

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 Health Access, Information, and Services in Emergencies (RAISE) Initiative, we write in support of Gynuity Health Projects' application for misoprostol to be added to WHO's Essential Medicines List (EML) for the indication of treatment of incomplete abortion and miscarriage. The RAISE Initiative and its partners work in settings of violent conflict and humanitarian crisis in which misoprostol, if approved, has the potential to treat women whose lives would otherwise be lost to due to incomplete abortion and miscarriage.

A wealth of scientific evidence, including numerous randomized and comparative clinical trials and several clinical guidelines, supports our view that misoprostol should be included in the EML for this indication. These data document repeatedly the safety and effectiveness of misoprostol for treatment of incomplete abortion and miscarriage. Over 2,000 women with incomplete abortion or miscarriage have participated in clinical trials of the drug. The most recent of these trials shows remarkably high success rates, in the range of 90 to 100%.¹⁻⁵ Of note, misoprostol is already included in the 14th and 15th editions of *WHO Model List of Essential Medicines (22.1 Oxytocic)* because of its proven safety and efficacy for medical abortion and labor induction.

Unsafe abortion contributes disproportionately to maternal morbidity and mortality in much of the developing world. In emergency settings, the situation is more dire still: according to UNFPA, as many as 25% to 50% of maternal deaths in refugee camps are due to unsafe abortion.⁶ Furthermore, incomplete abortion is one of the major clinical indications for which women present for care in settings where unsafe abortion is common. Medical evacuation of the uterus with misoprostol offers an alternative to surgical treatment, such as manual vacuum aspiration (MVA) or dilatation and curettage (D&C), which is often either unavailable or associated with higher morbidity in low-resource settings.

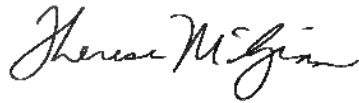
Misoprostol's wide availability, low cost, stability at room temperature, and ease of use for both patient and clinician make it an excellent treatment for use in low-resource settings. Importantly, misoprostol is a very acceptable treatment to women in

all types of settings. Research shows that many women prefer this non-invasive method of uterine evacuation to surgical methods.^{1,4,7}

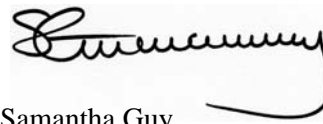
At present, some RAISE partners are unable to provide misoprostol because the product is not listed on the EML for this particular important women's health indication. Listing misoprostol for incomplete abortion will break down one of the major barriers to the use of this drug and facilitate access to safe and effective postabortion care in refugee settings and in many other settings throughout the world.

We thank you for considering the addition of this very important medication, misoprostol, to the EML for the indication of incomplete abortion and miscarriage.

Sincerely,



Therese McGinn
Director, RAISE Initiative



Samantha Guy
Deputy Director, RAISE Initiative

References

1. Bique C, Usta M, Debora B, Chong E, Westheimer E, Winikoff B. Comparison of misoprostol and manual vacuum aspiration for the treatment of incomplete abortion. *International Journal of Gynaecology & Obstetrics* 2007;98:222-6.
2. Dao B, Blum J, Thieba B, et al. Is misoprostol a safe, effective and acceptable alternative to manual vacuum aspiration for postabortion care? Results from a randomised trial in Burkina Faso, West Africa.[see comment]. *BJOG: An International Journal of Obstetrics & Gynaecology* 2007;114:1368-75.
3. Ngoc NTN, Blum J, Westheimer E, Quan TTV, Winikoff B. Medical treatment of missed abortion using misoprostol. *International Journal of Gynecology & Obstetrics* 2004;87:138-42.
4. Shwekerela B, Kalumuna R, Kipingili R, et al. Misoprostol for treatment of incomplete abortion at the regional hospital level: results from Tanzania.[see comment]. *BJOG: An International Journal of Obstetrics & Gynaecology* 2007;114:1363-7.
5. Weeks A, Alia G, Blum J, et al. A randomized trial of misoprostol compared with manual vacuum aspiration for incomplete abortion. *Obstetrics & Gynecology* 2005;106:540-7.
6. UNFPA (1999). "Reproductive health for refugees and displaced persons." New York: UNFPA.
7. Graziosi GC, Bruinse HW, Reuwer PJ, Mol BW. Women's preferences for misoprostol in case of early pregnancy failure. *European Journal of Obstetrics & Gynecology and Reproductive Biology* 2006;124:184-6.



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 this letter in support of Gynuity Health Projects' application for misoprostol to be added to WHO's Essential Medicines List (EML) for the treatment of incomplete abortion and miscarriage.

A wealth of scientific evidence, including numerous randomized and comparative clinical trials and several clinical guidelines, supports our view that misoprostol should be included in the EML for this indication. These data document repeatedly the safety and effectiveness of misoprostol for treatment of incomplete abortion and miscarriage. Over 2,000 women with incomplete abortion or miscarriage have participated in clinical trials of the drug. The most recent of these trials show remarkably high success rates, in the range of 90 to 100%.¹⁻⁵ Of note, misoprostol is already included in the 14th and 15th editions of *WHO Model List of Essential Medicines (22.1 Oxytocic)* because of its proven safety and efficacy for medical abortion and labor induction.

Unsafe abortion contributes disproportionately to maternal morbidity and mortality in much of the developing world. Incomplete abortion is one of the major clinical indications for which women present for care in settings where unsafe abortion is common. Medical evacuation of the uterus with misoprostol offers an alternative to surgical treatment, such as manual vacuum aspiration (MVA) and dilatation and curettage (D&C), which is often either unavailable or associated with higher morbidity in low-resource settings.

Misoprostol's wide availability, low-cost, stability at room temperature, and ease of use for both patient and clinician make it an excellent treatment in low-resource settings. Importantly, misoprostol is a very acceptable treatment to women in all types of settings. Research shows that many women prefer this non-invasive method of uterine evacuation to surgical methods.^{1, 4, 7}

The AMDD Program focuses on improving the availability, quality, and utilization of emergency obstetric care in the developing world. Misoprostol is a critical tool in saving the lives of women who have experienced unsafe or incomplete abortion or miscarriage. At present, many health providers and organizations are unable to provide misoprostol for incomplete abortion via standard drug registries because the product is not listed on the EML for this particularly important women's health indication.

Listing misoprostol for incomplete abortion will break down one of the major barriers to use of this drug and facilitate access to safe and effective postabortion care in many settings throughout the world.

We thank you for considering the addition of this very important medication, misoprostol, to the EML for the indication of incomplete abortion and miscarriage.

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. Bique C, Usta M, Debora B, Chong E, Westheimer E, Winikoff B. Comparison of misoprostol and manual vacuum aspiration for the treatment of incomplete abortion. *International Journal of Gynaecology & Obstetrics* 2007;98:222-6.
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Heilbrunn Department of Population and Family Health

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

Dear Committee Members:

On behalf of the Heilbrunn Department of Population and Family Health at Columbia University's Mailman School of Public Health, I write in support of Gynuity Health Projects' application for misoprostol to be added to WHO's Essential Medicines List (EML), for the indication of treatment of incomplete abortion and miscarriage.

A wealth of scientific evidence, including numerous randomized and comparative clinical trials and several clinical guidelines, supports our view that misoprostol should be included in the EDL for this indication. These data document repeatedly the safety and effectiveness of misoprostol for treatment of incomplete abortion and miscarriage. Over 2,000 women with incomplete abortion or miscarriage have participated in clinical trials of the drug. The most recent of these trials shows remarkably high success rates, in the range of 90 to 100%.¹⁻⁵ Of note, misoprostol is already included in the 14th and 15th editions of *WHO Model List of Essential Medicines (22.1 Oxytocic)* because of its proven safety and efficacy for medical abortion and labor induction.

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Misoprostol's wide availability, low-cost, stability at room temperature, and ease of use for both patient and clinician make it an excellent treatment for use in low-resource settings. Importantly, misoprostol is a very acceptable treatment to women in all types of settings. Research shows that many women prefer this non-invasive method of uterine evacuation to surgical methods.^{1,4,7}

The Heilbrunn Department of Population and Family Health considers the areas of research and service delivery to be highly interdependent, and advocates for the swift implementation of evidence-based best practices in the public health field. Misoprostol is a critical tool in saving the

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lives of women who have experienced unsafe or incomplete abortion or miscarriage. At present, many health providers and organizations are unable to provide misoprostol for incomplete abortion via standard drug registries because the product is not listed on the EDL for this particularly important women's health indication. Listing misoprostol for incomplete abortion will break down one of the major barriers to use of this drug and facilitate access to safe and effective postabortion care in many settings throughout the world.

I thank you for considering the addition of this very important medication, misoprostol, to the EML for the indication of incomplete abortion and miscarriage.

Sincerely,



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

References

1. Bique C, Usta M, Debora B, Chong E, Westheimer E, Winikoff B. Comparison of misoprostol and manual vacuum aspiration for the treatment of incomplete abortion. *International Journal of Gynaecology & Obstetrics* 2007;98:222-6.
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