

## Misoprostol for the Prevention of Postpartum Hemorrhage in Home Birth Settings in Rural Pakistan

### *Summary of Research*

#### **Introduction**

Postpartum hemorrhage (PPH) is the single largest cause of maternal mortality worldwide, accounting for nearly 25% of all maternal deaths. A woman suffering from excessive bleeding after childbirth can die quickly unless she receives immediate and appropriate medical care. In rural, low-resource settings, where the majority of deliveries take place at home without a skilled birth attendant present, women face great risk of serious complications or even death from PPH due to limited access to emergency maternal health care services.

While oxytocics are the recommended treatment for PPH in hospital settings, many rural areas have neither access to these drugs nor the means to store or administer them. Few studies have addressed the reality of managing PPH where access to oxytocics is limited. Effective use of oxytocin requires refrigeration, sterile equipment for safe injection, and trained medical providers for administration. Given these constraints, misoprostol has been investigated as a potential alternative therapy for PPH prevention and has shown similar effectiveness to that of standard injectable oxytocics. Misoprostol offers several important advantages over standard regimens, including its oral administration, stability at high temperature, wide availability, and low cost. In order to determine the impact of postpartum administration of misoprostol on PPH in home birth settings where access to oxytocin is limited, the Aga Khan University-Karachi, Aga Khan Health Services-Pakistan & France, and Gynuity Health Projects-New York are jointly conducting a community-based study in Pakistan's North-West Frontier Province. It is hoped that this study provides evidence that will facilitate the development of sustainable means of PPH prevention for use in low-resource settings where the need for low-tech services is greatest.

#### **Study Description**

This double-blinded randomized-controlled trial enrolling 1,600 women aims to test whether oral misoprostol reduces the incidence of PPH when administered by trained traditional birth attendants (TBAs) during the third stage of labor. As of October 2005, consenting women are randomized to receive either 600µg oral misoprostol or matching placebo. Women with pregnancy complications or who plan to deliver at a health center are not eligible to participate in the study. Data collection on outcomes including rate of PPH (• 500mls), change in hemoglobin, and mean blood loss will be completed in early 2007.

In this study, specially trained TBAs, Lady Health Visitors (LHVs), and Community Health Nurses (CHNs) share the responsibility of delivery care, data collection and protocol compliance. LHVs and CHNs located at 18 primary-care Aga Khan Health Service facilities are responsible for consenting pregnant women, conducting interviews during antenatal care visits, and measuring blood loss and hemoglobin pre- and post-delivery. TBAs are responsible for conducting deliveries, administering study medication, collecting blood loss, and recording any side effects experienced by study participants.

The primary objective of this study is to demonstrate a significant reduction in rate of PPH in a setting where currently no other uterotonic therapy is available. Additional benefits of the study may also include prompt detection of severe PPH due to standardized blood collection, an increase in referrals for emergency care, improved postpartum care, early recognition of anemia, and stronger linkages between TBAs and primary care health facilities.

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