

30 January 2009

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

Dear Committee Members:

On behalf of the Reproductive Access, Information, and Services in Emergencies (RAISE) Initiative, we are writing in support of Gynuity Health Projects' application for the inclusion of misoprostol in the World Health Organization's (WHO) Essential Medicines List, for the indication of postpartum hemorrhage (PPH).

The RAISE Initiative aims to address the full range of reproductive health needs for refugees and internally displaced persons (IDPs). Ninety-nine percent of maternal deaths occur in the developing world, which is also the location of the majority of humanitarian emergencies.<sup>1</sup> Postpartum hemorrhage remains one of the largest contributors to maternal morbidity and mortality in low-resource settings, accounting for nearly one-quarter of all maternal deaths worldwide.<sup>2</sup> It poses a particular threat in crisis situations, where resources for even basic emergency obstetric care are scarce.

Misoprostol offers a safe, highly effective, and easily administered alternative to other standard treatments for PPH. The drug's efficacy in preventing postpartum hemorrhage or reducing blood loss during PPH has been proven in numerous clinical trials.<sup>3,4</sup> In contrast to other PPH treatments such as injectable oxytocin and ergometrine, misoprostol requires neither a cold chain nor skilled administration. Finally, it is widely available and inexpensive. All of these factors make it an excellent treatment for use in low-resource settings. Through the use of misoprostol for the indication of PPH, numerous maternal deaths could be prevented each year.

Several bodies, including the World Health Organization, The International Federation of Gynecologists and Obstetricians and the International Consortium of Midwives have documented their support for the use of misoprostol to prevent PPH in various circumstances. For instance, the *WHO Recommendations for the Prevention of Postpartum Haemorrhage* (2007) recommends misoprostol for use as PPH prevention in the absence of active

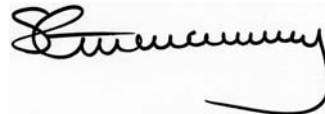
management of the third stage of labor.<sup>4</sup> A FIGO and ICM statement (2006) on the management of the third stage of labor to prevent postpartum hemorrhage recommends the use of misoprostol for PPH prevention when oxytocin is not available and/or birth attendants' skills are limited.<sup>5</sup>

We thank you for considering the addition of this vital medication to the WHO EML for the prevention of postpartum hemorrhage. We hope you agree that the evidence supports the inclusion of misoprostol for this important women's health indication.

Sincerely,



Therese McGinn  
Director, RAISE Initiative



Samantha Guy  
Deputy Director, RAISE Initiative

#### References

1. UNFPA (2005). Reproductive health fact sheet. New York: UNFPA. [http://www.unfpa.org/swp/2005/presskit/factsheets/facts\\_rh.htm](http://www.unfpa.org/swp/2005/presskit/factsheets/facts_rh.htm)
2. Khan S K et al. WHO analysis of causes of maternal death: a systematic review. *Lancet* 2006; 367: 1066-74
3. Derman RJ, Kodkany BS, Goudar SS, Geller SE, Nail VA, Bellad MB, Patted SS, Patel A, Edlavitch SA, Chakraborty H, Moss N: Oral misoprostol in preventing postpartum haemorrhage in resource-poor communities: a randomised controlled trial. *Lancet* 2006, 268:1248-1253.
4. Alfirevic Z, Blum J, Walraven G, Weeks A, Winikoff, B. Prevention of postpartum haemorrhage with misoprostol. *International Journal of Gynecology and Obstetrics* 2007; 99(supplement2):S198-S201.
5. WHO DoMPS. (2007). WHO recommendations for the prevention of postpartum haemorrhage. Geneva: World Health Organization.
6. International Confederation of Midwives, International Federation of Gynaecologists and Obstetricians. Joint Statement: Management of the third stage of labour to prevent postpartum haemorrhage. *Midwifery and Women's Health* 2004; 49 76-7.



MAILMAN SCHOOL OF PUBLIC HEALTH  
Columbia University

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Medicine Access and Rational Use (MAR)  
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20 Avenue Appia  
CH-1211 Geneva 27  
Switzerland

Dear Committee Members:

On behalf of the Averting Maternal Death and Disability (AMDD) Program, we write in support of Gynuity Health Projects' application for the inclusion of misoprostol in the World Health Organization's (WHO) Essential Medicines List for the indication of postpartum hemorrhage (PPH).

The AMDD Program works to improve the availability, quality, and utilization of emergency obstetric care in the developing world. Postpartum hemorrhage remains one of the largest contributors to maternal morbidity and mortality in low-resource settings, accounting for nearly one-quarter of all maternal deaths worldwide—approximately 125,000 deaths per year.<sup>1</sup>

Misoprostol offers a safe, highly effective, and easily administered alternative to other standard treatments for PPH. The drug's efficacy in preventing postpartum hemorrhage or reducing blood loss during PPH has been proven in numerous clinical trials.<sup>2,3</sup> In contrast to other PPH treatments such as injectable oxytocin and ergometrine, misoprostol requires neither a cold chain nor skilled administration. Furthermore, it is widely available and inexpensive. All of these factors make it an excellent treatment for use in low-resource settings. Through the use of misoprostol for the indication of PPH, numerous maternal deaths could be prevented each year.

Several bodies, including the World Health Organization, The International Federation of Gynecologists and Obstetricians, and the International Consortium of Midwives have documented their support for use of misoprostol in the prevention of PPH in various circumstances. For instance, the *WHO Recommendations for the Prevention of Postpartum Haemorrhage* (2007) recommends misoprostol for use as PPH prevention in the absence of active management of the third stage of labor.<sup>4</sup> A FIGO and ICM statement (2006) on the management of the third stage of labor to prevent postpartum hemorrhage recommends the use of misoprostol for PPH prevention when oxytocin is not available and/or birth attendants' skills are limited.<sup>5</sup>

We thank you for considering the addition of this vital medication to the WHO EML for the prevention of postpartum hemorrhage. We hope you agree that the evidence supports the inclusion of misoprostol for this important women's health indication.

Sincerely,



Lynn P. Freedman, JD, MPH  
Director, Averting Maternal Death and Disability Program  
Professor, Clinical Population and Family Health  
Columbia University Mailman School of Public Health

#### References

1. Khan S K et al. WHO analysis of causes of maternal death: a systematic review. *Lancet* 2006; 367: 1066-74
2. Derman RJ, Kodkany BS, Goudar SS, Geller SE, Nail VA, Bellad MB, Patted SS, Patel A, Edlavitch SA, Chakraborty H, Moss N: Oral misoprostol in preventing postpartum haemorrhage in resource-poor communities: a randomised controlled trial. *Lancet* 2006, 268:1248-1253.
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Heilbrunn Department of Population and Family Health

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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

Dear Sir/Madam:

On behalf of the Heilbrunn Department of Population and Family Health at Columbia University's Mailman School of Public Health, I am writing in support of Gynuity Health Projects' application for the inclusion of misoprostol in the World Health Organization's (WHO) Essential Medicines List (EML) for the indication of postpartum hemorrhage (PPH).

Postpartum hemorrhage remains one of the greatest contributors to maternal morbidity and mortality in low-resource settings, accounting for nearly one-quarter of all maternal deaths worldwide—approximately 125,000 deaths per year.<sup>1</sup> Misoprostol offers a safe, highly effective, and easily administered alternative to other standard treatments for PPH. The drug's efficacy in preventing postpartum hemorrhage or reducing blood loss during PPH has been proven in numerous clinical trials.<sup>2,3</sup> In contrast to other PPH treatments such as injectable oxytocin and ergometrine, misoprostol requires neither a cold chain nor skilled administration. Furthermore, it is widely available and inexpensive. All of these factors make it an excellent treatment for use in low-resource settings. Through the use of misoprostol for the indication of PPH, numerous maternal deaths could be prevented each year.

The Heilbrunn Department of Population and Family Health strongly advocates the swift implementation of evidence-based practices wherever they can positively affect—or indeed, save—people's lives. Based on the available research, several bodies, including the World Health Organization, the International Federation of Gynecologists and Obstetricians, and the International Consortium of Midwives have documented their support for the use of misoprostol in the prevention of PPH in various circumstances. For instance, the *WHO Recommendations for the Prevention of Postpartum Haemorrhage* (2007) recommends misoprostol for use as PPH prevention in the absence of active management of the third stage of labor.<sup>4</sup> A FIGO and ICM statement (2006) on the management of the third stage of labor to prevent postpartum hemorrhage recommends

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the use of misoprostol for PPH prevention when oxytocin is not available and/or birth attendants' skills are limited.<sup>5</sup>

Thank you for considering the addition of this vital medication, misoprostol, to the WHO EML for the treatment of postpartum hemorrhage. We hope you agree that the evidence supports the inclusion of misoprostol for this important women's health indication.

Sincerely,



John Santelli, MD, MPH  
Chair, Heilbrunn Department of Population and Family Health  
Mailman School of Public Health  
Columbia University

#### References

1. Selo-Ojeme, DO. Primary postpartum haemorrhage. *Journal of Obstetrics and Gynaecology*. 2002;22:463-469.
2. Derman RJ, Kodkany BS, Goudar SS, Geller SE, Nail VA, Bellad MB, Patted SS, Patel A, Edlavitch SA, Chakraborty H, Moss N: Oral misoprostol in preventing postpartum haemorrhage in resource-poor communities: a randomised controlled trial. *Lancet* 2006, 268:1248-1253.
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