer lactate. Can be higher for treatment.

•Misoprostol, 400 to 600 mcg orally for prevention; 600 to 1,000 mcg rectally/orally/buccally for treatment

- 15 methyl F2 alpha, 250 mcg IM for treatment
- Ergometrine, .2 mm IM/IV for prevention and treatment

Vehicles for use:

- Oxytocin: Ampoule, preloaded syringes (e.g. including Uniject)
- Prostaglandin, 15 Methyl F2alpha (Carboprost) Preloaded
- Ergometrine: Ampoule
- Misoprostol: Tablet

Storage and transport needs

- Oxytocin: 15° – 30° C. Can be kept at room temperature for three months according to the manufacturer's label.
- Ergometrine: Refrigeration required 2° – 8° C. Keep away from light.
- Carboprost: Keep refrigerated.
- Misoprostol: Stable at room temp. Store in dry place.

Recommendations for availability

- Include misoprostol on WHO Essential Medicines List for PPH
- Follow country steps for availability
- Steps to Product Availability in a Country:
 - Add to country's Essential Drugs List or National Drug List, and include in country's Standard Treatment Guidelines (STGs). This means drug is approved for use for PPH. This can be supported in a formal policy statement.
 - Prequalification and GMP for public procurement.
 - Engage a low cost manufacturer.
 - South-South trade
 - Manufacturer must be willing to submit registration for PPH indication.
 - Determine level of availability and evaluate distribution channels
 - Drug registration by country's drug regulatory authority. This is a legal approval of a specific manufacturer's product, for sale by a local distributor, by prescription.
 - Build awareness: Educate doctors, midwives, and community health workers. Develop and use posters, brochures.
 - Distribution systems: Commercial marketing; social franchising and marketing; free distribution through public systems.

Collaborators and Partners

The workshop was made possible by the joint effort involving several partners, namely:

United Nations Agencies:

- WHO
- UNICEF

Partner Organizations

- USAID
- Jawaharlal Nehru Medical College, Belgaum
- University of Missouri –Kansas City School of Medicine
- Dept of Health and Human Services (NIH, NICHD),
- ACCESS project,
- JHPIEGO (affiliate of the Johns Hopkins University)
- MOH/ Government of India
- PATH/POPPHI project,
- MSH/RPM Plus

Next Steps

Immediate Follow-up Activities

- Circulate summary of congress outcomes to colleagues in MSH and USAID.
- Inclusion of activity to address pharmaceutical management issues on Misoprostol in 06/07 work plan such as the development of policy briefs to enable policy makers to make informed decisions about incorporating misoprostol in STGs and EML for PPH

Important Upcoming Activities or Benchmarks in Program

RPM Plus plans to support the scale-up of the AMSTL program in Benin, Ghana and Mali. RPM Plus initiated the planning of an assessment of AMTSL practices at the facility level which includes an analysis of the availability, storage conditions and use of uterotonics in Benin and Ghana.

Annex 1: Congress Objectives and Highlights

Objectives of the Congress:

- Assemble international experts and policy makers to share new data and assist translation of research findings into policy recommendations
- Review new evidence and provide a framework that supports strategies for prevention and treatment of PPH in health care facilities and home settings by skilled providers as well as by community health workers and family members
- Develop action plans for implementing large-scale programs to prevent and treat PPH
- Forge Public-Private Partnerships for developing and implementing programs to reduce the burden of mortality from PPH

Highlights of Scientific Sessions:

- The Worldwide Burden of Postpartum Hemorrhage
- A Critical Review of Literature on Prevention and Treatment approaches to PPH
- Results of a Randomized Controlled Trial of Oral Misoprostol for Prevention of PPH in rural India
- Reports of other Misoprostol trials in Community and Hospital Based Settings
- Pharmaceuticals for prevention/treatment of PPH –Importation, Registration, Storage, Distribution and Availability
- Novel Approaches to Assess Postpartum Blood Loss – “BRASSS-V Drape”
- Redefining Postpartum Hemorrhage in the Developing World
- Training of Rural Health Workers for Prevention and Treatment of PPH
- New low-cost technologies in the management of PPH – Uniject, BRASSS-V Drape, Uterine Tamponade, and Non-inflatable anti-Shock Garment
- Evaluating PPH programs in the field
- Translating Research into Practice
- Role of USAID, MOH & NGO's supporting PPH initiatives

Annex 2: RPM Plus Presentation at the Congress

Uterotonics for the Active Management of the Third Stage of Labor: Supply Management Considerations and Examples from West Africa

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Management Sciences for Health / Rational Pharmaceutical Management Plus Program



Senegal's health care system is the largest cause of maternal mortality, accounting for almost two-thirds of maternal deaths worldwide. In the Africa region, postpartum hemorrhage (PPH) contributes to an even higher proportion of maternal mortality. The effectiveness of active management of the third stage of labor (AMTSL) in preventing PPH has been well-documented, and many countries have worked to make AMTSL standard procedure. Yet, some well-funded providers will not be able to provide quality care unless there is assured availability of stable and effective uterotonics. Effectively managing uterotonics requires careful product selection, procurement, storage, distribution, and use, supported by a policy and regulatory environment that protects the widespread provision of high-quality products. Program planners need to consider key aspects of the pharmaceutical management cycle.

Pharmaceutical Management Cycle



Uterotonic Supply Management Issues to Consider

Selection

- Choosing the uterotonic medicine cycle health need
- Do national experts have a plan for AMTSL to be used on the ground?
- Are these selection criteria being used?
- Who will oversee criteria and overall level of the health system?
- What types of uterotonics needed, and what is the first-aid medicine?
- What is the cost?
- Are the medicines safe and effective?
- How do they need to be stored (quality and stability)?
- Are they amenable for procurement?
- Are they registered for use in country?
- Are selected uterotonics in national essential medicines list (NEML) and standard treatment guidelines?

Procurement

- Assure that an adequate quantity of quality medicine are procured efficiently
- How is a regular, equitable of contract in these aspects?
- Has cost been analyzed?
- Has quality been considered?
- How is supplier performance evaluated?
- Is there a transparent information system to monitor consumption?

Storage and Distribution

- Ability use quality medicines get to where they need to be
- What effect will hardware have on the medication?
- Are cold chain equipment and transportation available?
 - Cold box or pack
 - Refrigeration
 - Transport
- Is there an inventory monitoring system in place?
 - Stock cards and register
- Is there an adequate distribution network?
 - Owned supply system (vertical or integrated)
 - Delivery list system
 - Non-facility locations

Use

- Promoting appropriate prescribing, dispensing, and use
- Who is allowed to prescribe/medicate?
- What medicines needed for AMTSL?
- Are service delivery protocols in place?
 - Indications
 - Dose
 - Contraindications
 - Adverse effects
- Are checks conducted?

Management Support Systems

- Risky cycle regular
- Are standard operating procedures in place?
- Is budgeting funding available?
- Is there an information management system?
- What are the human resources considerations?
 - In-service education
- Are mechanisms for adequate monitoring and oversight in place?

Policy and Legal Framework

- To support the entire cycle
- Are uterotonics included on NEML?
- Are uterotonics imported or can they be manufactured domestically?
- Are there financing mechanisms in place?
 - Cost recovery
 - Cost sharing
 - Insurance

Conclusion

Availability of uterotonics to allow procurement of quality AMTSL interventions is a positive approach to ensuring safe and effective supply of high-quality services to prevent PPH.

Some Examples from the Results of a Policy Review in Five West African Countries⁴

Selection

- In four of the five countries, therapeutic guidelines do not mention use of uterotonics for the prevention of PPH. In addition, oxytocin is included for the induction of labor.
- In four of the five countries, reproductive health guidelines have not been recently updated and do not include AMTSL.

Procurement

- Procurement of each of uterotonics was reported in all of the five countries. This was at least in part due to past globalization and privatization of service stock.
- Most of the problems with quality of uterotonics were due to lack of consideration of full use of oxytocin (i.e., for induction of labor, prevention and treatment of PPH).
- The variety of products available from different manufacturers and in different dosages led to problems during procurement.

Storage and Distribution

- Storage issues at Central Medical Stores—temperature could be measured, vehicles were not temperature records are not kept. In some countries, products were even stored in direct sunlight.
- The standard operating procedures for maintaining the cold chain when products are distributed to regional stores are not well-defined.
- No quality assurance systems are in place.

Use

- The service guidelines AMTSL is not evident in four of the countries—PPH is taught, but assumed to be known to manage the third stage of labor through practice.
- Most countries have cost-established, in-service training programs for AMTSL.
- Products not included in NEML are reportedly used (i.e., misappropriated).

Policy

- In all five countries, oxytocin and ergometrine are present on NEML.
- In all five countries, misoprostol is not on the NEML.

⁴ These examples are from results of a national-level review of policies and supply chain issues. They were collected through key informant interviews with officials in Ministries of Health, International Reproductive Health Programs, Drug Regulatory Authorities, and Central Medical Stores in five West African countries: Burkina Faso, Senegal, Mali, Côte d'Ivoire, and Cameroon. Interviews were conducted from November 2009 to February 2010.



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