TO: World Health Organization,  
    Executive Board, World Health Assembly  
    Committee on Essential Medications  
FROM: Maternal Life International,  
    Drs. George Mulcaire-Jones and Robert Scanlon  
DATE: February 6, 2011  
SUBJECT: INCLUSION OF MISOPROSTOL AS AN ESSENTIAL MEDICATION

Dear Committee Members:

Introduction:

This correspondence of Maternal Life International (MLI) is from Dr. George Mulcaire-Jones, president and medical director of MLI, and Dr. Robert Scanlon, board member and director of MLI’s maternal health programs. Maternal Life is a United States-based 501 (c) 3 nonprofit organization that has provided training and resource assistance for obstetrical and newborn care in Africa for the last fourteen years. Throughout this time, MLI has also developed programs for HIV/AIDS prevention, including Prevention of Mother to Child Transmission.

Dr. Mulcaire-Jones is the founder of MLI. He practiced family medicine in Cameroon for two years as part of a medical outreach program based in Los Angeles. Dr. Scanlon has a decade of extensive on-the-ground knowledge of African health care, both as a fistula repair surgeon and a teacher of safe birthing techniques under MLI’s “Safe Passages” program. Each doctor possesses expert knowledge of evidence based obstetrical practices that work or do not work in an African setting. They also have worked in developing and teaching community based programs in maternal and family health which interface with hospital based obstetrical care.

Position:

We urge the WHO Committee on Essential Medications to carefully re-examine the literature in regards to misoprostol, as well as consider the expert recommendations you have previously developed on this drug. We believe there are significant dangers in the unregulated use of misoprostol. These dangers have been underplayed by misoprostol advocates whose real agenda
is not evidence based obstetrical care but rather unregulated medical abortion. Specifically, we oppose the use of misoprostol outside of an adequately equipped health care facility with trained staff, and we oppose its use for medical abortions. We believe misoprostol has a role in the induction of labor and the medical evacuation of an incomplete miscarriage, but only in the setting of a hospital capable of providing essential obstetrical care. Outside of this setting, misoprostol will lead to more and not fewer maternal deaths.

As the accompanying paper reflects, misoprostol perpetuates a dangerous double standard:

(1) Women in resource limited settings are expected to give birth with unskilled or semi-skilled birth attendants. This fact alone leads to higher maternal and infant mortality rates than those in developed countries.

(2) Adding the unregulated availability of misoprostol to this situation will give these women -- most of whom have few educational opportunities to evaluate the risks -- the false assurance that their deliveries will be “safe.” However, misoprostol can be a dangerous medication, especially when used improperly and outside of a facility capable of providing fluid resuscitation, blood transfusion, surgical evacuation, and, in the case of uterine rupture, emergency laparotomy.

We honor the United Nation’s Universal Declaration of Human Rights and the constitution of the WHO with the objective of “the attainment by all people of the highest possible level of health.” The stated major task of the WHO is to combat disease and to “promote the general health” of the people of the world. Such an objective involves doing no harm. We find this principle in the original Hippocratic Oath which codifies the ethical conduct of physicians in providing safe and effective care, including a proscription against abortion. Unregulated use of misoprostol promotes none of these objectives and could easily lead to fatal consequences.

Our alternative to the unrestricted use of misoprostol is better funding for birth attendant training and the provision of medicines and equipment that will not injure women in pregnancy, labor and delivery, but only help them. In this way, we share WHO’s commitment to the Millenium Development Goals, especially in regard to reducing maternal and infant mortality; a goal that may only be reached through a paradigm that respects the life and dignity of all persons, born and unborn.

Sincerely,

George Mulcaire-Jones, M.D.  Robert Scanlon, M.D., DAFOG
Misoprostol: Perpetuating a Dangerous Double Standard

Misoprostol, a synthetic prostaglandin analogue, originally developed for prevention of gastric ulcers in patients taking anti-inflammatory medications\(^1\) has now been approved as an essential obstetrical medication in seventeen African countries. As of January 2010, approval was also being sought in at least ten additional African countries. Advocates for the inclusion of misoprostol as an essential obstetrical medication, point to its role and efficacy in inducing labor, in inducing medical abortion (either alone or in combination with mifepristone) and for medical evacuation of an incomplete abortion. Misoprostol has also been used to reduce the frequency and severity of post-partum hemorrhage in hospital settings as part of the active management of the third stage of labor.

While misoprostol has a role in obstetrical care, the role is strictly contextual.

- Misoprostol should only be used in a hospital setting
- Misoprostol role is secondary to the role of oxytocin in the prevention and treatment of post-partum hemorrhage
- Misoprostol by itself is unlikely to decrease maternal deaths from post-partum hemorrhage. It’s use must be accompanied by an array of other measures including volume replacement, uterine massage and blood transfusion

These recommendations are based upon evidence which is often ignored or misrepresented by misoprostol advocates.

- The Bellagio Conference in 2007 convened a panel of experts and developed recommendations for the use and dosing of misoprostol. These recommendations do not support the use of misoprostol outside of a health care facility. They note misoprostol is “not as effective as oxytocin or ergometrine” for PPH prophylaxis and there is “limited evidence of benefit” for the use of misoprostol in the treatment of PPH and “conventional oxytocics should be used first.”\(^2\)

- The World Health Organization (WHO) has clearly stated that the medication of choice for prevention of PPH is oxytocin and not misoprostol.\(^3\) The WHO has further noted

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\(^1\) (Prod Info Cytotec(R), 2002a)


\(^3\) Gülmezoglu, Dr A M Review: Misoprostol and intramuscular prostaglandins do not prevent postpartum haemorrhage more than injectable uterotonics. (Evid Based Med 2008;13:82 doi:10.1136/ebm.13.3.82)
with misoprostol, “there is an unresolved concern of a possible increase in maternal mortality.”

In addition to advocating for in hospital use of misoprostol, some advocates have recommended the widespread distribution and use of misoprostol at the community level, where it would be dispersed by unskilled or semi-skilled birth attendants or patients themselves. They have clearly expressed their intent to use the medication as an abortifacient, going as far as training pharmacists and nurses in how to distribute and use misoprostol for abortion outside of a medical setting. In so doing, they are putting women’s lives in peril:

- A recent study of 22,368 “safe” medical abortions in Finland, compared with 20,251 “safe” surgical abortions demonstrated that one out of twenty women who underwent “safe” surgical abortion had complications including hemorrhage, incomplete abortion and need for repeat surgery. Those women undergoing “safe” medical abortion had four times the complication rate (one out of four women hemorrhaged, had incomplete abortion and required surgery).
- In a WHO sponsored study from 2006, one out of every five women who had “safe” misoprostol abortions failed to abort and required surgical intervention, or continued a pregnancy now exposed to a drug known to cause severe fetal malformations.
- A recent study from Ethiopia indicated that legalization of abortion actually led to more abortion-related deaths. Regardless of the legality or illegality of abortion, when the number of abortions increase so does the abortion complication and death rate.

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4 Gülmezoglu, Dr A M Review: Misoprostol and intramuscular prostaglandins do not prevent postpartum haemorrhage more than injectable uterotonics. (Evid Based Med 2008;13:82 doi:10.1136/ebm.13.3.82)

5 “One woman who received misoprostol said she felt comfort and security knowing she had the life-saving tablets so she could protect herself no matter where she delivered.” http://www.globalgiving.com/projects/help-stop-maternal-mortality-in-africa/updates/


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especially in resource limited settings where women may not have access to medical care, surgical evacuation and blood transfusions.\textsuperscript{9}

Regardless of one’s stance towards medical abortion, misoprostol advocacy perpetuates a dangerous double standard. Pregnant women in rural Africa are expected to give birth in a village with an unskilled or semi-skilled birth attendant, now with the false assurance they will deliver safely with misoprostol tablets at hand. Misoprostol does nothing to address women’s underlying anemia, malaria or HIV status, all of which make them vulnerable to death in pregnancy. In the absence of skilled birth attendance, women in Africa will continue to die from hemorrhage, obstructed labor, infection, and hypertensive diseases. At the same time, women in well resourced countries give birth in health care facilities with every available intervention: ultrasound, fetal monitoring, blood banking, anesthesia, Cesarean section and neonatal resuscitation. The double standard has led to an unprecedented disparity in maternal mortality: in Africa the lifetime risk of a woman dying in pregnancy and childbirth is 1 in 37 compared to 1 in 4000 in industrialized countries.\textsuperscript{10}

A recent expert commentary published in the Lancet highlighted the dangers of “shortcuts” on the road to reducing maternal mortality. These short cuts include “safe birth kits,” “semi-skilled birth attendants,” “one complication programs,” (such as post-partum hemorrhage) and “advocacy without a clear connection to actions that actually help reduce maternal deaths.” Such shortcuts are actually “detours” in “which people could think maternal mortality is being addressed in a substantial way when this is not the case.”\textsuperscript{11} Indeed advocacy for the unregulated use of misoprostol is a detour and not a shortcut – which leads to more and not fewer maternal deaths.


\textsuperscript{11} Maine, Deborah. Detours and Shortcuts on the road to maternal mortality reduction. Lancet 2007; 370: 1380-2