

The Secretary of the 17th Expert Committee on the Selection and Use of Essential Medicines
Medicine Access and Rational Use (MAR)
Department of Essential Medicines and Pharmaceutical Policies (EMP)
World Health Organization
20 Avenue Appia
CH-1211 Geneva 27
Switzerland

December 10, 2008

Dear Committee Members:

We are writing this letter in support of the application for misoprostol to be added to WHO's Essential Medicines List (EML) for the prevention of post-partum hemorrhage submitted by Gynuity Health Projects and Venture Strategies for Health and Development. POPPHI supports the addition of misoprostol to the Essential Medicine List (EML) for the prevention of post-partum hemorrhage and has collaborated with an EML task force that initially identified the need for a 2-page summary of the WHO recommendations from the October 2006 technical consultation as a reference for countries and programs interested in using misoprostol. As is well-evidenced in the international literature on maternal mortality and morbidity, postpartum hemorrhage (PPH) remains one of the largest contributors to maternal morbidity and mortality in low-resource settings and accounts for nearly one quarter of all maternal deaths worldwide. The addition of misoprostol to the EML as means of preventing PPH could help tackle the large burden of PPH in deliveries globally, and especially in low-resource settings where the maternal mortality is the highest. The drug's wide availability, low-cost, stability at room temperature, and ease of use for both patient and clinician make it an ideal drug for the prevention of PPH in low-resource settings.

The importance of misoprostol in women's health has been demonstrated in nearly 600 published studies on its use in obstetrics and gynecology that have involved well over 30,000 women. Misoprostol is a safe, effective, and low-cost drug that has been shown to reduce postpartum bleeding after delivery (Derman et al, 2006; Alfirevic et al, 2007). Administration of misoprostol to control postpartum bleeding offers an alternative to other standard treatments, including injectable oxytocin and ergometrine, both of which require a cold chain and skilled administration that are not always sustainable and/or available in low resource settings.

Based on a well-established efficacy of misoprostol for the prevention of PPH, we support the inclusion of misoprostol in the WHO List of Essential Medicines List (EML) to be specifically listed for its PPH indication in section 22.01.00.00 "Oxytocics." The use of misoprostol for PPH prevention is particularly important in places where traditional injectable uterotonics are not available and/or feasible. In addition, the *WHO Recommendations for the Prevention of Postpartum Haemorrhage* (WHO, 2007) recommends misoprostol for use as PPH prevention in the absence of active management of the third stage of labor. Furthermore, FIGO and ICM statement on the management of the third stage of labor to prevent postpartum hemorrhage, recommends the use of this drug when oxytocin is not available.

At present, some Ministries of Health find it difficult to include misoprostol for PPH prevention in their country's Essential Drugs List because the product is not listed on the WHO EML for this important women's health indication. Similarly, UN agencies and organizations active in emergency situations are frequently unable to offer this medication because of its absence from the WHO EML. Listing misoprostol for its PPH prevention indication will break down this barrier and facilitate easier access to misoprostol for PPH prevention, particularly in low-resource settings where it is most urgently needed.

We thank you for considering the addition of this very important medication to the WHO EML for the prevention of postpartum hemorrhage.

Sincerely,

Academy for Educational Development (AED), Africa's Health in 2010

Dr. André B. Lalonde, MD, FRCSC, MSc,
Executive Vice-president, on behalf of the Society of Obstetricians and Gynaecologists of Canada (SOGC)

The Board of Directors of the American College of Nurse-Midwives

Bixby Center for Global Reproductive Health, University of California, San Francisco

Harshad Sanghvi, Vice President and Medical Director and
Patricia Gomez, Technical Director, Maternal and Newborn Health
on behalf of JHPIEGO

Heidi Quinn
on behalf of Marie Stopes International

IntraHealth International, Inc

International Confederation of Midwives (ICM)

International Federation of Gynecology and Obstetrics (FIGO)

International Medical Corps

Louise Lee-Jones
on behalf of Marie Stopes International

Médecins Sans Frontières – OCB division

PATH

Pathfinder International

Private Nurses and Midwives in Tanzania (PRINMAT)

Reproductive Health Technologies Project (RHTP)

RTI International

Save the Children/US

Stacie E. Geller, PhD,

Director, on behalf of Center for Research on Women and Gender and the National Center of Excellence in Women's Health

The Women's Commission for Refugee Women and Children

References

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2. Derman RJ, Kodkany BS, Goudar SS, Geller SE, Naik VA, Bellad MB, Patted SS, Patel A, Edlavitch SA, Hartwell T, Chakraborty H, Moss N: Oral misoprostol in preventing postpartum haemorrhage in resource-poor communities: a randomised controlled trial. *Lancet* 2006, 368:1248-1253.
3. Alfirevic Z, Blum J, Walraven G, Weeks A, Winikoff B. Prevention of postpartum hemorrhage with misoprostol. *International Journal of Gynecology and Obstetrics* 2007;99(Supplement 2): S198-S201.
4. International Confederation of Midwives, International Federation of Gynaecologists and Obstetricians. Joint statement: management of the third stage of labor to prevent postpartum hemorrhage. *J Midwifery Womens Health* 2004; 49: 76-7.