

Misoprostol and medical abortion in Latin America and the Caribbean



More than 500,000 women in the world die every year from pregnancy-related causes, and close to 15,000 of these deaths occur in Latin America and the Caribbean.¹ Although the maternal mortality ratio in the region has decreased by 28 percent since 1990 (from 180 to 130 per 100,000 live births), this reduction will still not meet the Millennium Development Goals target by 2015.² In addition, this regional average masks the vast differences between countries where ratios can be as low as 16 in the Bahamas, Barbados and Chile and as high as 670 in Haiti.³ Despite improvements, the persistence of high maternal mortality underscores the need to find and implement effective solutions in the region. The medicine misoprostol, a proven technology for a variety of obstetric and gynecologic uses, can help save lives, particularly in Latin America and the Caribbean, where postpartum hemorrhage (PPH) and incomplete abortion account for a large portion of maternal deaths.

Misoprostol is important in the treatment of postpartum hemorrhage, which is the primary cause of maternal mortality in the world, and is a simple, non-invasive, safe and low-cost method for treatment of incomplete abortion, instead of sharp curettage or manual or electric vacuum aspiration.⁴ It can also be used for cervical ripening, labor induction (which can lead to a reduction of cesarean rates), and treatment of intrauterine fetal demise, as well as dilating the cervix prior to insertion of an intrauterine device (IUD) or performance of a hysteroscopy.⁵ In addition, it does not require hospitalization or the use of an operating room, and it prevents the complications that often result from surgical procedures.⁶ It also remains stable at room temperature and can be easily transported, an important advantage for use in primary health-care settings.⁷

Cost analysis

The results of a cost analysis conducted in Mexico prior to the legalization of abortion in 2007 estimated the average cost for treating serious complications from unsafe abortion at \$209 (U.S. dollars) per woman. The estimated cost for providing a safe medical abortion with misoprostol was only \$98 per woman.⁸

Misoprostol can also be used by itself or in combination with another medicine, mifepristone, to end an unwanted pregnancy safely and in a variety of settings. Medical abortion with misoprostol and mifepristone, or misoprostol alone, can save women's lives.

Throughout Latin America and the Caribbean, many women face serious obstacles to fertility control due to the lack of availability of information and supplies, the high cost of contraceptive methods, poor quality of care and socio-cultural barriers.⁹ In addition, legal access to abortion is significantly restricted in most of Latin America (except Cuba, Guyana, Puerto Rico and Mexico City). Although laws often permit abortion under certain circumstances, several barriers such as poor drug availability, procedure cost and lack of access to trained providers impede even legal abortions from being carried out in practice.¹⁰

Despite these restrictions, abortion is widely performed throughout the region. When carried out or supervised by properly trained medical personnel in a safe environment, abortion is a safer procedure than childbirth.¹¹ In legally restrictive contexts, however, abortion is associated with increased risk, and its safety is closely linked to the woman's socioeconomic status, provider ability and the conditions in which the abortion is performed. Each year, there are an estimated 3.9 million unsafe abortions in Latin America, making it one of the regions with the highest incidence rates worldwide (29 abortions per 1000 women 15-44 years old,¹² or close to one unsafe abortion for every three live births). Poor women experience the most adverse consequences of clandestine abortion since they may resort to dangerous methods, including insertion of sharp objects (a knitting needle, the stem of a plant, a catheter, etc.), liquids (soapy water, vinegar), or chemicals (potassium permanganate) inside the vagina or uterus; ingestion of acidic substances, caustic products or herbal teas; and infliction of external physical trauma to produce contusions in the uterus.¹³ Approximately 2000 women in the region die due to unsafe abortion annually, representing 11 percent of all maternal deaths.¹⁴ Close to one million women are hospitalized each year due to complications from unsafe abortions,¹⁵ the most common of which are incomplete abortion, hemorrhage and infection. Serious complications can require highly complex emergency medical care that frequently is not accessible or is very costly, or result in long term or chronic morbidity, including secondary infertility.¹⁶ In addition, women may delay seeking medical care, whether out of fear of legal repercussions or due to the social stigma surrounding abortion. It is estimated that between 10 and 20 percent of all women who have abortions need, but do not receive, medical attention for serious complications caused by unsafe methods.¹⁷

Common terms

Mifepristone: A medication that stops a pregnancy from developing and softens the cervix (the opening to the womb). Used with misoprostol for medical abortion.

Misoprostol: A medication that causes the cervix to soften and the uterus to contract. Can be used to prevent and treat postpartum hemorrhage, treat incomplete abortion or miscarriage, induce abortion (by itself or with mifepristone), and induce labor.



The promise of medical abortion

Medical abortion is a feasible and safe alternative for use in the region. It can be used without significant facility space, medical equipment or highly trained providers, which makes it suitable for the most local level of care. Although mifepristone and misoprostol used together is the most effective form of medical abortion (up to 98.5 percent effective up to nine weeks gestation),^{18,19,20} misoprostol used alone (up to 90 percent effective up to nine weeks gestation)^{21,22} is the most readily accessible alternative option for safe abortion in Latin America and the Caribbean.

The use of misoprostol has radically transformed the management of induced abortion. For the first time, in places where other safe abortion services are not available, women have a method that is non-invasive, amply safe and effective, and which does not require third party participation. Abortion with misoprostol is on the rise throughout the region, and in countries where abortion is not legal it has increased the safety of self-induced procedures by reducing complications related to unsafe abortion.^{23,24,25,26}

In 2009, the World Health Organization (WHO) included misoprostol for the treatment of incomplete abortion in its List of Essential Medicines (with a special note indicating “where permitted under national law and where culturally acceptable”).²⁷ In addition, the Latin American Federation of Obstetrics and Gynecology Societies (FLASOG) developed a manual entitled “*The Use of Misoprostol in Gynecology and Obstetrics*” with the purpose of providing clear guidelines for the medical community.²⁸ The International Federation of

Gynecology and Obstetrics (FIGO) has also endorsed the use of misoprostol for a diverse range of obstetric indications.

Country case studies

The use of misoprostol for self-induced abortion was first reported in Brazil, where it began to be marketed in 1986. Research from this country has documented an association between the use of misoprostol and the reduction of complications from unsafe abortions.^{29,30,31} In 1991, the government restricted the availability of the drug, and since then abortion-related morbidity and mortality have increased once again.³²

In contrast, since misoprostol was introduced in the Dominican Republic in 1986, reports indicate that severe abortion-related complications have been reduced by 75 percent.³³

Access to mifepristone and misoprostol in Latin America and the Caribbean

In most Latin American countries, misoprostol is approved for the treatment of gastric ulcers, its original indication, and is widely available. In contrast, mifepristone is currently available in only one country in the entire region (Guyana).

Despite the proven advantages of this medication, misoprostol has only been registered for gynecology and obstetric indications in three countries (Brazil, Peru

and Colombia).³⁴ Nevertheless, the absence of regulation has not impeded it from becoming ever more important in ob-gyn practice.³⁵ In March of 2007, WHO included misoprostol in its List of Essential Medicines as a medication for pregnancy termination.

In a 2009 study sponsored by the Latin American Consortium Against Unsafe Abortion (CLACAI),³⁶ at least 39 medications containing misoprostol were identified in the region and the cost varied widely, ranging from \$1 to almost \$38 per tablet, making it quite expensive.

In addition, because women are now using misoprostol for self-induced abortion, some governments and pharmaceutical companies are taking measures to restrict access to the drug. These measures ignore the significant reduction that misoprostol use has caused in unsafe abortion as well as its contribution to reducing maternal morbidity and mortality.

Most countries in Latin America and the Caribbean have legal indications for abortion, however there are few clinical protocols that guide abortion care. This is because the existing regulations are designed to establish legal mechanisms that restrict access to abortion, rather than to establish adequate standards for quality abortion care. Colombia and Bolivia have developed such standards, and several hospitals in Peru have implemented their own technical guidelines for care, although the legal restrictions in place in these countries continue to limit access.

The latest policy advances in Mexico City have had the greatest impact on access to legal abortion in the region. On April 24, 2007, lawmakers voted for legislation permitting abortion upon request during the first three months of pregnancy. The law requires that the Mexico City Ministry of Health provide legal abortion services, free of charge for district residents, to any woman who requests them. In Mexico City, three years after the law was passed, records showed that almost

40,000 women had been attended at public facilities³⁸, largely with misoprostol. This experience demonstrates that establishing abortion care regulations, under laws that allow their application, facilitate women's access to safe abortion services.

Strategies for expanding access to medical abortion in Latin America and the Caribbean

Adequate provision of contraceptive services is a key step to reducing the number of unsafe abortions in the Latin American region. However, access to safe abortion services will always be necessary and medical abortion in the first trimester is one of the best options for safe and effective early pregnancy termination, leading to the reduction of morbidity and mortality. Despite the fact that misoprostol is easy to use and potentially widely available, there is no guarantee that women will be able to access it. Different strategies are needed that involve the medical community, sexual and reproductive rights activists, researchers and health decisionmakers.

Strategy #1: Expand policies, guidelines and service delivery protocols

- Draw on FLASOG protocols to develop national standards and service delivery protocols for induced abortion, with a focus on safety and quality of care.
- Include misoprostol on essential medicines lists and in guidelines for induced abortion and for the treatment of obstetric complications, including incomplete abortion, missed abortion and postpartum hemorrhage.
- Design protocols that emphasize provision of misoprostol at the primary-care level and by a range of health-care workers.

Access and information for women

In most countries in Latin America, information about misoprostol is spread by word of mouth. Pharmacies often provide guidance and dispense the medication despite the fact that regulations in most countries require that it be sold only by prescription. It is also accessed through providers in informal settings or on the Internet. According to a review by Ipas of global data on misoprostol sales, Latin America is the region in which misoprostol is sold at the highest prices.³⁷

Women who use misoprostol do not always receive accurate instructions for its use, including information about when it can be safely used, the possible side effects and warning signs. Counseling is crucial so that women can be taught to recognize the symptoms and side effects, along with timely detection of complications as they go through the abortion process.

- Create service delivery protocols for use of misoprostol, highlighting its inclusion in the WHO List of Essential Medicines.
- Ensure that service delivery protocols and procurement systems adequately include contraceptive counseling and provision, including emergency contraception.
- Ensure that policies, guidelines and protocols address the special needs of women who have experienced sexual violence.
- Organize accompaniment for women, trainings, community visits and activities, and strengthen the participation of nongovernmental organizations (NGOs) and community leaders.
- Build the knowledge and capacity of women and men by partnering with community groups to increase awareness and empower women, especially young women.

Strategy #2: Educate a full range of providers and advocates

- Familiarize health professionals with the existing scientific evidence on misoprostol, such as basic pharmacokinetics, efficacy, acceptability, dosage, routes of administration, etc.
- Include the use of misoprostol for the treatment of obstetric complications in the training curricula for health professionals, and train health teams (doctors, nurses, midwives) on the use of misoprostol for different indications as well as on counseling for side effects, warning signs and when to make referrals to other facilities.
- Develop a critical mass of professionals in every country in the region who are experienced in the use of misoprostol and can support and provide guidance for the development of local technical guidelines for its use, as well as serve as mentors to support other health-care professionals and facilities in integrating misoprostol.
- Train providers in human rights, values clarification and medical ethics as they relate to women's reproductive rights and health.
- Train advocates to promote broad interpretation of laws and engage in legal reform efforts that improve women's access to care, as well as help protect people who engage in the off-label use of misoprostol.

Strategy #3: Work with women and their communities

- Disseminate information about the use of misoprostol in the general population through media: telephone hotlines, the Internet, brochures, radio spots, television and short films with post-viewing debates.

Reducing risks and harm related to unsafe abortion

In response to the serious public health problem caused by unsafe abortion, the Uruguayan organization "*Iniciativas Sanitarias Contra el Aborto Provocado en Condiciones de Riesgo*" (Health Initiatives Against Induced Abortion in High Risk Conditions) developed a strategy of comprehensive care for women with unwanted pregnancies based on access to information through pre- and postabortion counseling. In the counseling session, information and guidance is given regarding the correct use of misoprostol, but the medication is not prescribed or provided. Each woman decides whether to obtain the medication, and if she uses it, the organization offers follow-up and postabortion care. This strategy is based on the recognition of women's rights to information, privacy, and confidentiality and it appeals to health professionals' ethical obligation to address the problem of unsafe abortion. Since the implementation of this strategy, significant reductions in postabortion complications and maternal deaths have been reported.³⁹

Strategy #4: Mobilize pharmacists

- Train pharmacy staff to become key stakeholders in the provision of accurate misoprostol information, services and referrals.
- Collaborate with pharmacy associations to inform and support key decisionmakers and champions within the pharmacy community.

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