



A global overview of ongoing misoprostol studies

Ndola Prata *

University of California, Berkeley, School of Public Health, 314 Warren Hall, Berkeley, CA 94720-6390, USA

Clinical research has the potential to advance knowledge in the use of a technology and to help inform the decision-making process involving the public health benefits of such technology. In the last decade, one of the most important advances in maternal health, with special significance for developing countries, was the research on the gynecological indications of the use of misoprostol. Numerous studies have shown misoprostol's efficacy in the management of postpartum hemorrhage (PPH), pregnancy termination, labor induction, and cervical ripening. Its multiple non-parenteral routes of administration, long shelf-life, and stability without refrigeration under field conditions make it the perfect candidate for resource-poor settings, especially those with lack of skilled providers.

Current evidence demonstrates that misoprostol is a powerful and relatively safe uterotonic agent [1]. Its side effects, which appear to be dose and route dependent, are mild, transient, and not life-threatening [2]. It can be used in low resource settings, especially where no skilled attendants are available [3,4].

Although several studies are still ongoing (see Table 1) some countries have started to translate research into practice. In particular, steps have been taken to introduce misoprostol as a standard practice by (in no particular order): including it in the

essential drugs list; registering the drug for use in the prevention and treatment of PPH; training the health care work force to understand the usefulness of misoprostol; performing market assessment/ distributions systems; determining the needs for the public and private markets; identifying barriers to access; determining affordability and willingness to pay; and, finally, beginning to use misoprostol where it is clinically indicated in the field.

For example, in Afghanistan, prevention of PPH at homebirths with misoprostol is ongoing in six districts. Trained community health volunteers identify pregnant women in the community, educate them on PPH, birth preparedness and complications readiness, and distribute misoprostol with clear instructions for self-administration.

In addition, Ethiopia has made significant progress to introduce misoprostol. From the above list, all steps were thought through and made part of their national PPH prevention campaign. The Ethiopian strategy involves, among other activities, an awareness campaign through women's groups, and introduction of misoprostol in the public health care system from selected tertiary level facilities to health posts. The latter benefit from a recently created cadre of health extension workers (HEWs), which will play a pivotal role linking the community to the formal health care sector.

It is important that additional misoprostol studies be carried out. Having said this, the presently available evidence shows that all levels of health care service including trained TBAs can effectively

* Corresponding author. Tel.: +1 510 643-4284.
E-mail: ndola@berkeley.edu (N. Prata).

Table 1 Ongoing misoprostol studies for prevention of PPH

| Institution | Type of Study | Study Setting | Assessment |
|--|--|--|--|
| JHPIEGO Nepal, Afghanistan | Intervention trial miso 600 mcg oral self-administered | Non-assisted home births; miso distributed by CHV | Safety, feasibility, acceptability and program effectiveness |
| UC Berkeley/Venture Strategies GK Bangladesh | Intervention trial miso 600 mcg oral | Home births assisted by TBAs | Safety, program effectiveness |
| UC Berkeley/Venture Strategies Ethiopia, Tigray Health Bureau; ESOG Ethiopia | Intervention trial miso 600 mcg oral | Home births assisted by TBAs | Safety, program effectiveness |
| Gynuity, Aga Khan Foundation, Aga Khan Health Services Pakistan | Placebo RCT miso 600 mcg oral | Home births assisted by TBAs | Safety, efficacy |
| University of Witwatersrand, Gynuity Uganda, South Africa, Nigeria | Placebo RCT miso 600 mcg oral | Hospital | Misoprostol as adjunct prophylaxis |
| UCSF Tibet | RCT – (ZB11) vs. misoprostol 600 mcg oral | Maternity hospital | Safety, feasibility, acceptability of western medicine, efficacy |

Notes: Information taken from the POPPHI database <http://www.pphprevention.org/documents/Misoresearchinprogressv3.pdf> and author's communication with study principal investigators.

CHV: community health volunteer; RCT: randomized controlled trial; TBAs: traditional births attendants; ZB11: Herbal medicine used in Tibet for management of PPH.

administer misoprostol, and that parturient women have also proven to be able to safely self-administer the drug.

References

- [1] Langenbach C. Misoprostol in preventing postpartum hemorrhage: a meta-analysis. *Int J Gynaecol Obstet* 2006;92(1): 10–8.
- [2] Lumbiganon P, et al. Misoprostol dose-related shivering and pyrexia in the third stage of labor. WHO collaborative trial of misoprostol in the management of the third stage of labor. *Bjog* 1999;106(4):304–8.
- [3] Prata N, et al. Controlling postpartum hemorrhage after home births in Tanzania. *Int J Gynaecol Obstet* 2005;90(1): 51–5.
- [4] Walraven G, et al. Misoprostol in the management of the third stage of labour in the home delivery setting in rural Gambia: a randomised controlled trial. *Bjog* 2005;112(9): 1277–83.