POLICY FRAMEWORK: MISOPROSTOL FOR POSTPARTUM HEMORRHAGE
Need for Policy Guidance

- Misoprostol frequently used in clinical settings – great variability, rarely evidence-based protocols
- Evidence growing over last decade – national clinical guidelines slow to adapt
- International and national organizations provide guidance to governments
World Health Organization: Prevention

Recommendations on the Prevention of Postpartum Hemorrhage, 2007

- “In the absence of AMTSL, a uterotonic drug (oxytocin or misoprostol) should be offered by a health worker trained in its use for prevention of PPH.”

- Additional remarks acknowledge the ease of administration of an oral drug in settings where other care is not available
World Health Organization: Treatment

Guidelines for the Management of PPH and Retained Placenta, 2009

- “Misoprostol may be considered as a third line of treatment for the management of PPH, because of its ease of administration and low cost compared with injectable prostaglandins.”

- Additional remarks acknowledge that in cases where oxy and other injectable uterotonic drugs are not available, misoprostol maybe considered as a treatment option
WHO does not recommend distribution of misoprostol to community level health workers or women and their families for routine or emergency use. WHO recommends research at the community-level to investigate how postpartum haemorrhage can be managed effectively at this level.
In 2006, in a joint statement the International Confederation of Midwives and FIGO stated:

- **Prevention**
  - "In situations where no oxytocin is available or birth attendants’ skills are limited, administering misoprostol soon after the birth of the baby reduces the occurrence of haemorrhage."

- **Treatment**
  - “…it [misoprostol] may be appropriate for use in low resource settings and has been used alone, in combination with oxytocin, and as a last resort for PPH treatment.”
Current guidelines based on expert review of existing evidence; published in IJGO supp. 2007

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<th>Indication</th>
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| Prevention | 600 mcg oral single dose     | o Prophylaxis administered after birth of baby and before placental expulsion  
 o Not as effective as oxytocin or ergometrine  |
| Treatment  | 600 mcg oral or sublingual single dose | o Misoprostol should be used only after the provider has exhausted all standard PPH treatments  |
Guidelines for the Prevention and treatment of Post-partum Hemorrhage in Low Resource settings (forthcoming 2011), to include:

- Misoprostol indicated when oxytocin not available:
  - Prevention: 600 mcg oral misoprostol
  - Treatment: 800 mcg sublingual misoprostol
National Guidelines
Prevention

"... in situations where no oxytocin is available or birth attendants’ facilities are limited (for example, a home birth) misoprostol reduces the risk of haemorrhage."

Treatment

For uterine atony, misoprostol is included in the list of possible pharmacological measures.

Misoprostol may be an appropriate alternative in settings where parenteral prostaglandins are not available or where there are contraindications to prostaglandin F2.
Misoprostol is included in the list of additional uterotonics to be used as the first-line treatment for hemorrhage in the event of decreased uterine tone.
Essential Medicines List
What is it?

The WHO Model List of Essential Medicines (EML) is an evidence-based resource that can be used:

- by countries to guide development of natl. EMLs to procure and supply medicines in public & private sector; medical reimbursements; donations; guide local medicine production
- by UNICEF, UNHCR & UNFPA & various intl. non-profit supply agencies as basis of medicine supply
- to develop intl. lists for special conditions, e.g.: The Interagency Emergency Health Kit & Essential Medicines for Reproductive Health
Benefits and Possible Impacts of WHO EML

- Identifying a limited number of essential medicines may lead to a better supply, more rational use & lower costs
- The selection of medicines, linked with clinical treatment guidelines and M&E, can impact access, quality of care, and cost of treatment
- Can help normalize misoprostol use for PPH indications
2011 EML: Misoprostol for PPH Prevention

- Application prepared by Gynuity Health Projects and Venture Strategies for Health
- Application approved by Expert Committee
- Recommended regimen: 600 mcg orally
  - “…Committee decided to add misoprostol to the List for the prevention of PPH in settings where parenteral uterotonics are not available or feasible.”
  - Report cited Mobeen et al. study demonstrating potential benefit “…from use of misoprostol by traditional birth attendants or assistants trained on the use of the product at home deliveries.”
  - Moved misoprostol from complementary to core list
2011 EML: Misoprostol for PPH Treatment

- Application prepared by Gynuity Health Projects
- Suggested regimen: 800 mcg sublingually
- Expert Committee did not approve due to concerns:
  - a joint recommendation of misoprostol for both PPH prevention and treatment may reduce attempts to make oxytocin more available
  - lack of data to support the safety and efficacy for treatment when given to women who have received 600 mcg prophylactic misoprostol
  - possible side effects after 800 mcg misoprostol
Beyond Policy Guidance

- What do the whole of recommendations tell us?
- What are the challenges and limitations of existing guidelines?
- **Advocacy and education** play key role to:
  - inform countries of EML status of drugs and international guidelines on use of misoprostol for PPH
  - promote inclusion of misoprostol in clinical and national maternal health policy guidelines
  - ensure evidence-based regimens are adopted