

Misoprostol for Postpartum Hemorrhage: Questions and Answers for Policy Makers

This document provides information and answers to decision makers' most commonly asked questions and concerns regarding misoprostol's role in preventing and treating life-threatening postpartum bleeding.

Background information

Why is misoprostol needed?

Every few minutes, somewhere in the world, a woman who has just given birth bleeds to death. Almost all of these cases of postpartum hemorrhage (PPH) can be prevented or effectively treated if every woman has access to essential health services and medicines, such as misoprostol and oxytocin, which help the uterus contract after birth.

In many low-resource countries, more than half of births take place at home, and many more occur in health facilities that lack electricity, refrigeration, and/or skilled health providers. Misoprostol, stable at room temperature and given by mouth, is often the best available option for preventing and treating PPH in such settings, and may be a woman's only chance for surviving PPH.

What is misoprostol?

Misoprostol is a medicine initially developed to prevent stomach ulcers from use of non-steroidal anti-inflammatory drugs. Misoprostol stimulates contractions of the uterus and is used for a number of maternal and reproductive health conditions, including PPH, induction of labor, treatment of miscarriage, and induced abortion (alone or in combination with mifepristone). Misoprostol is off-patent, and is inexpensive and widely available as a generic medicine in many countries.

Global health organizations and health professional associations, including the World Health Organization (WHO), the United Nations Commission on Life-Saving Commodities for Women and Children (UNCoLSC), and the International Federation of Gynecology and Obstetrics (FIGO), support the use of misoprostol for PPH in settings where oxytocin is not available.¹⁻⁴

What are misoprostol's advantages?

Oxytocin—the recommended standard of care for PPH prevention and treatment—requires cold storage and is an injection administered by a skilled health care provider. Misoprostol offers a number of advantages over oxytocin: it is available in tablet form, can be stored without refrigeration, and can be administered without any specialized skills. In low-level health facilities and in community and home-birth settings, where oxytocin is not available or where its administration is not feasible, misoprostol provides an effective option for preventing and treating life-threatening bleeding.⁵⁻⁸

Is misoprostol safe and effective?

Extensive research has shown misoprostol is safe and effective in preventing and treating PPH in health facilities and community settings.⁹⁻¹² Misoprostol is recommended by WHO for prevention of PPH (three tablets of 200 micrograms given orally) and for treatment of PPH (four tablets of 200 micrograms under the tongue) when oxytocin is not available or cannot be safely used.

Women who use misoprostol can experience temporary side effects, but these symptoms can be easily managed at home. Common side effects include shivering, increased body temperature, nausea, and/or diarrhea.¹⁴

How can governments procure misoprostol?

Misoprostol is registered for PPH indications in more than 30 countries. While registration grants permission for a product to be marketed in a country for a specific medical indication, misoprostol is also used off-label.

Many manufacturers produce misoprostol; not all manufacturers follow established standards of quality, safety, and efficacy. Governments should procure quality-assured products, which have either been prequalified by WHO, by a Stringent Regulatory Authority (SRA), or a national mechanism for ensuring quality assurance. There are two misoprostol products pre-qualified by WHO (Misoprost and GyMiso) and one product approved by the European Medicines Agency (Hemoprostol).

Who can provide misoprostol?

Research has shown that misoprostol can be safely administered by skilled health providers and by community health workers.¹⁵⁻¹⁷ In its 2012 “Recommendations for Optimizing Health Worker Roles to Improve Access to Key Maternal and Newborn Health Interventions through Task Shifting,” the WHO recommends administration of misoprostol by community and lay health workers for PPH prevention at home deliveries when oxytocin is unavailable.¹⁸

Addressing concerns

Will community distribution of misoprostol decrease use of health facilities for childbirth?

Research has shown that providing misoprostol at the community level does not

decrease use of facilities for childbirth. In fact, in some countries, such as Nepal, Afghanistan and Zambia, community PPH programs that include distribution and use of misoprostol are associated with increases in the number of women who go to facilities for delivery.¹⁹

Will wider availability of misoprostol result in its use for other indications?

Misoprostol is an essential part of a package of strategies to improve maternal health. Other alternative uses for misoprostol, including abortion, should not lead to restrictions on its availability for PPH. In countries with misoprostol for PPH programs, misoprostol was used appropriately for the indication for which it was intended; women and health providers did not use the medicine for anything other than PPH.²⁰

Is community-based distribution of misoprostol a safe and effective strategy for reaching women who give birth at home?

A review of published studies and programs for prevention of PPH at home birth using misoprostol showed that these programs can achieve high distribution and use of misoprostol.¹⁹ Misoprostol can be used safely and correctly when administered by health providers or distributed by community health workers. In addition, women who receive misoprostol during pregnancy (a strategy known as self-administration) store it safely and use it appropriately, provided there is clear instruction and adequate counseling.²²

Actions for governments

What can governments and national policy makers do to increase access to misoprostol for PPH?

Governments and implementing partners should take action to ensure that misoprostol for PPH is more widely available in the public sector. They should:

- 1. Establish clear and evidence-based policies and guidelines** that prioritize misoprostol's role in PPH prevention and treatment, and that support the distribution of misoprostol by community health workers and health providers.
- 2. Train and support health providers and community health workers** on appropriate use and administration of misoprostol for PPH.
- 3. Ensure a reliable supply of misoprostol products** by procuring quality-assured products from manufacturers in sufficient quantities to ensure rollout and stock maintenance at the community level and in health facilities.
- 4. Allocate sufficient funds in national (and subnational) budgets** that support misoprostol's rollout in the national health system.
- 5. Strengthen the supply chain** to address inefficiencies to ensure availability at all levels of the health system.

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