

Second Edition

## Medical Abortion Study Guide

Disclaimer: The regularly updated *Clinical Updates in Reproductive Health* (www.ipas.org/clinicalupdates) provides Ipas's most up-to-date clinical guidance, which supersedes any guidance that may differ in Ipas curricula or other materials.



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Ipas is a nonprofit organization that works around the world to increase women's ability to exercise their sexual and reproductive rights, especially the right to safe abortion. We seek to eliminate unsafe abortion and the resulting deaths and injuries and to expand women's access to comprehensive abortion care, including contraception and related reproductive health information and care. We strive to foster a legal, policy and social environment supportive of women's rights to make their own sexual and reproductive health decisions freely and safely.

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## Ipas abortion-related training and service delivery curricula and other resources CD-Rom – Relevant materials for this curriculum:

Medical Abortion Study Guide (pdf file)

Medical Abortion Training Guide (pdf file)

Medical Abortion Training Guide PowerPoint Presentation (ppt file)

Quiz Show PowerPoint and Flash Plug-in (ppt and swf file)

Medical Abortion in Early Pregnancy: Information, Education, and Communication (IEC) Materials and Job Aids

MA Supply Guidance Spreadsheet (xls file)

Woman-Centered, Comprehensive Abortion Care: Reference Manual and Trainer's Manual, Second Edition (pdf and ppt files)

Abortion Care for Young Women: A Training Toolkit (pdf and ppt files)

Effective Training in Reproductive Health: Course Design and Delivery. Reference Manual and Trainer's Manual (pdf and ppt files)

## About the Medical Abortion Study Guide

The Medical Abortion Study Guide is one of two companion documents in the Ipas medical abortion (MA) training package. The Medical Abortion Study Guide and the companion Training Guide were designed as a supplement to accompany Ipas's more comprehensive abortion care training curriculum, Woman-Centered, Comprehensive Abortion Care: Reference and Trainer's Manuals, Second Edition.

- *MA Study Guide* to be used for self-directed study prior to attending an in-person workshop and clinical practicum and a resource document for future reference.
- *MA Training Guide* to be used by clinical trainers to lead participants through an in-person workshop followed by a clinical practicum.

#### Clinical updates

All the clinical information in this manual is up-to-date at the time of publication. For updated clinical guidance, please see the *Clinical Updates for Reproductive Health* series at Ipas's website, www.ipas.org.

#### **Purpose**

The *MA Study Guide* describes the use of medications for first-trimester abortion. It is intended to prepare health-care providers for the in-person skills training and clinical practicum portions of MA training programs. It can also serve as a reference manual during training events and for future reference.

#### **Objectives**

Upon completion of the MA Study Guide, learners should be able to:

- 1. Explain Ipas-recommended MA drug regimens
- 2. Describe eligibility, contraindications and precautions
- 3. State expected and potential side effects of MA
- 4. Explain information the woman should know about MA, including warning signs to seek medical care
- 5. Identify when women need urgent follow-up care

6. Identify personnel, facility, record-keeping and supplies requirements needed to implement MA services at their work site

Each module in the study guide has three sections: the contents, review questions and reflection questions.

The modules provide information about MA: recommended regimens, eligibility, clinical care, counseling and information, and service delivery issues.

The *Review* section provides questions that focus on key learning points. Correct answers are listed in the answer key.

The *Reflect* section is designed to stimulate thinking about what is currently in place for MA services and how to apply the contents of the study guide to actual service delivery settings.

#### Second edition

This study guide was designed to train providers on the delivery of high-quality, clinic-based, first-trimester medical abortion (MA), particularly in limited-resource settings. This second edition has been updated to reflect the latest evidence from the World Health Organization (WHO 2012) and other important source documents. These updates include current clinical evidence and recommendations on providing appropriate MA care to young women and working with communities to improve information, social support and access.

This curriculum focuses on provision of MA by trained health-care providers working in facilities in the formal health-care system. There is increasing attention on making MA information and drugs more widely available to women in real and virtual communities outside the formal health system, particularly in settings where women face serious risks due to lack of access to safe services. Ipas has policies, materials and programs to support these efforts. In this second edition, we have included some recommendations on how to increase access and improve linkages between communities and health facilities. For more information on this, please see Additional Resources, Community Access.

In this second edition, we address young women's unique needs in an effort to increase MA service delivery and access. Young women are disproportionately affected by unsafe abortion. Girls aged 10 -19 in developing countries undergo at least 2.2 to 4 million unsafe abortions and account for approximately 45 percent of unsafe abortion-related deaths each year (WHO 2007). Women under the age of 20 make up 70 percent of all hospitalizations from unsafe abortion complications (Plan 2007). We note where there is evidence for any clinical or other differences for young versus adult women. Where it is relevant, we also note where there is a lack of evidence. Throughout this manual, we generally refer to young women (ages 10-24). Where the evidence specifically applies to adolescents (ages 10-19, per WHO), we use that term. For more information on abortion care for young women, please see Additional Resources, Young Women.

## About the MA Training Program

The Ipas MA training program has been designed to train providers on the delivery of high-quality, clinic-based, first-trimester MA, particularly in limited-resource settings. The *Medical Abortion Study Guide* and the companion *Training Guide* were designed to accompany Ipas's more comprehensive abortion care training curriculum, *Woman-Centered*, *Comprehensive Abortion Care: Reference and Trainer's Manuals*, *Second Edition*. There are three major components to this training program:

- Self-directed study
- In-person workshop
- Clinical practicum

This blended learning approach combines the acquisition of essential knowledge through self-guided study with skills development in a face-to-face workshop setting that can then be applied to an actual clinical practice setting during the practicum.

As a participant in this training program, individuals are required to complete self-guided study using the *Medical Abortion Study Guide* prior to attending the workshop and practicum. We recommend administering a pre-test prior to the workshop that covers the information included in the *MA Study Guide* and requiring learners to score 75 percent or higher on this test to participate in the workshop and practicum. This requirement ensures all trainees have a base of requisite knowledge that they apply through skills practice in the in-person training and practicum.

Learners who do not have access to mifepristone can skip Module 2A, Medical abortion with mifepristone and misoprostol, and instead use Module 2B, Medical abortion with misoprostol only. Because MA using both mifepristone and misoprostol is more effective than misoprostol only, Ipas recommends that MA be provided with the combination of the two wherever possible.

Additional options for self-guided learning are available at IpasUniversity, which offers free, online, on-demand courses for reproductive health professionals on safe abortion care and postabortion care. These courses can be used for self-guided learning or as the online component of a blended learning model. For the IpasUniversity course catalog, see http://www.ipas.org/en/Resources/Ipas%20Publications/IpasUniversity-course-catalog. aspx; to register and take courses, please go to www.IpasU.org.

#### Intended participants

This training program is designed for health-care providers, including midwives, nurses and other mid-level providers, general practice physicians, obstetrician/gynecologists and any other providers who are authorized in their setting to provide clinic-based, first-trimester medical abortion. The content focuses on the basic information necessary for provision of care but includes resources for further study or expansion of skills, depending on participants' needs. The content builds on participants' prerequisite knowledge, skills and training in comprehensive abortion care, which are listed below. Where participants have not had this comprehensive training, trainers should supplement the MA content, drawing from Ipas' *Woman-Centered Abortion Care* curriculum, which is included on the CD-Rom and available on www.ipas.org/resources.

#### **Prerequisites**

Participants in the MA training program should minimally already be able to:

- Demonstrate knowledge of the anatomy and physiology of the female reproductive system
- Demonstrate skills in taking a medical history and conducting a physical exam
- Accurately assess the gestational age of an early pregnancy
- Recognize and manage or refer women for treatment of abortion complications

Participants ideally should already be able to:

- Describe the key components of woman-centered abortion care: choice, quality and access and the importance of prioritizing each woman's individual needs
- Describe circumstances under which abortion is permitted and those under which it is restricted by law or policy
- Perform or refer women for vacuum aspiration services when needed
- Recognize clinical symptoms of ectopic pregnancy and perform or refer for appropriate treatment

#### Duration of training program

The following are estimates; actual times will vary:

• Self-directed study: 4-6 hours to read and complete the review and reflect questions in the *Study Guide*.

- Workshop: 2-4 days depending on use of the modules and expansion or reduction of content. The workshop agenda should be tailored to meet participants' learning needs.
- Clinical practicum: 4-6 hours to complete a focused clinical practicum. These estimates are highly variable and depend greatly on the setting, caseloads and other considerations.

Ipas Medical Abortion Study Guide

### Module 1: Overview

#### Introduction

Medical abortion (MA) using mifepristone and misoprostol or misoprostol only is a safe, effective, and acceptable option for terminating pregnancies (RCOG 2004, WHO 2012, Winikoff 2008, von Hertzen 2003, von Hertzen 2007, Hamoda & Templeton 2010). Millions of women throughout the world have chosen MA (also referred to as medication abortion, pharmacological abortion, or the abortion pill) and find it to be a highly acceptable option. Many women describe MA as a method that feels more natural and can be taken at home in private, thereby allowing them more control than with other methods.

Women who do not have access to safe abortion are too often forced to resort to unskilled providers who work in unhygienic conditions, in many cases causing death and disability. Worldwide in 2008, 21.6 million unsafe abortions took place, leading to an estimated 47,000 preventable maternal deaths (WHO 2011). In low-

resource settings and where access to other safe abortion methods is limited, MA has the potential to dramatically reduce maternal morbidity and mortality. In 2003, young women comprised approximately 45 percent of all estimated unsafe abortion-related deaths globally (WHO 2007) and stand to benefit from the many advantages of MA. Therefore we make special mention of MA for young women whenever appropriate in this study guide and hope this will lead to increased service delivery and access for young women.

This module provides a short overview of first-trimester abortion methods, describes how MA has the potential to improve access to safe abortion care, and briefly reviews MA acceptability. Subsequent modules include details on success rates, drug regimens, side effects, pain medications, follow-up and complications.

#### Abortion methods

Uterine evacuation (removal of the contents of the uterus) may be accomplished in the first trimester by medications, vacuum aspiration or sharp curettage. Although sharp curettage is common in many countries, WHO guidelines state that it should be used only when vacuum aspiration or MA are not available (WHO 2012). A recent statement by the International Federation of Gynecology and Obstetrics (FIGO) supported the use of vacuum aspiration or medications over sharp curettage for uterine evacuation (FIGO 2011). Therefore, health-system officials and administrators should make all possible efforts to replace sharp curettage with vacuum aspiration or MA. If services are being introduced for the first time, vacuum aspiration and medical abortion should be introduced rather than sharp curettage.

With vacuum aspiration, the contents of the uterus are evacuated through a plastic or metal cannula using suction provided by a handheld, portable aspirator (manual vacuum aspiration) or by an electric pump (electric vacuum aspiration). Vacuum aspiration is an important alternative to and occasional back-up for MA.

MA, a globally endorsed method, involves the use of various medicines to evacuate the uterus. WHO stated in 2003 and reiterated in 2012 that "medical methods of abortion have been proved to be safe and effective" (WHO 2003, WHO 2012). In 2005 WHO added mifepristone with misoprostol and misoprostol only to its Model List of Essential Medicines (WHO 2005). Mifepristone with misoprostol was also included in the Interagency List of Essential Medicines for Reproductive Health, compiled by several of the UN agencies and other international NGOs, specifically for medical abortion within 9 weeks gestation (WHO 2006).

The medications mifepristone and misoprostol are increasingly used worldwide for MA (Gynuity Health Projects 2011). Other medications, namely methotrexate, and other prostaglandins, such

as gemeprost, are sometimes used. This study guide focuses on the use of mifepristone and misoprostol or misoprostol only.

Adolescents may use the same methods of uterine evacuation as adult women. A recent study showed that adolescent women seeking medical abortion have similar or lower rates of adverse outcomes than adult women (Niinimäki 2011).

#### Access

MA has the potential to greatly improve access to safe abortion and may be particularly beneficial in settings where uterine evacuation services are limited or completely unavailable. MA offers the following advantages in low-resource settings or in communities where access to safe abortion is restricted:

- MA services are simple to deliver, easy to manage and the medications do not require refrigeration. MA may require less equipment, facilities and staffing.
- MA may be more accessible than vacuum aspiration because many provider cadres can be trained to provide MA, and research has demonstrated that appropriately trained cadres of providers can administer medical abortion as safely as doctors in low-resource settings (Warriner, et al 2011). This facilitates care being provided at the most local level, close to where women live and work. This may particularly benefit young women, who are known to have reduced access to safe abortion (Turner 2011).
- In many settings, clinicians can provide information on correct MA doses and regimens to women even if they are not authorized to directly dispense the drugs.
- In settings where sharp curettage has been the main method of uterine evacuation, MA provides an especially desirable alternative, eliminating the potential need for general anesthesia and a hospital stay.
- MA is the safest and perhaps only abortion option available in some clinical situations (Creinin 1996):
  - When a woman has certain uterine anomalies that preclude the use of MVA or sharp curettage
  - When cervical dilation is or would be difficult, such as with cervical stenosis.
- MA may be cost-effective when compared with other methods. Costs vary depending on the price of medications, number of clinic visits and specific clinical protocols (Murthy &Creinin 2003, Creinin 2000).

#### Acceptability

MA is highly acceptable to women in a variety of settings, including where resources are limited. Studies consistently show that 85 to 95 percent of women are satisfied or highly satisfied with the method, and would be willing to use it again or recommend it to a friend if needed (Winikoff 1997, Karki 2009). Women should be given a choice of method whenever possible and be provided sufficient information to make an informed decision.

Young women in multiple settings have similarly high satisfaction with MA(Carbonell 2001, Creinin 1996, Mamers 1997, Phelps 2001, Velazco 2000) and 92 percent of the young women in the Cuba studies would recommend the method to a friend (Carbonell 2001, Velazco 2000).

- Women often mention the non-surgical aspect of MA, compared to a vacuum aspiration procedure, as a significant benefit.
- Some women, including young women, perceive MA as a more private and natural method. Women may take the medications at home, which gives them more control over the conditions under which they have the abortion.

#### Review

Circle *all* correct answers. There may be more than one correct answer per question.

- 1. What are the preferred methods for uterine evacuation in the first trimester according to the World Health Organization (WHO)?
  - a. Medical abortion
  - b. Sharp curettage
  - c. Vacuum aspiration
  - d. Uterotonic instillation
- 2. Why does MA have the potential to improve access to safe abortion, particularly in settings where there are limited or no uterine evacuation services currently available?
  - a. It is simple and easy to use.
  - b. Many different types of providers can be trained to provide information and the medicines.
  - c. The drugs do not need refrigeration.
  - d. MA can only be provided in health-care facilities.
- 3. Why do many women find medical abortion highly acceptable?
  - a. The medicines can be taken at home.
  - b. It must be administered by a trained provider.
  - c. It can feel like a natural process.
  - d. It allows providers more control over the process.

#### Reflect

The following questions are designed to help you think about what is currently in place for MA service delivery and how to apply the contents of this module to your setting.

What are the current legal indications for abortion in your country or setting? Are they different for young women than for adult women? To what extent are safe abortion services available and accessible for all women who are legally entitled according to the current law in your country or setting? Are they as accessible for young women as adult women? What abortion methods are most often used by providers in your setting? 3. What research has been conducted on women's preferred abortion methods in your setting? Has the research explored young women's preferences compared to those of adult women? What medications are registered with the government for abortion care? 5. To what extent is there off-label use of medications, such as misoprostol, for MA?

# Module 2A: Medical Abortion with Mifepristone and Misoprostol

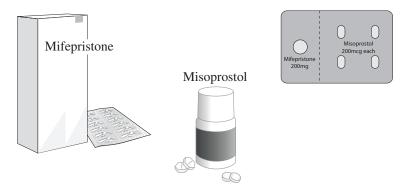
This module is about MA with mifepristone and misoprostol. All references to MA in this module refer to mifepristone with misoprostol.

#### Overview

The combination of mifepristone plus misoprostol is more effective in achieving complete abortion than either drug used alone (Ngoc 2011, Kulier 2011). In the first trimester, the combination of mifepristone and misoprostol results in successful abortion with no need for aspiration evacuation in over 95% of cases.

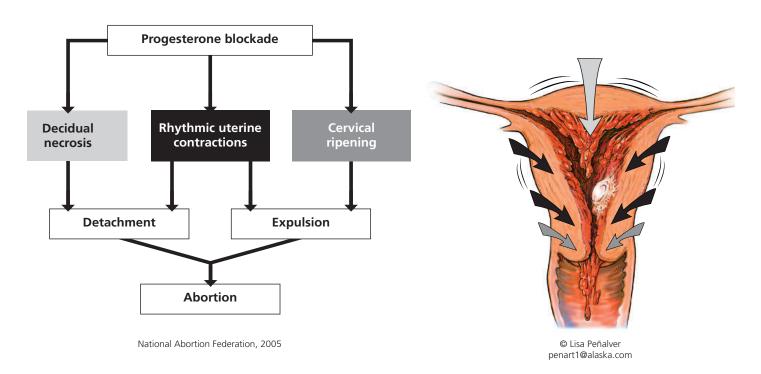
Mifepristone, developed in France and originally known as RU-486, was first approved for clinical use in 1988. Mifepristone blocks progesterone activity in the uterus, leading to detachment of the pregnancy. Mifepristone increases uterine sensitivity to prostaglandins (like misoprostol) and softens the cervix.

Misoprostol, a synthetic prostaglandin, stimulates cervical ripening (softening) and uterine contractions, causing uterine evacuation. Misoprostol is inexpensive and available in many countries for the prevention and treatment of gastric ulcers. Although it is stable at room temperature, the potency of misoprostol can degrade over time depending on its packaging or if it is exposed to high heat or humidity (Hall 2011). In 2009, misoprostol was added to the WHO list of essential medications for treatment of incomplete abortion and miscarriage and in 2011 for prevention of postpartum hemorrhage. It can also be used for cervical preparation before vacuum aspiration and other intrauterine procedures, labor induction and treatment of postpartum hemorrhage. For more information on this, please see Additional Resources, Misoprostol Other Uses.



Medical abortion pills

The image below illustrates the two medications' combined mechanism of action. For more information on this, please see Additional Resources, Mechanisms of Action.



#### Eligibility

#### Indication

• Termination of first-trimester intrauterine pregnancy

#### Contraindications for MA

If a woman has these specific conditions, under no circumstances should she be offered MA. MVA should be considered or she should be referred to a facility where she can be offered alternate care.

- Previous allergic reaction to one of the drugs involved
- Inherited porphyria
- · Chronic adrenal failure
- Known or suspected ectopic pregnancy

#### Precautions for MA

If a woman has these specific conditions, MA has higher risks than normal. The risks, benefits and availability of alternatives to MA must be considered. MA provision may require a higher degree of clinical judgment, skill and monitoring. Referral to a higher-level facility may be appropriate.

- IUD in place. Evaluate for the presence of ectopic pregnancy. If none, remove the IUD.
- Severe uncontrolled asthma or long-term corticosteroid therapy. No evidence exists regarding use of mifepristone in steroid-dependent women. Providers must use clinical judgment if no other alternatives to safe abortion exist.
   Increase steroid dose for 3-4 days and monitor the woman very closely. Conditions such as poorly controlled asthma may still be worsened.
- Severe/unstable health problems including but not limited to hemorrhagic disorders, heart disease and severe anemia. No evidence exists on the use of MA in women with hemorrhagic disorder, heart disease, severe anemia or severe/unstable health problems. Whether to provide medical abortion to women with these conditions will depend on the available options for safe abortion care, referrals, and clinical judgment. If medical abortion is given, it should be given under close observation.

For more information, please see Additional Resources, Contraindications and Precautions. For information about MA for termination of second-trimester intrauterine pregnancy, see Additional Resources, MA for Second-Trimester Abortion.

#### **Ectopic pregnancy**

Women who are pregnant and have a history of ectopic pregnancy, tubal surgery or have an IUD in place are at a significantly elevated risk of ectopic pregnancy. An ectopic pregnancy occurs when a fertilized egg attaches itself outside of the uterus, most often in a fallopian tube. Ectopic pregnancy is rare, occurring in less than 1% of women presenting for an abortion (Edwards & Creinin 1997). If an ectopic pregnancy is unrecognized, it can cause potentially life-threatening complications from rupture and hemorrhage. For this reason, ectopic pregnancy is a leading cause of maternal mortality in the first trimester (Khan 2006, WHO 1985). Therefore, providers should maintain a high index of suspicion for ectopic pregnancy and carefully evaluate women's risk before providing medical abortion. Uterine evacuation methods, whether vacuum aspiration or MA using misoprostol with or without mifepristone, will not terminate an ectopic pregnancy. Any woman with a suspected ectopic pregnancy should be educated about the risks, including tubal rupture, hemorrhage and death. Ruptured ectopic pregnancy occurs more frequently in women who have limited contact with health-care providers and present late for care (Obed 2006). Ruptured ectopic pregnancy is a gynecologic emergency that requires immediate surgical intervention.

#### Special considerations

MA with mifepristone and misoprostol may be given to women in the following categories:

#### Young women

MA is safe and effective in adolescents (Phelps 2001). MA has been shown to be even more effective in women who have not given birth before (Chien 2009, Le Febvre 2008). MA failure was found to be independently associated with women's older age, previous spontaneous abortions, multigravidity and earlier follow-up visit (Haimov-Kochman 2007). A Finnish study found that adolescents had fewer incomplete abortions, less need for surgical (re)evacuation, fewer hemorrhages and fewer complications than non-adolescents having surgical and medical abortion (Niinimäki 2011).

#### **Asthma**

Women using asthma inhalers including inhaled corticosteroids may have MA, because the medications in asthma inhalers are not systemically absorbed. Although some prostaglandins are vasoconstrictors, misoprostol is a type of prostaglandin that promotes bronchodilation, decreases inflammation and increases oxygen flow (Bernstein & Kandinow 2004).

#### **HIV and AIDS**

Women living with HIV and AIDS may use MA.

Women living with HIV or AIDS may be at risk for anemia, especially if they have malaria or are taking certain antiretroviral therapies (Gangopadhyay 2011). As with any woman, if heavy bleeding occurs, treat promptly with vacuum aspiration.

#### Breastfeeding

Women who are breastfeeding may take mifepristone and misoprostol for MA. Low levels of misoprostol have been detected in breast milk 30 minutes after oral dosing with a peak concentration at one hour. Although no harmful effects have been found in infants after maternal misoprostol ingestion, women who are concerned may nurse immediately before taking medications or wait four to five hours after their last dose of medication (Vogel 2004, Abdel-Aleem 2003, Saav 2010).

#### Sexually Transmitted Infections (STIs)

If a woman is found to have an STI at the time she requests MA, the STI treatment may be started on the same day she receives mifepristone (Davis & Easterling 2009, Achilles & Reeves 2011).

#### Obesity

There is no difference in efficacy with mifepristone and misoprostol among obese women compared to non-obese women (Strafford 2009). Thus, no dose adjustment for mifepristone or misoprostol is required.

#### Multiple gestation

A woman who is pregnant with twins (or other multiple gestations) may take mifepristone and misoprostol using the standard dosages of medications. The success rate for women with multiple gestations is comparable to those with singleton pregnancies (Hayes 2011).

## Mifepristone and misoprostol regimens up to 13 weeks

| Table 2A-1: Mifepristone and misoprostol regimens for medical abortion up to 13 weeks |                   |  |  |
|---|-------------------|--|--|
| Gestational age   | Mifepristone dose | Misoprostol dose, route and timing   |  |
| Up to 9 weeks<br>(Kulier 2011)  | 200mg orally      | After 24-48 hours, 800mcg buccally, sublingually or vaginally for one dose   |  |
| 9-10 weeks<br>(Winikoff 2012)   | 200mg orally      | After 24-48 hours, 800mcg buccally for one dose  |  |
| 10-13 weeks<br>(Hamoda 2005a,<br>Hamoda 2005b)  | 200mg orally      | After 36-48 hours, 800mcg vaginally followed by 400mcg vaginally or sublingually every 3 hours for a maximum of 5 doses of misoprostol |  |

MA has been shown to be safe and effective between 9 and 13 weeks, although this is based on fewer studies compared to earlier in pregnancy (Hamoda 2005a, Hamoda 2005b). Recommendations for 11-13 weeks (Winikoff 2012) are based on even smaller numbers of women.

Please see Appendix A for a Quick Reference Guide to the regimens.

#### Routes for taking medicines

#### Mifepristone

Mifepristone is taken orally (swallowing the pill) on day one of the abortion.

#### Misoprostol

There are a range of options in misoprostol route, dosage and timing. Buccal, sublingual or vaginal are recommended routes throughout the first trimester.

#### Buccal use of misoprostol

- Place two pills between each cheek and gums (four total)
- After 30 minutes, swallow any remaining pill fragments.

#### Sublingual use of misoprostol

• Place four pills under the tongue.

After 30 minutes, swallow any remaining pill fragments.



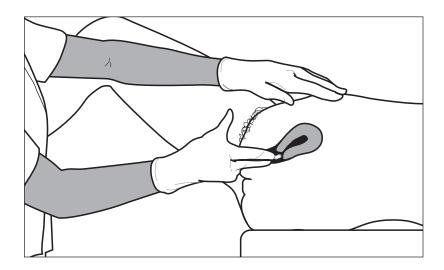
Buccal Use of Misoprostol



Sublingual Use of Misoprostol

#### Vaginal use of misoprostol

- The woman empties her bladder and lies down.
- If a provider is inserting pills, the provider washes hands and puts on clean exam gloves.
- All the misoprostol pills are inserted.
- The pills need to be inserted as far into the vagina as possible; they do not need to be in any special place in the vagina.
- Often the pills will not dissolve but the medication is still absorbed.
- Fragments of the pills may remain visible for many hours.
- After lying down for 30 minutes, if pills fall out when a
  woman stands up or goes to the bathroom, the pills do not
  need to be reinserted; the active medicine has absorbed by
  that time.





#### Review

Circle all correct answers.

- 1. How does mifepristone work to cause abortion?
  - a. Prevents sperm from fertilizing the egg
  - b. Prevents ovulation
  - c. Causes detachment of the pregnancy from the uterine wall and cervical softening
  - d. Causes an increase in pregnancy hormones
- 2. Which of the following are contraindications to mifepristone with misoprostol MA?
  - a. Living with HIV or AIDS
  - b. Allergy to the medicines
  - c. Breastfeeding
  - d. Age under 20
- 3. What are the Ipas-recommended routes for taking misoprostol?
  - a. Oral
  - b. Vaginal
  - c. Sublingual
  - d. Buccal
- 4. What are other gynecological or obstetric uses for misoprostol?
  - a. Labor induction
  - b. Cervical preparation before intra-uterine procedures
  - c. Treatment of postpartum hemorrhage.
  - d. Treatment for ectopic pregnancy

#### Reflect

The following questions are designed to help you think about what is currently in place for MA service delivery and how to apply the contents of this module to your setting.

1. What do women in your setting know about abortion with medications? Specifically, what do young women in your setting know about abortion with medications?

2. Is MA currently being offered in your setting? Is MA provided to both young women and adult women?

3. Are there established protocols for MA in your setting? If so, how do they compare with the protocols in this Study Guide?

4. If there are approved MA protocols, how closely do providers follow them?

5. If there are not established MA protocols, how do health-care providers determine which protocols to follow?

Ipas Medical Abortion Study Guide

# Module 2B: Medical Abortion with Misoprostol Only

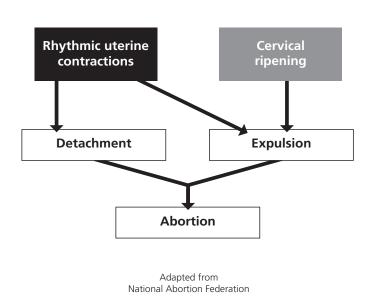
This module is exclusively about MA with misoprostol only, for those facilities in which mifepristone is unavailable. All references to MA in this module refer to misoprostol only unless mifepristone with misoprostol is specifically mentioned.

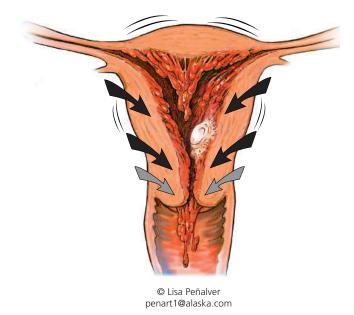
#### Overview

Medical abortion (MA) using misoprostol only is an important option in settings where mifepristone is not available. In the first trimester, the rate of successful abortion with misoprostol only without need for further intervention is approximately 85% (Carbonell 2001, von Hertzen 2007). The rate of ongoing pregnancy after misoprostol-only abortion is approximately 5% (vonHertzen 2007). Abortions performed with misoprostol only usually take longer and have a lower success rate than those performed with the combined mifepristone and misoprostol regimen (Kulier 2011, Ngoc 2011). If mifepristone is available, the combined regimen is recommended.

Misoprostol, a synthetic prostaglandin, stimulates cervical ripening (softening) and uterine contractions, causing uterine evacuation. Misoprostol is inexpensive and available in many countries for the prevention and treatment of gastric ulcers. Although it is stable at room temperature, the potency of misoprostol can degrade over time depending on its packaging or if it is exposed to high heat or humidity (Hall 2011). Misoprostol was added to the WHO list of essential medications in 2009 for treatment of incomplete abortion and miscarriage and in 2011 for prevention of postpartum hemorrhage. It can also be used for cervical preparation before vacuum aspiration and other intra-uterine procedures, labor induction and treatment of postpartum hemorrhage. For more information on this, please see Additional Resources, Misoprostol Other Uses.

The image below illustrates the mechanism of action. For more information on this, please see Additional Resources, Mechanisms of Action.





Eligibility

#### Indication

• Termination of first-trimester intrauterine pregnancy

#### **Contraindications**

If a woman has these specific conditions, under no circumstances should she be offered MA. MVA should be considered or she should be referred to a facility where she can be offered alternate care.

Previous allergic reaction to misoprostol

Known or suspected ectopic pregnancy

#### **Precautions**

If a woman has these specific conditions, MA has higher risks than normal. The risks, benefits and availability of alternatives to MA must be considered. MA provision may require a higher degree of clinical judgment, skill and monitoring. Referral to a higher-level facility may be appropriate.

- IUD in place evaluate for the presence of ectopic pregnancy. If none, remove IUD.
- Severe/unstable health problems including but not limited to hemorrhagic disorders, heart disease and severe anemia. No evidence exists on the use of misoprostol in women with hemorrhagic disorder, heart disease, severe anemia or severe/ unstable health problems. Whether to provide misoprostol to women with these conditions will depend on the available options for safe abortion care, referrals, and clinical judgment. If misoprostol is given, it should be given under close observation.

For more information, please see Additional Resources, Contraindications and Precautions.

#### Ectopic pregnancy

Women who are pregnant and have a history of ectopic pregnancy, tubal surgery or have an IUD in place are at a significantly elevated risk of ectopic pregnancy. An ectopic pregnancy occurs when a fertilized egg attaches itself outside of the uterus, most often in a fallopian tube. Ectopic pregnancy is rare, occurring in less than 1% of women presenting for an abortion (Edwards & Creinin 1997). If an ectopic pregnancy is unrecognized, it can cause potentially life-threatening complications from rupture and hemorrhage. For this reason, ectopic pregnancy is a leading cause of maternal mortality in the first trimester (Khan 2006, WHO 1985). Therefore, providers should maintain a high index of suspicion for ectopic pregnancy and carefully evaluate women's risk before providing medical abortion. Uterine evacuation methods, whether vacuum aspiration or MA using misoprostol with or without mifepristone, will not terminate an ectopic pregnancy. Any woman with a suspected ectopic pregnancy should be educated about the risks, including tubal rupture, hemorrhage and death. Ruptured ectopic pregnancy occurs more frequently in women who have limited contact with health-care providers and present late for care (Obed 2006). Ruptured ectopic pregnancy is a gynecologic emergency that requires immediate surgical intervention.

For information about MA for termination of second-trimester intrauterine pregnancy, see Additional Resources, MA for Second-Trimester Abortion.

#### Special considerations

Women in the following categories may use MA with misoprostol only:

#### Young women

Limited data suggests that misoprostol-only abortion has similar efficacy and side effect profiles for adolescents and adult women (Carbonell 2001, Velazco 2000).

#### **Asthma**

Women with asthma may undergo misoprostol-only abortion. Although some prostaglandins are vasoconstrictors, misoprostol is a type of prostaglandin that promotes bronchodilation, decreases inflammation and increases oxygen flow (Bernstein 2004).

#### **HIV and AIDS**

Women living with HIV may use misoprostol.

Women living with HIV may be at risk for anemia, especially if they have malaria or are taking certain antiretroviral therapies (Gangopadhyay 2011). As with any woman, if heavy bleeding occurs, treat promptly with vacuum aspiration.

#### Breastfeeding

Women who are breastfeeding may take misoprostol for MA. Low levels of misoprostol have been detected in breast milk 30 minutes after oral dosing with a peak concentration at one hour. Although no harmful effects have been found in infants after maternal misoprostol ingestion, women who are concerned may nurse immediately before taking medications or wait four to five hours after their last dose of medication (Vogel 2004, Abdel-Aleem 2003).

#### Sexually Transmitted Infections (STIs)

If a woman is found to have an STI at the time she requests MA, the STI treatment can be started on the same day she starts misoprostol (Achilles 2011).

#### Obesity and multiple gestations

There are no studies of misoprostol-only MA in women who are obese or with multiple gestations. Because success rates are similar in non-obese and obese women and women with multiple gestations when mifepristone and misoprostol are used, misoprostol-only MA may be offered to women with these conditions with no change in dosing.

## Misoprostol-only regimen up to 13 weeks

| Table 2B-1: Misoprostol-only regimens up to 13 weeks (WHO 2012.<br>von Hertzen 2007, Carbonell 1998, 1999a & 2001) |            |  |  |  |
|--|------------|--|--|--|
| Misoprostol 800mcg<br>(four 200mcg pills)  | Vaginal    | Every 3 -12 hours for a maximum of 3 doses |  |  |
| Misoprostol 800mcg<br>(four 200mcg pills)  | Sublingual | Every 3 hours for a maximum of 3 doses     |  |  |

Sublingual dosing is as effective as vaginal dosing up to 9 weeks but is associated with an increased risk of side effects (vonHertzen 2007). There have been relatively few studies that have looked at misoprostol-only abortion between 9 and 13 weeks.

See Appendix A for a Quick Reference Guide to the regimens.

## Routes for taking misoprostol

Ipas recommends the sublingual or vaginal misoprostol routes throughout the first trimester.

## Sublingual use of misoprostol

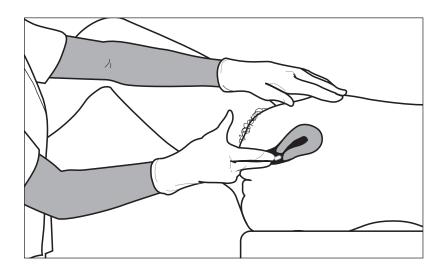
- Place four pills under the tongue.
- After 30 minutes, swallow anything remaining of the pills.

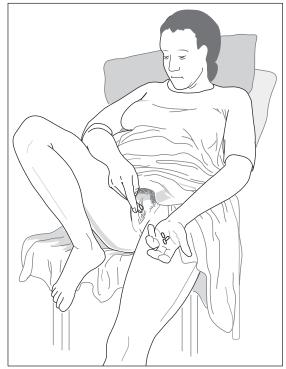


Sublingual Use of Misoprostol

### Vaginal use of misoprostol

- The woman empties her bladder and lies down.
- If a provider is inserting pills, the provider washes hands and puts on clean exam gloves.
- All the misoprostol pills are inserted.
- The pills need to be inserted as far into the vagina as possible; they do not need to be in any special place in the vagina.
- Often the pills will not dissolve but the medication is still absorbed.
- Fragments of the pills may remain visible for many hours.
- After lying down for 30 minutes, if pills fall out when a
  woman stands up or goes to the bathroom, the pills do not
  need to be reinserted; the active medicine has absorbed by
  that time.





### Review

Circle *all* correct answers. There may be more than one correct answer per question.

- 1. How does misoprostol work to cause abortion?
  - a. Prevents sperm from fertilizing the egg
  - b. Prevents ovulation
  - c. Causes cervical softening and uterine contractions
  - d. Causes an increase in pregnancy hormones
- 2. Which of the following are contraindications to misoprostol-only MA?
  - a. Living with HIV or AIDS
  - b. Allergy to the medicines
  - c. Breastfeeding
  - d. Age under 20
- 3. What are the route options for taking misoprostol up to 13 weeks in abortions with misoprostol only?
  - a. Oral
  - b. Vaginal
  - c. Sublingual
  - d. Buccal
- 4. What are other gynecological or obstetric uses for misoprostol?
  - a. Labor induction
  - b. Cervical preparation before intra-uterine procedures
  - c. Treatment of postpartum hemorrhage.
  - d. Treatment for ectopic pregnancy

### Reflect

The following questions are designed to help you think about what is currently in place for MA service delivery and how to apply the contents of this module to your setting.

What do women in your setting know about abortion with medications? Specifically, what do young women in your setting know about abortion with medications? Is MA currently being offered in your setting? Is MA provided to both young women and adult women? Are there established protocols for MA in your setting? If so, how do they compare with the protocols in this Study Guide? If there are approved MA protocols, how closely do providers follow them? If there are not established MA protocols, how do health-care providers determine which protocols to follow? What back-up uterine evacuation services are available to women if misoprostol-only abortion fails? How accessible are these services for young women?

## Module 3: Clinical Care

## Clinical assessment

Clinical assessment prior to medical abortion (MA) includes gestational dating and assessment of the woman's general health and any contraindications or precautions to the abortion method chosen. As with any procedure, the woman needs to know what to expect; this is especially true with MA because in many cases, the woman will take the misoprostol herself and the abortion will take place outside the clinic. For information on more comprehensive clinical assessment to address additional health concerns, please see Ipas's Woman-Centered, Comprehensive Abortion Care: Reference Manual, Second Edition, Clinical Assessment module.

## Gestational dating

Clinicians who prescribe medications for MA should have strong skills in pelvic examination and be competent in diagnosing and dating early pregnancy. Three commonly used approaches to pregnancy dating are:

- determining the date of the last menstrual period (LMP)
- performing a pelvic exam to assess uterine size
- using ultrasound

Gestational age can be accurately estimated based on LMP and pelvic examination (Fielding 2002, Blanchard 2007, Clark 2007a, Clark 2007b, Bracken 2011).

Ultrasound is not needed for routine abortion provision. Underestimating gestational age is not likely to be clinically important, because MA efficacy and safety decrease only gradually as gestational age increases (Blanchard 2007, Castleman 2009, Lökeland 2010, Bracken 2011). Ultrasound may be used for women whose gestational age is unclear based on history and exam or to confirm an intrauterine pregnancy in the case of a suspected ectopic pregnancy. MA can still be offered in these cases if ultrasound services are not available.

### Last menstrual period

The LMP refers to the first day of a woman's last menstrual period. A woman may have a difficult time remembering this date. Questions about where she was, what she was doing and what was happening in her life may help her recall when her last period began.

LMP estimations may be difficult for other reasons, including:

- Some women experience bleeding during early pregnancy which they can mistake for a menstrual period.
  - A young woman may experience irregular menstrual cycles or may never have experienced a menstrual period before she becomes pregnant.
- Breastfeeding women may become pregnant without having regular menstrual periods.

Use of LMP to estimate gestational age may be more accurate for women who rely heavily on fertility awareness methods. However, a woman's LMP should not be the only factor in determining the length of a pregnancy.

### Pelvic examination

Prior to performing a pelvic exam, the clinician should ask the woman to empty her bladder and let her know what to expect. This is especially important if this is the woman's first pelvic exam.

To assess the uterus and adnexa, the clinician places two fingers into the vagina and then palpates the abdomen with the other hand. The size of the uterus is then compared with the history of amenorrhea. After 6 weeks gestation, the uterus increases in size by approximately 1 centimeter per week and takes on a roundish shape.

Assessing the uterus in early pregnancy can be challenging and requires training and supervised practice. There are different training techniques to teach clinicians how to accurately assess uterine size. Regardless of the technique used, MA service delivery programs should ensure that clinicians are properly trained in pregnancy dating. Provider assessment of uterine size has been shown to be sufficient for providing MA to women with gestations of less than 9 weeks (Blanchard 2007, Mundle 2007). The technique of assessing uterine size is the same in all women, including young women.

If the uterus is **smaller** than expected, providers should consider one of thefollowing conditions:

- The woman is not pregnant
- Inaccurate menstrual dating
- Ectopic pregnancy
- Early pregnancy failure, including missed abortion
- Normal variation between women at a given length of pregnancy

If the uterus is **larger** than expected, providers should consider one of the following conditions:

- Inaccurate menstrual dating
- Multiple pregnancies
- Uterine anomalies such as fibroids or bicornuate uterus
- Gestational trophoblastic neoplasm/molar pregnancy (although the uterus can sometimes be smaller also)
- Normal variation between women at a given length of pregnancy

Situations that make it difficult to accurately assess uterine size include fibroids, retroverted position of the uterus, obesity, full bladder or the woman contracting (not relaxing) her abdominal muscles. If there is uncertainty about the gestational age, or if there is a discrepancy between uterine size and gestational age as determined by LMP, it may be helpful to use an ultrasound, if available, or to ask another clinician to check the uterine size by bimanual exam.

For more information on the use of history and bimanual exam to confirm completion of medical abortion, please see Module 5: Follow-Up Care.

### **Ultrasound**

Ultrasound is not required for early abortion provision. Ultrasound can be used when there is difficulty assessing gestational age based on history and exam (Clark2007a, Clark 2007b, Fielding 2002, WHO 2012), to assess abortion completion and to diagnose other conditions requiring treatment, such as ectopic pregnancy. Routine ultrasound may increase the cost of the procedure and the likelihood of unnecessary intervention; it may also prevent some providers from offering MA due to a lack of equipment (Gynuity 2007). MA can be offered even if ultrasound services are not available.

To learn more about ultrasound, please see Additional Resources, Ultrasound.

## **Ectopic pregnancy**

Ectopic pregnancy may be suspected in women during clinical assessment for MA due to her history, risk factors or physical exam or in the course of follow-up care (Yao & Tulandi 1997, Barnhart 2009). The symptoms of ectopic pregnancy are nonspecific and may be associated with threatened or spontaneous abortion or normally developing intrauterine pregnancy. Even with careful screening, only half of women presenting to an emergency room with ectopic pregnancy have risk factors or a suspicious physical exam (Stovall et al 1990). Ultrasound and serial BHCG testing can aid in the diagnosis of unruptured ectopic pregnancy, but access to these tests may be limited in developing countries (Obed 2006). Vacuum aspiration can assist in the diagnosis of ectopic pregnancy. If a woman has risk factors or signs and symptoms of an unruptured ectopic pregnancy, vacuum aspiration and careful tissue inspection can confirm an intrauterine pregnancy (Rubin et al 1980).

| Table 3-1: Ectopic pregnancy                     |  |
|--|--|
| Risk factors for ectopic pregnancy               | Risk of ectopic in the current pregnancy |
| Previous ectopic pregnancy                       | 10-15%                                   |
| History of tubal surgery including sterilization | 25-50%                                   |
| Presence of intrauterine device                  | 25-50%                                   |

### **Antibiotics**

Infection rates after MA are very low (Shannon 2004). Prophylactic antibiotics are not recommended for routine MA provision (WHO 2012, Achilles 2011). The potential disadvantages of routine provision of prophylactic antibiotics include higher service delivery costs, women's overexposure to antibiotics and

side effects—plus potentially rare adverse events arising from the antibiotics themselves. These disadvantages outweigh the potential advantages of prophylactic treatment because a high percentage of women would be treated unnecessarily to prevent the few infections that may occur.

If local guidelines include prophylactic antibiotic use, one commonly used regimen is doxycycline 100mg orally twice a day for 7 days (Fjerstad 2009a).

## Rh-immunoglobulin

Lack of Rh-immunoglobulin should not be a barrier to abortion care. In settings where the prevalence of Rh-negative status is high and Rh-immunoglobulin is available and affordable, it can be given to Rh-negative women at the time of taking the mifepristone or prior to taking misoprostol.

There are no data regarding the risk of sensitization of Rhnegative women who have MA after 9 weeks (Fiala 2003). When providing MA for 10 through 13 weeks, providers should follow the local standard for Rh-testing and giving Rh-immunoglobulin for Rh-negative women as is used for other types of uterine evacuation (e.g. aspiration abortion and miscarriage).

## Abortion process

Thorough information on what the woman might expect helps her to be prepared. Reassurance and support during the abortion process, either by clinic staff or a person at home, can also be helpful.

When taking mifepristone (for abortion with mifepristone and misoprostol), most women feel no change after taking the pills. Approximately 8-25 percent of women will have some spotting or bleeding after mifepristone, prior to taking misoprostol (Schaff 2001, Schaff 2002).

Once a woman takes misoprostol, the MA process may feel like an intense menstrual period or similar to a spontaneous miscarriage. The normal, expected effects — vaginal bleeding and cramping — should be distinguished from side effects of the medications or warning signs of true complications.

## Pain and cramping

Most women will experience lower abdominal pain and cramping during a medical abortion because uterine contractions are needed to expel the pregnancy (Honkannen 2004). Cramping usually begins one to three hours after taking misoprostol. As the uterus contracts and its contents are expelled through the cervix, women generally feel some degree of cramping, which diminishes

soon after passing the pregnancy (Paul 2007). Women's experience of pain is highly individual, which makes it impossible to predict how much pain a particular woman will experience. However, there are some predictors of pain associated with medical abortion that apply in general. Older age, having given birth before, and a higher number of previous births are associated with reduced pain with medical abortion (Hamoda 2004, Suhonen 2011). Young women and women who have never been pregnant tend to experience increased pain. Women with painful periods may also experience increased pain with medical abortion independent of other factors such as age or reproductive history (Suhonen 2011).

### Pain management

Most women find MA-related pain to be manageable, especially if they are prepared for the range of pain they might experience and take pain medicines as advised. Women should be provided with pain medication or a prescription at their first clinic visit.

The best regimen for pain control for MA has not been established (Jackson & Kapp 2011). NSAIDs such as ibuprofen are more effective than acetaminophen (Livshits 2009). However, acetaminophen may reduce the dose of narcotics that a woman uses during MA (Jackson & Kapp 2011). The dose of acetaminophen must not exceed 4 grams in a 24-hour period to avoid liver toxicity (Creinin 2009). Ibuprofen can be given with misoprostol (Avraham 2012) or once cramping starts (Livshits 2009). Ibuprofen does not reduce the effectiveness of medical abortion. Narcotic analgesics are another option for pain control although the optimal drug, dose and timing is not known. One potential strategy is to provide women with NSAIDs and narcotic analgesics and advise them to begin with NSAIDs either with misoprostol or once cramping starts and alternate the two medications should they continue to experience pain.

In addition to medical management, other methods that may help women manage pain during a medical abortion are thorough counseling, a supportive environment and applying a heating pad or hot water bottle to the lower abdomen. Music and guided imagery are effective for pain management in surgical abortion and may be helpful for medical abortion as well (Renner 2009). These methods are complementary but not adequate substitutes for pain management with medications.

Research indicates that young women's experiences with medical abortion are similar to those of older women. However, pain perception appears to be related to age. The perception of pain and use of analgesia has been found to be higher in younger women than older women (Hamoda 2004, Ingham & Lee 2008, Velazco 2000, Westhoff 2000a and 2000b). Lower parity has also been associated with increased perceived pain and/or analgesia needed (Bartley 2000, Hamoda 2004, Honkanen 2004, Suhonen 2003, Teal 2007, Westhoff 2000a, Westhoff 2000b). Providers should be aware

that young women may be more susceptible to pain and take necessary measures to reduce pain and improve a young women's abortion experience.

## Vaginal bleeding

## Onset of bleeding

Vaginal bleeding, often accompanied by passage of clots, is usually heavier than a menstrual period but sometimes may be lighter. With a combined regimen, bleeding most often starts within three hours after taking misoprostol (Creinin 2003) and tends to decrease after the pregnancy tissue has been expelled (Paul 2007).

## Duration of bleeding

In one of the few large studies to follow the bleeding patterns of women choosing MA or aspiration, the duration of heavy bleeding, menstrual-type bleeding and spotting was significantly longer in women undergoing MA. (Harper 1998) Despite the longer duration of bleeding, women who had MA did not have a clinically significant drop in hemoglobin (>2g/dL) when compared to women who had an aspiration. Most importantly in this study, women who had the proper expectations about duration and level of bleeding were satisfied with their experience with MA.

After MA with mifepristone and misoprostol, the average duration of bleeding is approximately 14 days (Spitz 1998, Davis 2000). Approximately 20 percent of women undergoing MA continued to bleed or spot for 35 to 42 days, which may include start of the first postabortion menses (Davis 2000).

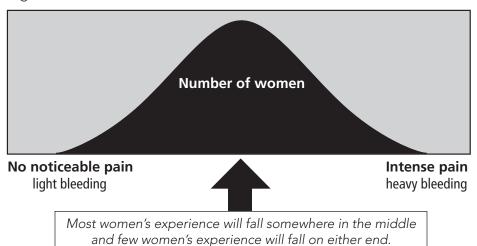
There is less data about the duration of bleeding after MA with misoprostol only, though it appears to be similar to MA with mifepristone and misoprostol. In the largest study of misoprostol—only abortion, the mean duration of bleeding was around 11.5 days, which is similar to combined regimens (von Hertzen 2007).

## Discussing bleeding and pain with women

Clinicians new to MA, as well as women themselves, will have questions about how to tell the difference between normal and abnormal bleeding and pain. All women should be given information about the bleeding and pain they might experience during medical abortion, keeping in mind factors that might put them at higher or lower risk of experiencing these symptoms. Accurately describing the sensations a woman might feel during a medical abortion can alleviate fear and anxiety that may make pain worse (Kruse 2000). The bell curve (Figure 1) may be helpful for both providers and patients to understand a range of symptoms women might experience. Providers may use the bell

curve to explain that most women fall in the middle part under the curve, experiencing symptoms that are of an average duration or intensity. However, some women will be at either ends of the curve and will experience less or more symptoms than most women. Not all women will understand the picture of the bell curve, but they all should be told about the range of symptoms they might experience in a way that makes sense to them.

Figure 1: The Bell Curve



Although some women do not feel any pain and others experience intense pain, the majority of women fall somewhere in the middle. Similarly, most women have bleeding that lasts around two weeks but some will have more and others less.

A woman may have concerns about where she may begin bleeding and how to maintain privacy and obtain support during the abortion process. Her provider should be prepared to support her in thinking through and deciding on the most private and comfortable location to have her abortion and who in her family or social network might be the most supportive and trustworthy person to support her through the process.

## Timing of expulsion

With the mifepristone and misoprostol regimen before 9 weeks gestation, the median time from misoprostol use to expulsion has been found to be three hours for women who used sublingual misoprostol and four hours for women who used vaginal misoprostol (von Hertzen 2010). The buccal route shows timing similar to that of the vaginal route (Meckstroth 2006, Schaff 2005).

For misoprostol-only abortion, the average expulsion time is seven to eight hours after the first misoprostol dose (Salakos 2005, von Hertzen 2007). Of the expulsions that occur, 80 percent take place within 24 hours and 95 percent take place within 48 hours (Faundes 2007). Expulsion is faster if the dosing interval is shorter (every 3 hours) (von Hertzen 2007).

Normally, women continue to feel better after the day they use misoprostol. Women can resume their usual routines within a few days of taking misoprostol. Nausea and vomiting, which are associated both with misoprostol use and pregnancy symptoms, usually resolve within one to two days of using misoprostol, as does cramping, which is part of the MA process, not a pregnancy symptom (Bracken 2006).

### What the woman might see

Most women will not see the expelled pregnancy but rather just blood and clots, some of which may be large. Occasionally women with pregnancies between 8-9 weeks may see a recognizable embryo though it is usually not visible.

If a woman is concerned about what she might see, especially after 8 weeks of pregnancy, a life-size drawing of an 8-9 week embryo may help prepare her. An embryo at 9 weeks is about 2.3 cm in length, or less than one inch (Callen 2008). Women undergoing MA from 10-13 weeks are more likely to see a recognizable fetus, although it may be wrapped in a blood clot or tissue and they may not see it unless they actually look. A fetus at 12 weeks is about 7.5 cm long, or almost three inches (Mayo Clinic 2009).

Providers may want to have accurately-sized images of embryos or fetuses, in case they would help women know what they might see. Please see Appendix B for a life-sized (to scale) illustration of an 8-9 week embryo.

## Disposal

Women may simply flush expelled products down the toilet or dispose of sanitary pads as they would after a normal menstrual period.

### Medical abortion from nine to ten weeks

Because the success rate of medical abortion with mifepristone and misoprostol is the same between eight and nine and nine and ten weeks without an increase in adverse events, offering women up to ten weeks gestation a single dose of buccal misoprostol at home rather than repeat doses in a facility may be appropriate in some settings (Boersma 2011, Winikoff 2012). The single United States based multi-center study that showed that home use of misoprostol can be extended to ten weeks used ultrasound to determine gestational eligibility. Programs using this approach in different conditions should monitor their results to ensure success in their settings.

### Medical abortion over 10 weeks

Women over ten weeks may take mifepristone at home but need to return to the health-care facility to take misoprostol and stay there until the abortion is complete (WHO 2012). Women who are using misoprostol only should take the whole regimen in the facility. Providers should give pain medicine while the woman is in the health-care facility. Pain medicine may be started with the first dose of misoprostol before the woman has pain and can be repeated as frequently as needed. Repeating the dose of misoprostol increases the success rate of abortion over nine weeks. Providers should give the repeat dose of misoprostol at the correct time. If the time between doses is increased, the success rates decrease and the time to expulsion lengthens. Even if a woman has pain or cramping, the provider should give the next dose of misoprostol until the woman expels the pregnancy. The provider should inspect the products of conception to confirm that the abortion was successful.

### Potential side effects

The following side effects are associated with misoprostol use and apply to women undergoing either mifepristone and misoprostol or misoprostol-only abortion:

- Nausea
- Vomiting
- Diarrhea
- Fever, warmth or chills
- Headache
- Weakness
- Dizziness

Some of these symptoms may be caused by the pregnancy itself rather than MA. These pregnancy symptoms can actually decrease after MA begins (Honkanen 2004). Those symptoms that increase after taking misoprostol include temporary fever and diarrhea (Honkanen 2004) as well as nausea and vomiting (Faundes 2007).

Over half of women in clinical trials of mifepristone and misoprostol or misoprostol only experience gastrointestinal side effects including nausea, vomiting and diarrhea. Fever and chills are also commonly seen with misoprostol but they are usually short lived and should resolve with antipyretics. Headache, weakness and dizziness are also common. Most of these side effects are mild and self-limited and can be treated at home. However, women who complain of prolonged or severe side effects that continue to occur 24 hours after the last dose of medications should be evaluated. For more information on this, please see Complications.

## Complications

Side effects and complications often happen on a continuum. For example, all women will experience bleeding, some women will experience prolonged bleeding that is an annoyance but is not harmful and very few women will experience heavy bleeding that requires further medical or surgical intervention. When counseling women before medical abortion, it is important to give them information about how to tell the difference between a side effect that can be taken care of at home with supportive care and a complication that needs medical attention. Women should contact their provider immediately if they experience:

- Excessive bleeding that soaks more than two sanitary pads per hour for two consecutive hours, especially if accompanied by prolonged dizziness, lightheadedness and increasing fatigue
- Fever that occurs any day after the day misoprostol is taken
- Unusual or bad-smelling vaginal discharge, especially if accompanied by severe cramps or abdominal pain
- Severe abdominal pain that occurs any day after the day misoprostol is taken
- Feeling very sick, with or without fever, and persistent severe nausea or vomiting after the day misoprostol is used

Women should return to the clinic before their follow-up visit (if one is scheduled) if they experience little to no bleeding one to two days following misoprostol. This is not an emergency, but rather cause for seeking early follow-up care. Anecdotal experience of very light bleeding suggests that there may be a continuing pregnancy, or that the treatment is working, but the pregnancy was at a very early gestation.

Women who experience complications of MA need clear, evidence-based explanations of the situation and should be included in decision making about their treatment options. Fears about complications, perhaps compounded by pain, can add to the emotional stress that may accompany the abortion process. Most women cope better with their situation when they receive accurate, thorough information and have the opportunity to ask questions and express their feelings. For more information, please see Ipas's Woman-Centered, Comprehensive Abortion Care: Reference Manual, Second Edition, Complications module.

## Postabortion contraception

After MA, a woman may have vaginal intercourse when she feels comfortable doing so. If she is trying to avoid pregnancy, she and her partner should wait until her chosen contraceptive method becomes effective or use an interim method that is effective immediately, such as condoms or spermicides.

If a woman desires contraception, she should receive and begin her method of choice as soon as possible. On average, a

| Table 3-2: When to start contraception after MA        |  |  |  |  |
|--|--|--|--|--|
| Contraceptive method                                   | Initiation timing  |  |  |  |
| Oral contraceptive pills, contraceptive ring and patch | Day 1 of the MA regimen  |  |  |  |
| Implant  | Day 1 of the MA regimen  |  |  |  |
| Injection  | Day 1 of the MA regimen  |  |  |  |
| IUD  | As soon as reasonably sure woman is no longer pregnant                         |  |  |  |
| Sterilization  | As soon as reasonably sure woman is no longer pregnant                         |  |  |  |
| Natural family planning                                | Following one postabortion menses in a woman with a history of regular periods |  |  |  |

woman will ovulate within 20 days of a medical abortion with mifepristone and misoprostol, but can ovulate in as little as eight days (Schreiber 2011). Therefore, all women who wish to delay conception should leave the facility with an effective method of contraception. If a woman desires long-acting contraception or sterilization but it cannot be provided, an interim method should be given and referral made to the appropriate facility.

## Medical eligibility for contraceptive use after MA

In general, all modern contraceptive methods can be used immediately following first-trimester MA provided that there are no contraindications.

## Summary of the evidence

Contraception may be started with the first pill of a medical abortion (WHO 2012). This recommendation is based on expert opinion. A woman's immediate need for reliable contraception after MA coupled with the risk that delayed contraceptive provision reduces uptake strongly supports the recommendation to start these methods immediately.

IUDs may be inserted as soon as it is reasonably certain that the woman is no longer pregnant (Betstadt 2011, WHO Guidance 2012). Delaying IUD insertion puts women at risk of unintended pregnancy as rates of return visits are low (Bednarek 2011, Stanek 2009).

Natural family planning, or the fertility-awareness method, should only be used after a woman has had at least one postabortion menses and only if she had regular menstrual cycles prior to the abortion (WHO 2009a).

For more information on medical eligibility for contraceptive use after MA, please see Additional Resources, Contraception Post-MA.

### Review

Circle *all* correct answers. There may be more than one correct answer per question.

- 1. Which statements below are true?
  - a. Nausea and vomiting are very rare after using misoprostol.
  - b. All women experience gastrointestinal side effects after using misoprostol.
  - c. Bleeding is not a side effect, it is an expected effect after using misoprostol.
  - d. Experience of cramping or pain after using misoprostol is quite similar for all women.
- 2. What are the warning signs of complications?
  - a. Excessive bleeding soaking more than two sanitary pads per hour for two consecutive hours
  - b. Fever that occurs any day after the day misoprostol is taken
  - c. Unusual or bad-smelling vaginal discharge
  - d. Mild nausea and vomiting
- 3. Which contraceptive methods can be started on the day of taking misoprostol?
  - a. Oral pills
  - b. Injectables
  - c. IUDs
  - d. Implants

### Reflect

The following questions are designed to help you think about what is currently in place for MA service delivery and how to apply the contents of this module to your setting.

What methods of gestational dating will be most effective and feasible in your setting? Think about how you will practice explaining to women the range of expected effects and side effects and how to tell the difference between side effects and complications. How can you be sure women have understood this information? What challenges do you anticipate in explaining MA regimens to women, including young women? How can you explain regimens in a way women can easily understand, and how can you ensure they have understood them? What are local protocols and practices for disposal of fetal tissue in early miscarriage, abortion or fetal death and how might they affect MA tissue disposal? What contraceptive options are currently available to women following abortion? What staff, supply, logistical and other issues need to be addressed to help women receive contraception when using MA? What unique post-MA contraception concerns need to be addressed for young women?

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# Module 4: Informed Consent, Information and Counseling

## **Pregnancy options**

A woman seeking an abortion has usually carefully considered her options and decision prior to seeking care (Rowlands 2008); therefore, pregnancy options counseling should not be required or serve as a barrier to receiving abortion care. If a woman has questions about her pregnancy options, providers can discuss them with her. Pregnancy options include:

- Continue the pregnancy to term and parent or release the child for adoption
- Terminate the pregnancy

By providing any information needed and supporting a woman's decision, providers can help women feel confident and comfortable that they are making the decision about their pregnancy that is best for themselves and other important people in their lives.

### Informed consent

Informed consent is a process in which a woman gathers the information she needs to make a voluntary choice to undergo an abortion procedure. To ensure that women are giving informed consent for the abortion, providers should discuss and confirm that women have understood:

- The benefits and risks of and alternatives to abortion
- Consequences of not receiving abortion care
- Details of the planned procedure, once the method has been determined

Providers need to explain this information in simple language and ensure that women have understood it. Privacy and confidentiality are critical to the informed consent process. Also, providers should ensure that women have given consent voluntarily and are not being pressured or coerced by anyone else to consent to the abortion.

Young women are capable of making the decision to terminate a pregnancy. Because they are often not given adequate information or are specifically targeted with misinformation about sexuality, pregnancy and abortion, they may need more information to aid their decisionmaking and informed consent process. Young women have varying levels of maturity that do not always correspond with chronological age. Providers should listen to and talk with young women to gauge the degree of support they require. With correct information and support, young people are capable and have the right to make health-care decisions and provide informed consent for themselves (Lansdown 2005). For more information on abortion counseling and care for young women, please see Additional Resources, Young Women.

## Procedure options

Once a woman has clearly made a decision to terminate her pregnancy, providers will discuss the abortion procedure options that are available in that facility and appropriate for that woman's clinical condition. They should discuss the possible benefits, risks and what to expect with each procedure. The provider can help the woman explore her options and choose which procedure is best for her by reviewing the information in Table 3. As long as the different methods are clinically appropriate, providers should refrain from inserting their own method preferences into the discussion and support a woman's decision. After all of the woman's questions about procedure options are answered and she has made her decision about which procedure to have, providers will obtain her consent for the procedure.

| Table 4-1: Vacuum aspira         | tion and medical abortion ir   | the first trimester   |  |
|----------------------------------|--|---|--|
|                                  | Vacuum aspiration  | Mifepristone<br>and misoprostol MA  | Misoprostol-only MA  |
| What is it?                      | A procedure that uses electric or manual suction instruments to evacuate the uterus.   | Medications taken together that cause the uterus to expel the pregnancy.  | A medication that causes the uterus to expel the pregnancy.  |
| How does it work?                | The pregnancy is removed from the uterus through a tube inserted into an electric pump or handheld aspirator.  | Mifepristone makes the preg-<br>nancy detach from the side of<br>the uterus. Misoprostol causes<br>contractions that expel the<br>pregnancy.  | Misoprostol causes contractions that expel the pregnancy.  |
| When can it be used?             | From detection of pregnancy<br>to 13 weeks (throughout first<br>trimester).  | From detection of pregnancy to 13 weeks (throughout first trimester).   | From detection of pregnancy to 13 weeks (throughout first trimester).  |
| Where can it be used?            | In a health-care facility.   | Mifepristone (first pill) is usually given at the clinic. Misoprostol (second set of pills), may be taken at clinic or home for women with pregnancies under 10 weeks. For pregnancies from 10-13 weeks, women should take misoprostol in the facility. | Misoprostol may be taken at clinic or home for women with pregnancies under 9 weeks. For pregnancies from 9-13 weeks, women should take misoprostol in the facility. |
| How effective is it?             | 97%-99.5% effective  | 95%-98% effective   | 83%-87% effective  |
| What are the side effects?       | Bleeding and cramping.   | Bleeding and cramping are expected. Possible side effects are: nausea, vomiting, diarrhea, fever/chills or dizziness.   | Bleeding and cramping are<br>expected. Possible side effects<br>are: nausea, vomiting, diarrhea,<br>fever/chills or dizziness.                                       |
| What are possible complications? | Rare complications include injury to the uterus or cervix, excessive bleeding, infection and blood collecting in the uterus. Failed manual vacuum aspiration (MVA) occurs in less than 1% of women, especially when performed by a skilled provider. | Rare complications include excessive bleeding and infection. Failed MA occurs in 5% of women and ongoing pregnancy occurs in less than 1% of women.   | Rare complications include excessive bleeding and infection. Failed MA occurs in 15% of women and ongoing pregnancy occurs in 4%-6% of women.                        |
| How is it typically used?        | The pregnancy is removed with suction through a tube inserted into an electric pump or handheld aspirator. Procedure time is 2-10 minutes. Completion of the procedure is immediately confirmed, requiring only one facility visit.                  | Mifepristone is taken by mouth (swallowed). One or two days later, misoprostol is put either under the tongue, inside the cheek or in the vagina and then the abortion usually occurs within 4-6 hours, but can take up to several days.                | Misoprostol is put either under<br>the tongue or in the vagina<br>and then the abortion usually<br>occurs within 24 hours, but can<br>take up to several days.       |
| What if the abortion fails?      | The procedure is repeated.   | The pregnancy is removed through vacuum aspiration. If aspiration services are not available, a second dose of misoprostol can be offered with close follow up.   | The pregnancy is removed through vacuum aspiration.  |

### MA benefits and risks

### **Benefits**

The benefits of MA include safely and effectively terminating a pregnancy without the use of instruments. To some women, having an abortion using pills instead of instruments allows for more privacy and feels more like a natural process. Some women will tell family members that they are having a heavy period or a spontaneous miscarriage during the MA process. If the woman wants more support, she might choose to have family or friends with her.

### Risks (See also Module Six, Complications)

Every medical procedure carries some risk, which must be balanced against the risk of not having the procedure. Carrying a pregnancy to term has a higher risk of morbidity and mortality than terminating an early pregnancy (Raymond & Grimes 2012). The risk of death with MA is roughly equal to the risk of death with spontaneous abortion (Grimes 2005). Both vacuum aspiration and MA are very safe, but they do have some risk. Vacuum aspiration and MA both may cause heavy bleeding or infection. With both methods of uterine evacuation there is the risk of failure to complete the abortion. And for both procedures, there is a risk that if the initial procedure is not successful, women may need additional care to complete the abortion. With vacuum aspiration, there is risk of injury from the instruments, and if anesthesia is used, risk of reaction to anesthesia. In MA, there is the risk of side effects from the drugs.

| Table 4-2: Rates of unsuccessful abortion and ongoing pregnancy after medical abortion |                       |                   |  |
|--|-----------------------|-------------------|--|
|  | Unsuccessful abortion | Ongoing Pregnancy |  |
| Mifepristone-Misoprostol   |                       |                   |  |
| <9 weeks (von Hertzen 2010, Winikoff 2008, Tang 2003)                                  | 3%                    | <1%               |  |
| 9-10 weeks with single dose of buccal misoprostol (Winikoff 2012)                      | 7%                    | 3%                |  |
| 10-13 weeks with repeat doses of misoprostol<br>(Hamoda 2005a&b, Ashok 2002b)          | 3%-5%                 | 1%-2%             |  |
| Misoprostol Only   |                       |                   |  |
| <9 weeks (vonHertzen 2007)   | 15%-17%               | 4%-6%             |  |
| 9-13 weeks (Carbonell 1998, 1999a, 2008)   | 13%-17%               | 7%-8%             |  |

### Unsuccessful medical abortion

In the case of an unsuccessful medical abortion, a woman may need an aspiration or other procedure to treat heavy or problematic bleeding or terminate an ongoing pregnancy. Ongoing pregnancy is a particular concern with medical abortion because of fetal exposure to the misoprostol and what effect it might have on the fetus if the woman chooses to continue the pregnancy. The rates of unsuccessful abortion and ongoing pregnancy are significantly higher with misoprostol-only abortion compared to the combined mifepristone-misoprostol regimen and may increase slightly with later gestations (see Table 4). The steps to assess a successful abortion are outlined in module 5.

Women undergoing MA should understand that MA may fail to end the pregnancy. Women with pregnancies that continue after early misoprostol exposure should be offered information and uterine evacuation, as there is a slightly increased risk of birth defects. Providers should respect women's informed decision on this issue.

### Other risks

Other rare risks include excessive bleeding requiring emergency treatment, transfusion, pelvic infection, allergic reactions and death.

- The risk of very heavy bleeding requiring emergency treatment has been reported to range from two women in 10,000 to one in 100 (Ashok 1998, Hausknecht 2003, Schaff 1997). The wide variation in rates reflects differences in gestational age and definition of heavy bleeding.
- The risk of serious infection has been reported to be less than 1 percent (Shannon 2004).
- Data about the rate of allergic reactions has not been collected but virtually all have resolved without treatment, or have been treated with antihistamines, such as Benadryl<sup>®</sup>.
- Death is extremely rare. For example, the mortality rate from first-trimester MA with mifepristone and misoprostol is estimated to be about seven women per million (Grimes 2005, Raymond & Grimes 2012).

### Potential birth defects

The risk of birth defects is estimated to be fewer than 10 defects per 1,000 in pregnancies that continue after misoprostol use during the first trimester (Population Council 2002). The most common misoprostol-related birth defects are mobius sequence (facial nerve paralysis with associated anomalies) and limb defects (dal Pizzol 2006). Mifepristone has not been shown to cause fetal

### **Future Pregnancies**

MA appears to have no impact on future reproductive health (Hogue 2009). Records of 2,710 women in Denmark who had a previous MA were reviewed and there was no evidence that a previous MA increased the risk of spontaneous abortion, ectopic pregnancy, preterm birth or low-birth weight (Virk 2007).

malformations. For a comprehensive review of the association of misoprostol with birth defects, please see Additional Resources, Birth Defect Risks with MA.

## Explaining the MA process to women

Using simple, non-technical language, health-care staff should help the woman understand the entire process before she takes any medications. The health-care worker should ask the woman if she has a companion with her and if she would prefer to be counseled by herself or if she would like her companion to hear the MA information as well. If she does, invite her companion to join the discussion.

Before leaving the clinic, the woman should receive instructions about the normal MA experience, what pills to take, when and how to take them, when to follow up, and when and where to seek medical help in case of a problem. Because some words are probably unfamiliar to her (such as sublingual or buccal), providers should use simple language (such as "under the tongue" and "inside the cheek" and can even provide drawings to visually aid her in understanding how medications should be taken either at home or in the facility. Please see Modules 2a and 2b for illustrations of routes.

When counseling a young woman, it is particularly important to use simple, non-clinical language to ensure understanding. Young women may use different words than the ones that providers use (de Bruyn & France 2001). Young women may have also had little opportunity to learn about sexual and reproductive health, and so may need more information and need the information repeated more frequently than many adult women. Also, they may be less comfortable and require more careful rapport-building. All these factors may result in counseling sessions with young women taking longer than with adult women (de Bruyn & Packer 2004).

A routine follow-up visit after medical abortion with mifepristone followed by misoprostol is not necessary; however, because of lower efficacy, routine follow-up after medical abortion with misoprostol only is recommended (WHO 2012). A woman who takes medication at home should receive explanation of how to recognize the signs of expulsion (bleeding and cramping) that occur with a successful medical abortion. In general, women who feel they have had a successful medical abortion do not need further care (Rossi 2004, Perriera 2010). However, if a woman takes the medication and has minimal or no bleeding or still feels pregnant, she should return to the provider to check whether she has had a successful abortion or if she needs a procedure to complete her abortion. If a woman is concerned about ongoing bleeding or other problems, she may return at any time. If a

### Success Checklist (based on Perriera 2010)

Ask the woman each question below and put a tick in the appropriate box.

|   | Yes | No |
|---|-----|----|
| 1. Did you have cramping after you took all of the medical abortion tablets?  |     |    |
| 2. Did you have bleeding at least as heavy as your usual period after you took all of the medical abortion tablets? |     |    |
| 3. Did you pass blood clots or tissue after you took all of the medical abortion tablets?                           |     |    |
| 4. Have your pregnancy symptoms gone away?  |     |    |
| 5. Do you think you are still pregnant?   |     |    |
| 6. Are you having heavy bleeding today?   |     |    |
| 7. Do you have a fever today?   |     |    |
| 8. Are you having bad cramping or pain today?   |     |    |

If there is at least one tick in the shaded area, she should see a health-care provider. She may still be pregnant or need additional medical care.

If there are no ticks in the shaded area, there is a high likelihood that her medical abortion was successful. She should use contraception to prevent an unwanted pregnancy.

woman desires reassurance after the abortion, she may return in a week to two weeks to confirm that she has had a successful abortion.

A pamphlet, card, or handout summarizing these points is often useful. A woman who is unable to read may still find it useful to take written instructions with her; she may have someone read it to her if she has questions. Pictorial resources for women who cannot read, such as illustrated guides outlining the MA regimen, side effects, and possible complications, may be very helpful. For MA-related images, please see the information, education and communication (IEC) materials and job aids on the *Medical Abortion Training Guide CD-ROM*.

MA information for women should include:

- · Eligibility and effectiveness
- Regimen and protocols (including a discussion about taking misoprostol at home versus at the clinic if both options are available)

- What she will experience
- How long the process typically takes
- The signs of a successful abortion
- Expected effects, potential side effects and complications
- Warning signs to seek help
- Ensuring access to emergency care
- Contraceptive needs
- When and where to obtain follow-up care if necessary

See Appendix C, Additional Medical Abortion Questions and Answers, for other questions that many women and providers may ask about MA.

In settings with telephones, contact information should be provided so the woman can call any time with questions or concerns. In many locations, a return to the health facility may be the only way for the woman to access information and for a clinician to assess her situation. Local referrals closer to a woman's home may be given in advance if the woman lives far from the clinic. Utilizing community health nurses or other community-based health workers or organizations can be a good source of local support and information for women, as long as they are well informed about MA counseling and care. See Module Six: Problems, Complications and Emergencies for a more detailed discussion of emergency response systems, and Ipas's Woman-Centered, Comprehensive Abortion Care: Reference Manual, Second Edition, Community Linkages module, for more information on working with the community.

## Woman-centered counseling

A woman's experience during an abortion is both physical and emotional. Health-care providers should be prepared to offer compassionate support and, if desired, counseling that focus on the woman's needs. Emotional support and respectful, empathetic interactions with health-care workers might improve women's abortion experience and outcomes and make them more inclined to trust health-care workers and seek appropriate medical care in the future (Hall 1988).

Health-care providers' attitudes and beliefs affect their interactions and counseling with women and carry considerable influence. Providers may subconsciously hold beliefs about who should control the abortion experience or about a woman's ability to determine what is happening in her body. Unlike vacuum aspiration and depending on the protocol, MA can put the abortion more in the control of the woman rather than the clinician. In many approved protocols, she can initiate and

manage the abortion process at home or another place outside a health-care facility where it is most convenient and comfortable for her. Providers' discomfort with women managing the abortion themselves, whether conscious or subconsciously, may negatively affect provision of MA and even cause them to resist offering MA services.

A woman-centered approach to care means that providers working in abortion care should:

- Identify their personal beliefs and values about abortion, and MA in particular;
- Separate their beliefs and values from those of their clients and focus on their clients' needs;
- Show respect to all women, regardless of their age, marital status, sexual and reproductive behaviors and decisions;
- Treat women with empathy—understanding their feelings and perspectives and communicating this understanding.

Values clarification can help providers identify their beliefs and values, explore the consequences of their actions, learn how to separate their values from those of their clients and offer care in a way that shows respect for a woman's rights and decisions (Turner 2008). Clinic managers and clinical mentors can help establish and maintain an environment of sensitivity and respect for women's needs through a variety of methods, including values clarification and other training, clinical coaching, supportive supervision, feedback from coworkers, anonymous evaluations and client surveys. For more information on woman-centered counseling and values clarification, please see Additional Resources, Counseling and Values Clarification.

### Review

Circle *all* correct answers. There may be more than one correct answer per question.

- 1. When explaining the MA process to women it is important to:
  - a. Use technical language
  - b. Ensure women understand the entire process prior to taking the medications
  - c. Use non-technical language and pictures if necessary to help explain
  - d. Avoid discussing complications, as they are rare
- 2. As part of informed consent for MA, ensure that each woman understands:
  - a. The benefits and risks of and alternatives to abortion
  - b. She must have an ultrasound prior to MA
  - c. Who else she must consult before making her decision
  - d. The entire MA process
- 3. MA information for women should include:
  - a. The range of normal bleeding they can expect
  - b. Possible side effects after taking misoprostol
  - c. Warning signs for which the woman should contact her provider
  - d. To take a pregnancy test before her follow-up visit
- 4. Providers should inform women that if MA fails:
  - a. They are obliged to complete the abortion.
  - b. They may need vacuum aspiration to complete the abortion.
  - c. If they choose to continue the pregnancy, there is a slightly increased risk of birth defects.
  - d. They must begin the entire regimen again.

### Reflect

The following questions are designed to help you think about what is currently in place for MA informed consent, information and counseling and how to apply the contents of this module to your setting.

- 1. If MA is already being provided in your setting, how well do you communicate with women about MA? How well do you communicate with young women in particular? What can you do to improve your skills?
- 2. If MA is already being provided in your setting, what challenges do you experience with providing informed consent, information and counseling? Are they delivered in a respectful way that meets women's needs?
- 3. If MA is being introduced now, how will you ensure that providers are well trained to provide informed consent, information and counseling? What specific efforts should be made to address the needs of young women?
- 4. How can you assess and, if needed, improve the quality of MA information and counseling for women?
- 5. What community-level health workers and organizations can you collaborate with to provide support and information to women about MA close to where they live and work?

Ipas Medical Abortion Study Guide

# Module 5: Follow-Up Care

### Overview

Because of the high success rate and low complication rate, there is no need for a routine medical follow-up after an uncomplicated medical abortion using mifepristone followed by misoprostol (WHO 2012). Women should be advised that follow-up care is available to treat any complications or a continuing or ectopic pregnancy, to provide contraception or address any questions or concerns related to her MA process, if needed or desired. Because of higher ongoing pregnancy rates when misoprostol only is used, routine follow-up is recommended with this regimen. For either regimen, women should be informed about the risks and symptoms of an unsuccessful abortion and ongoing pregnancy and given instructions about when and where to obtain follow-up care or assistance. If a woman prefers a follow-up visit because she wants to confirm that her abortion has been successful or wants reassurance, she should be given an appointment.

## Confirming success

Women and their providers are very accurate in assessing the success of MA using mifepristone followed by misoprostol. In multiple studies, women who believed that they had a successful abortion were correct over 99% of the time (Rossi 2004, Perriera 2010, Cameron 2012, Jackson 2012).

However, women are less accurate in assessing whether they have had an unsuccessful abortion or an ongoing pregnancy. Many but not all women may recognize an ongoing pregnancy from their symptoms alone. In one study of women treated with mifepristone and misoprostol for first-trimester abortion, two-thirds of the women with ongoing pregnancy recognized that they were still pregnant from their symptoms alone; the remaining third did not (Jackson 2012).

The risk of ongoing pregnancy for gestations less than 9 weeks is less than 1% after mifepristone and misoprostol (von Hertzen 2010, Winikoff 2008, Tang 2003) and 4% - 6% after misoprostol only (vonHertzen 2007). Nonetheless, the importance of a woman missing an ongoing pregnancy is significant. If MA fails and the pregnancy continues, there is a slightly increased risk of birth defects from exposure to misoprostol. If there is a delay in a woman's identification of the ongoing pregnancy and she wants to terminate it, the increased gestational age may limit her access to abortion services. To review success rates for medical abortion, please see Module 4: Informed Consent, Information and Counseling.

When desired or needed, success can also be confirmed by a provider at a follow-up visit approximately two weeks after medical abortion. Confirmation is usually possible by reviewing a symptom history and conducting a pelvic examination. Pregnancy testing and/or ultrasound may be useful (if available or by referral) if a woman is unsure about whether she passed her pregnancy. Use of less resource-intensive aids in determining success of MA, such as symptom diaries and questionnaires, is an area of ongoing research. In addition to confirming success, the provider can offer contraception if desired, address problems and answer remaining questions.

## Steps to assess successful abortion

- 1. Ask the woman whether she felt like she expelled the pregnancy. Did she have heavy bleeding and cramping after she took misoprostol? Did she pass tissue or clots?
- 2. Ask the woman if she ever felt pregnant, and if she still feels pregnant now. Review what pregnancy symptoms she experienced prior to and after the abortion. For example, if the woman had morning sickness and breast tenderness beforehand, has that resolved?

- 3. Review how she took each medication. For example, say "Tell me how and when you took each pill."
- 4. Perform a pelvic exam. Compare it to the exam documented prior to the MA.
  - If the woman had a pregnancy of up to 7 weeks gestation at the clinical assessment, the uterus should feel non-pregnant two weeks after taking the MA medications.
  - If the woman had a pregnancy of 8 weeks gestation or more, the uterus should be smaller two weeks after taking the MA medications.
- 5. The abortion is most likely complete if the woman believes she had a successful abortion. Clinical indications that the abortion is most likely complete are that the woman's pregnancy symptoms have stopped, her bleeding pattern is normal and her uterine size is non-pregnant or smaller than before.
- If there is any doubt, the provider can conduct or refer for an ultrasound to look for a gestational sac or an ongoing pregnancy.

## What to expect at a visit after MA

When women return for follow-up care or problem visits after MA, clinicians commonly encounter the following scenarios:

### Normal

This is the most common outcome if the woman took the medicines as instructed. In general, her bleeding and cramping may have been significant for about a day following misoprostol but then diminished over the following week. By two weeks after taking the medications, cramping is usually gone, and approximately 60 percent of women are still having light bleeding or spotting (Davis 2000). Women who had pregnancy symptoms prior to the MA should no longer have them by the time of a follow-up visit.

## Problematic bleeding

Some women report tiresome or problematic bleeding at a followup visit despite the fact that the pregnancy is not continuing, pregnancy symptoms have resolved and the uterus is smaller in size. These women should be offered additional treatment if it is appropriate as described below.

Various patterns of problematic bleeding are:

Persistent, heavy bleeding: This is when the woman bleeds as much as a heavy menstrual period continuously since taking misoprostol. If the woman has clinical symptoms of low blood

volume due to bleeding (fatigue, weakness especially upon standing, racing pulse, feeling faint), and/or if hemoglobin or hematocrit (if testing is available) has dropped significantly from the initial value, vacuum aspiration should be performed. If her bleeding is currently not heavy but is somewhat prolonged or erratic and she is clinically stable and feels well, a repeat dose of misoprostol may be offered as long as the woman is willing to return in one to three days for assessment. Providing a second dose of misoprostol to enhance uterine contractility is a common practice, but has not been shown to decrease days of bleeding (vonHertzen 2003, Mittal 2005). Fluid intake (oral hydration) and iron-rich foods or iron supplements should be strongly encouraged.

Erratic bleeding: Some women have days of very little or no bleeding followed irregularly by heavy, gushing bleeding. If she is symptomatic of anemia, the provider should perform a vacuum aspiration. Fluid intake (oral hydration) and iron-rich foods or iron supplements should be strongly encouraged.

Hemorrhage: (See Hemorrhage in Module Six: Problems, Complications and Emergencies)

Delayed bleeding: Very rarely, after several weeks of little or no bleeding and no other complications, a woman will experience sudden, heavy bleeding. The woman should be treated according to the severity of clinical presentation.

Problematic bleeding, along with continuing pregnancy, can indicate that MA may not be successful and the woman may need further treatment. If the woman is experiencing problematic, but not severe bleeding, the provider should discuss treatment options with her, including: 1) waiting and watching for several weeks; 2) repeating the dose of misoprostol to encourage uterine contractility (as discussed above); and 3) vacuum aspiration. Sometimes a woman is tired of persistent bleeding and requests vacuum aspiration even though it may not be clinically necessary; this option should be available to her if possible.

## Ongoing or ectopic pregnancy

Please see Module Six: Problems, Complications and Emergencies

## Contraception after MA

The woman may return for follow-up care because the method of her choice, such as an IUD, could not be provided at the time the MA medications were dispensed, or because she had not yet decided on a method. Providers should assess her fertility needs, provide information on the return of menses and provide contraceptive counseling and services, as needed.

## Reassurance and support

Ask the woman how she is feeling and provide emotional support if needed. Answer any questions or concerns the woman has.

### Addressing other needs at the time of follow-up care

When a woman does return to the facility for follow-up care, it is another opportunity to address any other needs she may have and provide comprehensive care. Evaluate and discuss any other health or emotional needs, as desired by the woman, and refer her to other services as needed.

## Alternatives to clinic-based follow-up

If a woman and her provider agree, the provider may offer to be available by telephone to provide information and support and help the woman assess the success of the MA procedure, as needed. Sites that offer this option should establish a protocol for telephone follow-up and provide women with a telephone number for the facility or provider. Sites can also utilize outreach professionals, such as community health nurses, whom women can turn to for support during MA and with contraceptive and other reproductive health needs. Consideration should be given to the costs and benefits of these follow-up alternatives. They may be more applicable in settings that use misoprostol only, where success is lower and more women may need follow-up care, than for women using mifepristone and misoprostol. Any contact by telephone initiated by a provider or by outreach workers should only be made if a woman gives her consent beforehand and must be carried out very carefully to maintain a woman's privacy.

### Review

Circle all correct answers. There may be more than one correct answer per question.

- 1. If a woman needs or would like follow-up care to ensure a successful MA, what is the best time for her to return after taking misoprostol?
  - a. One week
  - b. Two weeks
  - c. Two months
  - d. She should not be offered follow-up care because it is never needed.
- 2. What are some of the bleeding patterns providers can expect to see in a woman seeking follow-up care?
  - a. Normal
  - b. Erratic
  - c. Delayed
  - d. None
- 3. The abortion is most likely successful if:
  - a. The woman's pregnancy symptoms have stopped
  - b. Hemoglobin or hematocrit has dropped significantly
  - c. Her uterine size is smaller than before
  - d. Her bleeding pattern is normal

## Reflect

The following questions are designed to help you think about what is currently in place for MA service delivery and how to apply the contents of this module to your setting.

If MA is already being provided at your facility, what protocols for follow-up care do you use?

If MA is being introduced at your facility, what follow-up protocols do you plan to use? Are these the same for young women?

3. How will you confirm a successful MA if women return for a follow-up visit?

What concerns do you have about providing follow-up care and what are some ways you can address those concerns? How are these similar or different for young women?

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# Module 6: Problems, Complications and Emergencies

Medical abortion (MA) results in few serious complications. Please see Module 3: Clinical Care, *Warning Signs of Complications* for signs and symptoms that should prompt a woman to contact her provider or seek medical attention.

## **Problems**

The majority of women undergoing MA do not have any problems or complications. Problems following MA, if they occur, can range from minor to true emergencies. Major complications are rare, but can sometimes be avoided by intervening at the right time with the proper treatment. Problems can be reduced if women know what to expect, when to seek care and appropriate care is provided in a timely manner.

#### Failure of MA

Failure of MA is defined as situations requiring an intervention to

empty the uterus due to a continuing pregnancy or unacceptable symptoms such as hemorrhage (Winikoff 1996).

A continuing pregnancy occurs in less than 1% of women who take mifepristone and misoprostol and approximately 4%-6% of women who use misoprostol alone for gestations up to nine weeks (See Table 4-2 in Module 4). A continuing pregnancy is suggested by a lack of vaginal bleeding, persistent pregnancy symptoms and/or increasing uterine size.

#### MA up to 9 weeks since last menstrual period (LMP)

- Mifepristone and misoprostol
- The standard treatment for ongoing pregnancy is vacuum aspiration. Taking a repeat dose of misoprostol for an ongoing pregnancy is a less studied option. In one trial, only a third of women with gestations under nine weeks who had an ongoing pregnancy after mifepristone and misoprostol and took a second dose of misoprostol had a successful abortion (Reeves 2008). Although it is not a first-line recommendation, in areas where access to safe services for uterine evacuation is limited, a second dose of misoprostol 800mcg vaginally with close follow-up can be considered.
- Misoprostol only
  - When pregnancy continues after taking misoprostol only for abortion, vacuum aspiration is recommended.

#### MA from 9-13 weeks

Uterine evacuation is recommended for pregnancies continuing after any MA regimen from 9-13 weeks.

## Persistent pain

If a woman has intense pain that persists for longer than 4-6 hours after taking misoprostol, or if she reports intense pain unrelieved with ibuprofen and mild narcotics, consider the possibilities of:

- Pregnancy tissue trapped in the os. If this is the case, it can sometimes be grasped with an instrument such as ring forceps and gently removed.
- Ectopic pregnancy
- Upper reproductive tract infection
- Low pain tolerance

A woman who has intense or ongoing pain warrants further examination to ensure that she does not have one of these conditions. She should have a careful history taken along with a complete physical and bimanual exam, and management or referral as necessary.

## Ectopic pregnancy

All women should be evaluated for the possibility of ectopic pregnancy prior to receiving MA (Please see modules 2A, 2B, and 3 for more information on ectopic pregnancy). If a woman who has an ectopic pregnancy receives MA, mifepristone and misoprostol will not treat the ectopic pregnancy. A woman with an early ectopic pregnancy may not have any symptoms. If she does have signs and symptoms, they may include:

- Minimal vaginal bleeding after taking medications for abortion
- Uterine size that is smaller than expected
- Sudden, intense and persistent lower abdominal pain or cramping, initially one-sided then generalized, that may be accompanied by:
  - Irregular vaginal bleeding or spotting
  - Palpable adnexal mass
- Fainting, shoulder pain, rapid heartbeat or lightheadedness (from internal bleeding). Internal bleeding is not necessarily accompanied by vaginal bleeding.

A ruptured ectopic pregnancy is a gynecologic emergency that can be life threatening and requires immediate surgical intervention. A woman with suspected ectopic pregnancy should be treated or transferred as soon as possible to a facility that can confirm diagnosis and begin treatment. Early diagnosis and treatment of ectopic pregnancy save women's lives and help preserve their fertility.

## Complications

## Hemorrhage

Acute hemorrhage requiring transfusion following MA is rare (WHO 2000). In clinical trials of mifepristone and misoprostol, the risk of bleeding requiring transfusion ranges from 0.1% to 0.4% (Creinin & Gemzell-Danielsson 2009). With misoprostol-only regimens, the rate of hemorrhage requiring transfusion is less than 1% (vonHertzen 2007). The range in rates reflects differences in how studies defined heavy bleeding.

Indications that bleeding requires immediate attention are:

- Abundant gushing bleeding
- Bleeding like a heavy period that persists for weeks leading to significant anemia and hypovolemia
- Pale appearance accompanied by weakness, agitation or disorientation

- Blood pressure drop or woman feels faint when she stands up
- Rapid pulse especially when associated with low blood pressure

Other concerning signs and symptoms include paleness around the inner eyelids, mouth, palms or fingertips; dizziness and fainting; and decreased urine output.

Severe hemorrhage and prolonged heavy bleeding require immediate attention. Supportive therapy including intravenous fluid and blood replacement and oxygen administration should be started. Vacuum aspiration is the first option treatment for hemorrhage; this enables the uterus to contract and decrease bleeding.

Although the efficacy has not been tested in women with bleeding after medical abortion, therapies that may be given for bleeding or to stabilize a patient for transfer that have been used after vacuum aspiration or postpartum hemorrhage include (Lichtenberg & Grimes 2009, WHO 2009b):

- Vasopressin, 10 units in 20mL crystalloid injected transcervically into the myometrium
- Methylergonovine 0.2mg intramuscularly or intracervically
- Oxytocin 20 units in 1L IV at a rate of 60 drops per minute
- Misoprostol 200-800mcg orally, rectally or sublingually
- Intrauterine tamponade with sterile gauze packing or a 30-75mL foley balloon

If these measures appear necessary but are not available, refer the woman to a higher-resource site immediately.

#### Infection

MA is rarely associated with infection. One published review found that the frequency of infection after MA was less than one percent (Shannon 2004). Furthermore, this study included infections that were mild enough to be treated with oral medicines in the outpatient setting; the actual incidence of severe infections is much lower. Only four of the 46,400 women (0.009%) in this review required hospitalization for infection. Prophylactic antibiotics are not recommended for routine MA provision (WHO 2012, Achilles 2011).

A retrospective analysis of 227,823 medical abortions found a significant reduction in the rate of serious infection when misoprostol routing was changed to the buccal route instead of the vaginal route. The change to buccal route, however, was accompanied by one of two infection-reduction measures: either routine testing for chlamydia and treatment of positive results

or routine antibiotics (doxycycline 100mg orally for seven days) (Fjerstad 2009a).

After administration of misoprostol, a woman may occasionally develop a transient, low-grade fever. If fever of 38°C (100.4°F) or higher persists for 24 hours beyond taking misoprostol, or fever begins any day after misoprostol use, the woman should be evaluated by a clinician. If the woman displays signs and symptoms of uterine infection, broad-spectrum antibiotic treatment should be started. In the extremely rare case of severe infection or sepsis, the woman should be hospitalized for treatment.

If a woman appears ill with abdominal pain, and nausea or vomiting—regardless of whether or not she has a fever—provide or refer for full infection diagnostics. Some rare infections or even sepsis can present without fever.

## Allergic reactions

Allergic reactions to mifepristone and misoprostol are rare, but have been reported occasionally. These reactions have been accompanied by swelling of the hands or feet, rashes or wheezing (Davey 2006). Allergic reactions can be managed conventionally, for example with an antihistamine.

A severe allergic reaction is very rare but can occur with any medicine, food or substance. Women who experience sudden shortness of breath or swelling of the airway or any other severe or unusual reaction should receive emergency treatment.

## **Emergency response**

In rare situations, using existing emergency response systems may be necessary. In an emergency, sometimes women need to be transferred to a higher-resource center for care. Having plans for such a situation in advance saves time, prevents confusion and facilitates appropriate care in extremely urgent scenarios.

Emergency response plans may include:

## On-call provider

Ensure that a clinically knowledgeable person is available to answer women's questions and provide or refer for care 24 hours a day. This provider can triage those women who need reassurance or instructions versus those who need clinical assessment or emergency care. Because many women will take misoprostol at home, they may need reassurance that the process is normal and should be over in a few hours, or they may have a problem that requires immediate medical attention.

## Referral site relationship

It is important to put in place referral agreements (such as a memorandum of understanding) about transferring a woman to the referral center if necessary; it is preferable to refer women to the most accessible site.

If possible, providers can establish a relationship with emergency room staff and gynecologists at their referral hospital. It can be helpful to provide an information session for staff at referral hospitals. The session could include MA, the mechanism of action of the medicines, the continuum of expected effects and side effects, the types of complications that may be seen, and how to triage a woman having a MA emergency. Invite hospital staff to the clinic providing MA.

#### Information sharing

If a woman will be transferred to a referral hospital, providers will need to call the hospital to notify them that the woman is being transported, why she is being referred for care, her history, what measures have been taken in the clinic and her current condition.

Develop a mechanism to receive records or verbal reports of a woman who received emergency care at the hospital so that the clinic can stay informed of such cases and their outcome and provide appropriate follow-up care.

## Practicing for emergencies

On a routine basis, facility staff should review and practice how they will handle emergencies so that everyone knows their roles and protocols. Staff need to practice how to treat hemorrhage, shock, starting intravenous fluids, giving oxygen (if available), and cardiopulmonary resuscitation.

## **Supplies**

Have an emergency cart or container with all the medicines and supplies that may be useful in an emergency. Have a regular monthly check-list of the contents of the cart to be sure it is stocked and that supplies and medications are not expired.

#### Links to communities

Providers can work with community leaders and organizations, particularly women's groups, to educate them about signs and symptoms of medical abortion complications that require prompt medical attention, as well as how and where women can receive emergency care. Communities can prevent delays in getting women with emergencies to health services such as through community-based emergency transportation systems. Health-facility staff can train community health workers or local health volunteers to refer

women in emergency situations to health-care services, to follow up with women after care and to link women to family planning and other reproductive health services.

#### Review

Circle *all* correct answers. There may be more than one correct answer per question.

- 1. What are potential complications of MA?
  - a. Infection
  - b. Uterine perforation
  - c. Hemorrhage
  - d. Vomiting
- 2. Which of the following are true related to ectopic pregnancy?
  - a. All women with ectopic pregnancy will present with the classic signs and symptoms, such as bleeding, abdominal pain and palpable mass.
  - b. Mifepristone and misoprostol cannot terminate an ectopic pregnancy.
  - c. A woman with an early ectopic pregnancy may not have any symptoms.
  - d. Ectopic pregnancy should be considered as a possibility if a woman has persistent pain.
- 3. What should be done if pelvic infection is suspected after MA?
  - a. Give reassurance
  - b. Treat according to the severity and type of the infection
  - c. Provide a vaginal anti-fungal
  - d. Only treat if she has a fever too

## Reflect

The following questions are designed to help you think about what is currently in place and how to apply the contents of this module to your service delivery setting.

1. At your site, what is or will be your protocol for emergency referrals when needed?

2. How will all personnel be trained to recognize complications and manage or refer them?

3. How will providers track complications in your record-keeping system?

4. What concerns do you have about MA problems, complications and emergencies in your setting? What special concerns do you have about MA problems, complications and emergencies for young women? How do you plan to address these concerns?

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## Module 7: Service Provision

## Providing woman-centered medical abortion

Several factors need to be in place to provide high-quality, clinic-based woman-centered medical abortion (MA) within the health system. Facilities, supplies, personnel, referral systems and quality assurance mechanisms all contribute to the provision of services, as listed in detail below.

#### Facilities and health services

- Accessible service delivery days and hours, including times that are convenient for young women
- Private areas for information provision and counseling (both visual and sound privacy)
- Health-care worker practices and supplies to prevent infection (for example, clean gloves for pelvic exams)

- Sufficient number of toilets to accommodate women if they remain in the clinic after taking misoprostol
- Effective referral system for complications and other reproductive health needs
- Integrated family planning, including contraceptive services

#### Medication and supply management

- · Availability of misoprostol and where possible, mifepristone
- Systems for procurement of medications
- Adequate storage
- Pain management and other medications as needed
- · Sanitary pads or cotton wool
- Contraceptive supplies
- Clean drinking water (to take mifepristone where available)

#### Sustainable supply

To provide medical abortion services, facilities must have a reliable supply of the medications or be able to direct women to a nearby pharmacy that has a consistent supply. In many instances, national public health sectors have yet to focus on developing new systems or improving existing systems in order to ensure that medical abortion medications are available when and where they are needed. Existing weaknesses in national public health supply chains impact supply. Medical abortion supply-chain infrastructure strength is also impacted by other factors including the potential use of misoprostol for multiple health indications, the relatively short shelf life of medical abortion medications, and the potential for degradation of misoprostol due to excessive heat and humidity. Increasing usage of medical abortion may also result in stockouts if sites do not manage their inventory well. Site staff must monitor their usage of the medicines, develop inventory targets, and identify funding sources and reliable vendors. For tools to estimate recommended inventory levels, please see Additional Resources, Sustainable Supply.

## Staff knowledge, attitudes and skills

- Knowledge of: MA regimens, clinical assessment including gestational dating, provision of MA counseling and informed consent, process for administering the drugs, side effect management and warning signs for when follow-up might be needed
- Attitudes that are: positive, helpful and non-discriminatory toward women seeking abortion using the MA method—including toward both married and unmarried young women
- Skills to: perform clinical assessment, provide MA

information (including contraceptive counseling and obtaining informed consent), dispense MA, conduct follow-up and assessment of abortion success where needed and perform or refer women for emergency care

#### Client information

- Clear, simple information to help women make an informed decision about MA
- Consent forms
- Simple information about what to expect, and when and where to seek follow-up and emergency care if needed
- Contraceptive information, methods or referrals

## Record keeping

- Clear policies about information that needs to be recorded
- Record keeping that protects women's privacy (for example, lists with names of women obtaining referrals to other reproductive health services should not be visible to anyone other than staff)
- · Monthly registers or logbooks
- Individual client records
- Referral and adverse event reporting forms

## Monitoring and evaluation

- A monitoring and evaluation plan with clear definitions of services to be evaluated, sources of information and indicators for measurement
- Mechanisms for obtaining feedback from women
- Documentation and review of any serious complications (adverse events) that occur with MA

There are many resources for introducing abortion services to a health facility. For more on monitoring and evaluation, please see Additional Resources, Monitoring to Improve Services.

## Location of Taking the pills

Mifepristone may be taken in the clinic or at home if it is more convenient for the woman. Misoprostol should be taken one to two days after mifepristone.

When MA was first used for abortion, women took misoprostol in the clinic, where they often remained until they aborted. For several years since then, most clinicians give women up to 9 weeks LMP the choice of taking misoprostol at the clinic or at home. A recent study showed no difference in success rates, ongoing pregnancy and adverse events in women from 8 to 9 weeks gestation and women from 9 to 10 weeks. Therefore, giving women between 9 and 10 weeks buccal misoprostol at home is an option in some settings (Winikoff, 2012). For MA between 10 and 13 weeks, misoprostol should only be given in the clinic.

#### Home use of misoprostol

Multiple studies from different countries have shown that taking misoprostol at home as part of a mifepristone and misoprostol regimen is safe, effective and highly acceptable to women undergoing MA up to 9 weeks LMP (Fiala 2004, Elul 2001, Guengant 1999). Although studies have not specifically evaluated safety, efficacy and acceptability of home use of misoprostolonly regimens, the option of home use has been included in some studies (von Hertzen 2007).

Many women prefer taking misoprostol at home with familiar surroundings, people and personal belongings. Doing this also can save them money in transportation costs as well as time. In turn, it saves the facility staff resources as well.

Staff should give all women aborting at home the following:

- · Misoprostol pills or a prescription for them
- Detailed information on how to take the misoprostol
- Pain medicine, such as ibuprofen and/or mild narcotics with instructions about how to take it (see details in Module 3: Clinical Care about pain management)
- Written and pictorial information on the MA process, side effects and warning signs; what signs indicate that the abortion is successful; and information for follow-up contact, if desired
- Information on whom to contact (including a telephone number, where possible) in case of questions, problems, complications, or the possibility of an unsuccessful MA
- Other optional items: sanitary pads, cotton wool, contraceptive information and supplies

Many clinics give this information and supplies in a take-home packet. It is also helpful to talk with each woman about her specific situation. For example, does she have a partner or support person who can be with her when she takes the misoprostol and also after when she is likely to begin bleeding? If she has children, has she arranged child care in case she needs to rest? Does she have concerns about seeing and disposing of the embryo after it expels?

A conversation about what to consider can help women to be most prepared for their at-home medical abortion.

## Clinic use of misoprostol

Whenever possible, women should be offered a choice of taking the misoprostol at home or in the clinic, as different women have different needs and desires. For some women, home may be a more private place but for others, the clinic may afford a greater degree of privacy. If the woman chooses to take misoprostol vaginally in the clinic, she should be offered the choice of inserting the misoprostol herself or to have it inserted by a provider. She may also take the misoprostol buccally or sublingually.

After taking misoprostol, the woman may wait at the clinic for approximately 4 to 6 hours, depending on how long it takes the pregnancy to expel. A woman who has not expelled the pregnancy within that time may remain longer waiting for expulsion, or she may return to her home if she has transportation and can seek follow-up care if necessary.

Clinics may have rooms with beds or curtained cubicles or, more commonly, a room that has several cots or reclining chairs and a toilet nearby. There should be enough toilet facilities to accommodate the maximum number of women receiving misoprostol at a given time. Women do not need to be restricted to beds but can move around the clinic if they prefer. Depending on space and the ability to ensure the confidentiality of all the women receiving services, facilities should also consider allowing each woman to have her partner or a support person with her during this time. A clinician or counselor should be available to answer questions and to address any medical concerns.

Staff should provide hot-water bottles, bags or cloths (if possible) to relieve discomfort from cramping, as well as pain medications. For more information on pain management, please see Module 3: Clinical Care.

Expelled tissue should be observed by a clinician to confirm a complete abortion.

If the woman leaves the clinic before she aborts, providers should:

- Ensure that she has instructions and supplies for aborting at home
- Provide her with pain medication to take home
- Review instructions and provide information on signs of a successful MA, as well as warning signs of complications or an unsuccessful MA for which she should contact the clinic
- Provide her with providers or facilities' telephone numbers where possible
- Provide a contraceptive method if desired
- Inform her that she can return to the clinic any time if she desires follow-up care. If she wants reassurance that the abortion was successful, she should return after two weeks.

#### Review

Circle *all* correct answers. There may be more than one correct answer per question.

- 1. What factors should be in place to promote woman-centered MA?
  - a. Client information that is simple and clear
  - b. Medications and supplies for MA provision
  - c. Monitoring and evaluation system
  - d. Allowing women a choice between MA and MVA where available
- 2. What does allowing women to take misoprostol at home mean?
  - a. The MA will not be as safe
  - b. They can have family or friends present for support if they wish
  - c. They can have their personal belongings with them
  - d. The MA may not be as effective as in the clinic
- 3. What should be provided for all women undergoing MA?
  - a. Contact information in case of questions or emergencies
  - b. Information on warning signs
  - c. Sterilization procedure
  - d. Pain management

## Reflect

Answer the following questions by gathering information about the situation in your setting.

What medications will you need to keep in stock to provide MA services? (Refer to the MA regimen you will be using as well as pain management medications and other medications.)

What are the advantages and disadvantages of clinic versus home administration of misoprostol in your setting?

What are the costs of the different medications both to the facility and the woman?

Where will you get the medications and how will you manage and store them?

What steps do you need to take to make your MA services woman-centered? How are these steps the same or different for young women?

experience. How you might address these?

Think about all of the different barriers to MA care that women, including young women, might

## Review Questions: Answer Key

#### Module 1: Overview

- 1. a, c
- 2. a, b, c
- 3. a, c

## Module 2A: MA with Mifepristone and Misoprostol

- 1. c
- 2. b
- 3. b, c, d
- 4. a, b, c

#### Module 2B: MA with Misoprostol Only

- 1. c
- 2. b
- 3. b, c
- 4. a, b, c

#### Module 3: Clinical Care

- 1. c
- 2. a, b, c
- 3. a, b, d

#### Module 4: Informed Consent, Information and Counseling

- 1. b, c
- 2. a, d
- 3. a, b, c
- 4. b, c

#### Module 5: Follow-up

- 1. b
- 2. a, b, c, d
- 3. a, c, d

#### Module 6: Problems, Complications and Emergencies

- 1. a, c
- 2. b, c, d
- 3. b

#### Module 7: Service Provision

- 1. a, b, c, d
- 2. b, c
- 3. a, b, d

#### Additional resources

This study guide was designed to provide comprehensive coverage on the delivery of high-quality, clinic-based, first-trimester MA, particularly in limited-resource settings. For further information about a variety of issues related to abortion—and MA specifically—please see these additional resources.

## By topic

## Advocacy

Providers as Advocates for Safe Abortion Care: A Training Manual. www.ipas.org/en/Resources/Ipas%20Publications/Providers-as-advocates-for-safe-abortion-care--A-training-manual.aspx

#### **Antibiotics**

Low, N., Mueller, M., Van Vliet, H. A. A. M., & Kapp, N. (2012). Perioperative antibiotics to prevent infection after first-trimester abortion. *Cochrane database of systematic reviews*, 3, CD005217. http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD005217.pub2/abstract

#### Birth defect risks with MA

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Sparking Dialogue: Initiating Community Conversations on Safe Abortion. www.ipas.org/publications/en/SPARKDIA\_E05\_en.pdf

## Complications

Woman-Centered, Comprehensive Abortion Care: Reference Manual, Second Edition, Complications module. On MA Training Resources CD-ROM in Medical Abortion Training Guide or online www.ipas.org/Resources/Ipas%20Publications/Woman-centered-abortion-care--Reference-manual.aspx

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Woman-Centered, Comprehensive Abortion Care: Reference Manual, Second Edition, Contraceptive Services module. On MA Training Resources CD-ROM in Medical Abortion Training Guide or online www. ipas.org/Resources/Ipas%20Publications/Woman-centered-abortion-care--Reference-manual.aspx

Best Practices in Medication Abortion: Starting Contraception after First-trimester Medication Abortion. On MA Training Resources CD-ROM in Medical Abortion Training Guide or online: http://ipas.org/~/media/Files/Ipas%20Publications/MAFactsheet1.ashx

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#### MA for second-trimester abortion

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Women-Centered, Comprehensive Abortion Care: Reference Manual, Second Edition.On MA Training Resources CD-ROM in Medical Abortion Training Guide or online www.ipas.org/Resources/Ipas%20 Publications/Woman-centered-abortion-care--Reference-manual.aspx

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MA Supply Guidance Tool. On MA Training Resources CD-ROM in Medical Abortion Training Guide, available online at www.ipas.org/en/Resources/Ipas%20Publications/MA-Supply-Guidance-Tool--zip--in-English--French-and-Spanish.aspx

Or use online at http://www.ipas.org/What-We-Do/Comprehensive-Abortion-Care/Elements-of-Comprehensive-Abortion-Care/Medical-Abortion-MA-/Medical-Abortion-MA-Supply-Guidance.aspx

## Training

Effective Training in Reproductive Health: Course Design and Delivery, Reference Manual. On MA Training Resources CD-ROM in Medical Abortion Training Guide or online.http://ipas.org/en/Resources/Ipas%20Publications/Effective-training-in-reproductive-health--Course-design-and-delivery--Reference-manual-2.aspx

Effective Training in Reproductive Health: Course Design and Delivery, Trainer's Manual. On MA Training Resources CD-ROM in Medical Abortion Training Guide or online. http://ipas.org/en/Resources/Ipas%20Publications/Effective-training-in-reproductive-health--Course-design-and-delivery--Trainers-manual--2.aspx

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#### Values clarification

Abortion Attitude Transformation: A Values Clarification Toolkit for Global Audiences www.ipas. org/Resources/Ipas%20Publications/Abortion-attitude-transformation--A-values-clarification-toolkit-for-global-audiences.aspx

Abortion Attitude Transformation: Values Clarification Activities Adapted for Young Women www. ipas.org/en/Resources/Ipas%20Publications/Abortion-attitude-transformation--Values-clarificationactivities-adapted-for-young-women.aspx

#### Young women

Abortion Care for Young Women: A Training Toolkit. On MA Training Resources CD-ROM in Medical Abortion Training Guide or online www.ipas.org/Resources/Ipas%20Publications/Abortion-care-foryoung-women--A-training-toolkit.aspx

Abortion Attitude Transformation: Values Clarification Activities Adapted for Young Women www.ipas.org/en/Resources/Ipas%20Publications/Abortion-attitude-transformation--Valuesclarification-activities-adapted-for-young-women.aspx

## Related Ipas publications

Abortion Attitude Transformation: A Values Clarification Toolkit for Global Audiences www.ipas.org/Resources/Ipas%20Publications/Abortion-attitude-transformation--A-values-clarification-toolkit-for-global-audiences.aspx

Abortion Attitude Transformation: Values Clarification Activities Adapted for Young Women www.ipas.org/Resources/Ipas%20Publications/Abortion-attitude-transformation--Values-clarification-activities-adapted-for-young-women.aspx

Abortion Care for Young Women: A Training Toolkit

www.ipas.org/Resources/Ipas%20Publications/Abortion-care-for-young-women--A-training-toolkit.aspx

Best Practices in Medication Abortion: Starting Contraception After First-Trimester Medication Abortion www.ipas.org/Resources/Ipas%20Publications/Best-practices-in-medication-abortion--Starting-contraception-after-first-trimester-medica-2.aspx

Early First-Trimester Medical Abortion – Mifepristone and Misoprostol Wheel www.ipas.org/Resources/Ipas%20Publications/First-trimester-medical-abortion---mifepristone-and-misoprostol-wheel.aspx

Early First-Trimester Medical Abortion – Misoprostol-Only Wheel

www.ipas.org/Resources/Ipas%20Publications/First-trimester-medical-abortion---misoprostol-only-wheel.aspx

Information and Training Guide for Medical Abortion Counseling

www.ipas.org/Resources/Ipas%20Publications/Information-and-training-guide-for-medical-abortion-counseling.aspx

MA Supply Guidance Spreadsheet

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MA Supply Guidance Tool

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Medical Abortion in Early Pregnancy: Information, Education and Communication (IEC) Materials and Job Aids

www.ipas.org/Resources/Ipas%20Publications/Medical-abortion-in-early-pregnancy--Information--education-and-communication--IEC--materi-2.aspx

Medical Abortion Training Guide

www.ipas.org/Resources/Ipas%20Publications/Medical-abortion-training-guide.aspx

Misoprostol and Medical Abortion in Africa

www.ipas.org/Resources/Ipas%20Publications/Misoprostol-and-medical-abortion-in-Africa.aspx

Misoprostol and Medical Abortion in Latin America and the Caribbean

www.ipas.org/Resources/Ipas%20Publications/Misoprostol-and-medical-abortion-in-Latin-America-and-the-Caribbean.aspx

Misoprostol for Incomplete Abortions: Training Guide http://www.ipas.org/en/Resources/Ipas%20 Publications/Misoprostol-for-treatment-of-incomplete-abortions--Training-guide.aspx

Misoprostol Use in Postabortion Care: A Service Delivery Toolkit.

www.ipas.org/Resources/Ipas%20 Publications/Misoprostol-use-in-postabortion-care--A-service-delivery-toolkit.aspx

Protocols for Medical Abortion [Dosage Card]

www.ipas.org/Resources/Ipas%20Publications/Protocols-for-medical-abortion--dosage-card-.aspx

Woman-Centered, Comprehensive Abortion Care: Reference Manual, Second Edition On MA Training Resources CD-ROM in Medical Abortion Training Guide or online

www.ipas.org/Resources/Ipas%20Publications/Woman-centered-abortion-care--Reference-manual.aspx

Woman-Centered, Comprehensive Abortion Care: Trainer's Manual, Second Edition. On MA Training Resources CD-ROM in Medical Abortion Training Guide or online www.ipas.org/Resources/Ipas%20 Publications/Woman-centered-abortion-care--Trainers-manual.aspx

Woman-Centered Postabortion Care: Reference Manual, Second Edition www.ipas.org/Resources/Ipas%20Publications/Woman-centered-postabortion-care--Reference-manual.aspx

## Other related publications

Early Abortion Training Workbook, 3rd ed. Goodman S, Wolfe M, and the TEACH Trainers Collaborative Working Group. San Francisco (CA, USA): UCSF Bixby Center for Reproductive Health Research & Policy, 2007.

www.ansirh.org/training/workbook.php

First-Trimester abortion Guidelines and Protocols. Surgical and Medical Procedures (IPPF) www.ippf.org/en/Resources/Guides-toolkits/First+trimester+abortion+guidelines+and+protocols.htm

Frequently Asked Clinical Questions about Medical Abortion (WHO) www.who.int/reproductivehealth/publications/unsafe\_abortion/9241594845/en/

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Medication Abortion: A Guide for Health Professionals (Ibis Reproductive Health) www.ibisreproductivehealth.org/downloads/Medication\_abortion\_A\_guide\_for\_health\_professionals\_English.pdf

Misoprostol Use in Obstetrics and Gynecology (PATH) www.path.org/publications/details.php?i=1005

Providing Medical Abortion in Low-Resource Settings: An Introductory Guidebook, 2nd ed. (Gynuity) (Gynuity Health Projects) http://gynuity.org/resources/info/medical-abortion-guidebook

World Health Organization (2012). Safe abortion: *Technical and policy guidance for health systems* (second ed.). Geneva: World Health Organization. www.who.int/reproductivehealth/publications/unsafe\_abortion/9789241548434/en/index.html

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Ultrasound in Abortion Care (Planned Parenthood Consortium of Abortion Providers)[available through Affiliates Risk Management Services, Inc., arms@armsinc.org]

#### Related web sites

Gynuity Health Projects: www.gynuity.org

Ibis: www.medicationabortion.com

International Consortium for Medical Abortion: www.medicalabortionconsortium.org

International Planned Parenthood Federation: www.ippf.org

Ipas: www.ipas.org

 $Marie \ Stopes \ International: \ www.mariestopes.org/What\_we\_do/Safe\_abortion\_\%5E\_post\_abortion\_with a property of the prop$ 

care.aspx

Misoprostol in Obstetrics and Gynaecology: www.misoprostol.org

National Abortion Federation: www.prochoice.org/about\_abortion/facts/medical\_abortion.html

Women on Web: www.womenonweb.org

## Ipas online clinical and service delivery updates and courses

Clinical Updates for Reproductive Health - a series designed to provide up-to-date, evidence-based recommendations and clinical protocols. Available at Ipas's website, www.ipas.org

**IpasUniversity (IpasU)** - IpasUniversity offers free, online, on-demand courses for reproductive health professionals on safe abortion care and postabortion care. Available at www.lpasU.org

**Medical Abortion Matters** - a biannual newsletter, created to share global perspectives on medical abortion access, news and research. Subscribe online at: www.ipas.org/en/Pages/Newsletters.aspx

Service Delivery Matters - This biannual newsletter shares technical news and updates – including training and service delivery strategies and tools, clinical recommendations, programmatic interventions and research results – for healthcare providers, trainers, administrators, technical specialists and others who can positively influence how comprehensive abortion care is delivered. Subscribe online at: www.ipas.org/en/Pages/Newsletters.aspx

## Acronyms used in this guide

AIDS – acquired immune deficiency syndrome

BHCG – beta human chorionic gonadotropin

°C - degrees Celsius

cm - centimeters

**EC** – emergency contraception

**EVA** – electric vacuum aspiration

°F – degrees Fahrenheit

**FIGO** - International Federation of Gynecology and Obstetrics

**HIV** – human immunodeficiency virus

IEC - information, education and communication

IUD - intrauterine device

IV - intravenous

LMP – last menstrual period

MA - medical abortion

mcg – also μg, microgram

mg – milligram

mL - milliliter

MVA – manual vacuum aspiration

NSAIDs – non-steroidal anti-inflammatory drugs

RH - reproductive health

STI – sexually transmitted infection

**VA** – vacuum aspiration

**WHO** – World Health Organization

## Glossary

**Abortion** - The termination and expulsion of a pregnancy before birth.

**Abortion Pill** - Popular term for mifepristone, a medication used to terminate pregnancy. Sometimes used to describe the process of medical abortion to terminate and expel a pregnancy.

Adolescents - People aged 10-19 years of age.

**Adverse Event (AE)** - Any adverse or serious change in health that occurs in a patient receiving treatment (medication, medical procedure, etc.) related to the treatment or within a pre-specified period of time after their treatment has been completed. Adverse events must be reported following established protocol, and should be approached as opportunities to analyze what happened, learn from the event, and improve systems of care.

Amenorrhea - A lack of menstruation.

**Bimanual Examination** - Physical (two-handed) examination of the size, shape and position of the uterus. Used to compare the size of the uterus with the history of amenorrhea.

**Bronchodilation** - Expansion of the air passages leading to and in the lungs.

**Cervix** - A small canal which forms the opening to the cavity of the uterus.

**Combined Regimens** - Combined regimens for medical abortion include mifepristone and misoprostol used together.

**Comprehensive Abortion Care (CAC)** - Comprehensive abortion services—including treatment of incomplete abortion—that include a range of abortion options covering a wide span of gestational ages, as well as pre- and postabortion information and counseling, follow-up care, and referral services, including for contraception (see Woman-Centered Abortion Care).

**Conception** - The moment when the embryo attaches to the lining of the uterus and pregnancy begins. Also used to describe the fertilization of the egg.

**Contraception/Contraceptive** - Any behavior, device, medication or procedure used to prevent pregnancy.

**Contractions** - The muscle layers of the uterus tighten in a synchronous, rhythmic pattern. Contractions occur during medical abortion, miscarriage and childbirth, and after vacuum aspiration. These contractions aid in expulsion of the uterine contents, cause the uterus to shrink to pre-pregnant size, and also clamp tightly around interwoven blood vessels, thereby preventing hemorrhage.

**Contraindications for MA** - If a woman has these specific conditions, under no circumstances should she be offered MA. MVA should be considered or she should be referred to a facility where she can be offered alternate care.

**Dosage** - Administration of a therapeutic agent in prescribed amounts.

**Ectopic Pregnancy** - An ectopic pregnancy occurs when a fertilized egg attaches itself outside of the uterus, most often in a fallopian tube. An ectopic pregnancy can be life-threatening;

**Electric vacuum aspiration (EVA)** - The use of an electric pump which creates suction to perform uterine evacuation. Tubing is connected at one end to the electric pump, and at the other end is connected to a cannula which is inserted through the cervix into the uterus.

Emergency Contraception (EC) - Hormonal medication used to prevent pregnancy after unprotected vaginal intercourse. Must be started within 120 hours (five days) of intercourse, but is most effective if used as early as possible after unprotected intercourse. Copper containing IUDs can also be used as EC, if they are inserted within five days of unprotected intercourse.

Fetus - Beyond 10 weeks after a woman's last menstrual period, the pregnancy is called a fetus; before 10 weeks, it is referred to as an embryo.

**First Trimester** - The first three months of pregnancy.

Follow-up - The visit, phone call, or other mechanism through which a health-care provider confirms that the woman's abortion was successful and in which her progress is checked and any needs are met.

Gestational Age - This is the duration of pregnancy calculated from the first day of last menstrual cycle. It is usually measured in weeks.

Gestational Sac - A structure that develops in the uterus early in pregnancy; the first formation of an embryonic structure. In an ultrasound, the gestational sac should be visible by five weeks of pregnancy. In early pregnancy, the gestational sac is the first indication of an intrauterine pregnancy visible by ultrasound. A yolk sac within the gestational sac confirms intrauterine pregnancy.

Hydatidaform mole - An abnormal intrauterine growth of placental tissue that occurs after improper fertilization. A molar pregnancy may be complete (no fetal tissue) or partial (abnormal fetal tissue) but is non-viable. Treatment includes removal and pathology review for definitive diagnosis. Follow-up is required to determine that gestational trophoblastic neoplasm or choriocarcinoma do not develop.

HCG - A hormone normally produced during pregnancy. Can be tested for in urine or blood (serum hCG).

**Hemorrhage** - Heavy or excessive blood loss.

Home Administration - Self-administration of a drug or chemical outside of a clinical setting, usually in a woman's home or another safe location.

Hormonal Methods - Methods of birth control that use hormones to prevent pregnancy. These include implants, levonorgestrel-containing IUDs, the patch, the pill, the ring and the shot.

**Ibuprofen** - A non-steroidal anti-inflammatory drug (NSAID) commonly used to treat pain, swelling and fever.

**Incomplete Abortion** - An abortion—either spontaneous or induced—in which some pregnancy tissue passes out of the uterus but some remains.

Informed Consent - Voluntary decision to accept or not accept a health service after receiving adequate information about the risks and benefits of the procedure, as well as information about other available options.

**Intrauterine Device (IUD)** – A long acting reversible form of contraception. The IUD is a small device made of plastic, which may contain copper or a hormone, that is inserted into the uterus by a health-care provider to prevent pregnancy.

**LMP** - Last Menstrual Period; duration of pregnancy is calculated from the first day of last menstrual period.

**Manual Vacuum Aspiration (MVA)** - An in-clinic, early abortion procedure in which the uterus is emptied with the gentle suction of a hand-held syringe.

**Maternal Morbidity** - Serious disease, disability or physical damage to women caused by pregnancy-related complications.

**Maternal Mortality** - Deaths of women while they are pregnant or within 42 days of the end of a pregnancy (either an abortion or birth) caused by or related to the pregnancy or its management.

**Medical Abortion** - The use of one or more medications to end pregnancy. These medications terminate the pregnancy, which is then expelled by the uterus in a process similar to miscarriage. Medical abortion is sometimes called medication abortion, pharmacological abortion, pharmaceutical abortion or the abortion pill. Medical abortion does not include emergency contraception (EC), also known as the "morning-after pill," which prevents pregnancy from occurring.

**Mifepristone** - Originally known as RU-486, it blocks progesterone activity in the uterus, which stops the growth of the fetus and leads to detachment of the pregnancy. Additionally, it sensitizes the uterus to prostaglandins, increasing the impact of misoprostol, and helps to soften the cervix.

**Misoprostol** - A prostaglandin analogue administered at varying intervals to soften the cervix, stimulate uterine contractions and cause expulsion of the pregnancy.

**Missed Abortion** - A failed early pregnancy in which the pregnancy is no longer developing but the tissue has not been expelled from the uterus. A missed abortion may be managed expectantly, with misoprostol or with vacuum aspiration.

**Multiple gestation** - A pregnancy with more than one fetus such as twins, triplets or quadruplets.

**Pain Management** - Using medications, psychological support and other means to decrease a patient's reaction to pain.

**Policy** - Includes statements, plans, practices and regulations adopted by a government or other organization that are designed to guide or control institutional and community behavior.

**Postabortion Care (PAC)** - Postabortion care refers to a specific set of services for women experiencing complications of spontaneous or induced abortion, including retained tissue, hemorrhage and infection. PAC consists of several elements: (1) Uterine evacuation with medications or vacuum aspiration (2) Counseling to identify and respond to women's emotional and physical health needs and other concerns; (3) Contraceptive information and method provision for women who desire to postponeor limit future pregnancy; (4) Reproductive and other health services that are preferably provided on-site or via referrals to other accessible facilities in providers' networks; and (5) Community and service provider partnerships to help prevent unwanted pregnancies and unsafe abortion and mobilize resources to help women receive appropriate and timely care for complications of abortion.

**Precaution** - If a woman has these specific conditions, MA has higher risks than normal. The risks, benefits and alternatives to MA must be considered. MA provision may require a higher degree of clinical judgment, skill and monitoring. Referral to a higher-level facility may be appropriate.

**Progesterone** - A hormone produced in the ovaries of women that is important in the regulation of puberty, menstruation and pregnancy.

Prostaglandin - One of a number of hormone-like substances that participate in a wide range of bodily functions such as the contraction and relaxation of smooth muscle, the dilation and constriction of blood vessels, control of blood pressure, and modulation of inflammation. Misoprostol is a synthetic (man-made) prostaglandin used to induce uterine contractions for childbirth or abortion.

**Regimen** - A plan or regulated course of behavior or treatment designed to give a particular result.

Reproductive Health - A state of complete physical, mental and social wellbeing in all matters relating to the reproductive system and to its functions and processes.

Rh-immunoglobulin - A substance given to prevent a woman who has Rh-negative blood from forming antibodies to the blood of an Rh-positive fetus if there is maternal/fetal blood transfer. If pregnant woman with Rh-negative blood is exposed to the blood of an Rh-positive fetus, she may become sensitized. If she does become sensitized, the health of future pregnancies may be jeopardized because Rh antibodies cross the placenta and may cause the destruction of fetal red blood cells.

RU-486 - Name given to mifepristone during product development and sometimes still used to refer to the drug (see "Mifepristone").

Sanitary Pad - An absorbent "napkin" made of cotton or similar fibers that is worn against the vulva to absorb menstrual flow.

**Second Trimester** - The second 3 months of pregnancy.

Side Effects - A peripheral or secondary effect, especially an undesirable secondary effect, of a drug or therapy. The most common side effects of medical abortion are caused by misoprostol. In addition to cramps and bleeding (which are expected effects), other side effects may include headache, nausea, vomiting, diarrhea, fever, chills or fatigue.

**Sonogram** - A picture of the embryo or fetus in the uterus produced by the visualizing technology called ultrasonography (see Ultrasound).

Spontaneous Abortion - A miscarriage; the natural, involuntary termination of a pregnancy before viability. Spontaneous abortion occurs in at least 15-20 percent of all recognized pregnancies and usually takes place before the 13th week of pregnancy.

**Successful Abortion** - The pregnancy is expelled or removed with no need for further intervention or treatment. A medical abortion is successful if the embryo and sac have been expelled and a woman does not need an intervention due to problematic bleeding. On ultrasound, it is normal to see decidua and thickened endometrial tissue after medical abortion—this does not require more treatment.

**Tampon** - A firm roll of absorbent cotton or other fiber that is worn inside the vagina to absorb menstrual flow.

**Teratogenicity** - Having the ability to cause defects in a developing fetus. A teratogen is an agent (for example, a chemical or a medicine) that can disturb the development of the embryo or fetus by causing an abortion or producing a congenital malformation (a birth defect).

**Trimester** - The nine months of pregnancy are traditionally divided into three trimesters, distinct periods of roughly three months each in which different phases of fetal development take place.

**Ultrasound** - A medical technology that creates an image by bouncing sound waves off the internal organs (see Sonogram).

**Unsafe Abortion** - "A procedure for terminating an unwanted pregnancy either by persons lacking the necessary skills or in an environment lacking the minimal medical standards, or both" (WHO 1992).

**Uterine Perforation** - When the wall of the uterus is punctured by a medical instrument during a procedure.

**Uterus** - The pear-shaped, muscular reproductive organ where a pregnancy develops. Also called the "womb."

**Vacuum Aspiration (VA)** - A procedure in which a suction tube attached to an electric or manual vacuum pump is inserted through the cervix into the uterus to remove its contents.

Woman-Centered, Comprehensive Abortion Care (WCCAC) - A comprehensive approach to providing abortion services that takes into account the various factors that influence a woman's individual health needs—both physical and mental—as well as her ability to access services and her personalcircumstances. A woman-centered model for abortion care comprises three key elements: choice, access and quality (see Comprehensive Abortion Care).

Young women - People aged 10-24 years of age

## Appendix A: Quick reference guide to medical abortion

#### Indication

Termination of first-trimester intrauterine pregnancy

#### **Contraindications**

- · Previous allergic reaction to one of the drugs involved
- Inherited porphyria (contraindicated for mifepristone)
- Chronic adrenal failure (contraindicated for mifepristone)
- Known or suspected ectopic pregnancy

#### **Precautions**

- IUD in place. Evaluate for the presence of ectopic pregnancy. If none, remove the IUD.
- Severe uncontrolled asthma or long-term corticosteroid therapy (precaution for mifepristone).
   No evidence exists regarding use of mifepristone in steroid-dependent women. Providers must use clinical judgment if no other alternatives to safe abortion exist. Increase steroid dose for 3-4 days and monitor the woman very closely. Conditions such as poorly controlled asthma may still be worsened.
- Severe/unstable health problems including but not limited to hemorrhagic disorders, heart
  disease, severe anemia. No evidence exists on the use of MA in women with hemorrhagic
  disorder, heart disease, severe anemia or severe/unstable health problems. Whether to provide
  medical abortion to women with these conditions will depend on the available options for safe
  abortion care, referrals, and clinical judgment. If medical abortion is given, it should be given
  under close observation.

Medical abortion (MA) can be given to young women and women with: asthma who use inhalers (not systemic steroids), HIV &AIDS, breastfeeding babies or STIs (treat concurrently when beginning MA).

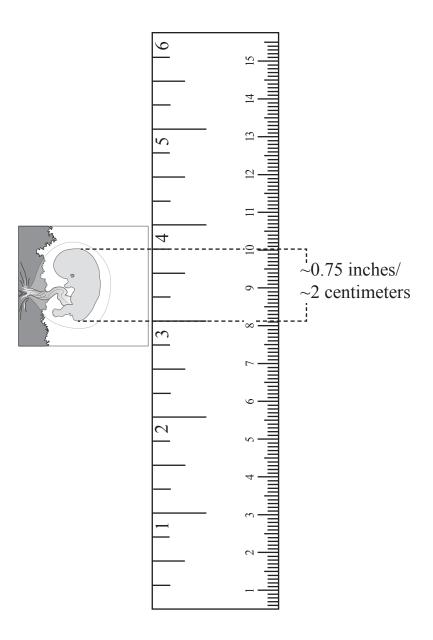
The dose is the same for **obese women** and women with **multiple gestations** using the combination mifepristone and misoprostol MA regimen. In the absence of data for misoprostol-only abortion, the dosage should be the same for them as well.

## Regimens

| Table 2A-1: Mifepristone and misoprostol regimens for medical abortion up to 13 weeks |                   |  |  |  |
|---|-------------------|--|--|--|
| Gestational age   | Mifepristone dose | Misoprostol dose, route and timing   |  |  |
| Up to 9 weeks<br>(Kulier 2011)  | 200mg orally      | After 24-48 hours, 800mcg buccally, sublingually or vaginally for one dose   |  |  |
| 9-10 weeks<br>(Winikoff 2012)   | 200mg orally      | After 24-48 hours, 800mcg buccally for one dose  |  |  |
| 10-13 weeks<br>(Hamoda 2005a,<br>Hamoda 2005b)  | 200mg orally      | After 36-48 hours, 800mcg vaginally followed by 400mcg vaginally or sublingually every 3 hours for a maximum of 5 doses of misoprostol |  |  |

| Table 2B-1: Misoprostol-only regimens up to 13 weeks (WHO 2012.<br>von Hertzen 2007, Carbonell 1998, 1999a & 2001) |            |  |  |  |  |
|--|------------|--|--|--|--|
| Misoprostol 800mcg<br>(four 200mcg pills)  | Vaginal    | Every 3 -12 hours for a maximum of 3 doses |  |  |  |
| Misoprostol 800mcg<br>(four 200mcg pills)  | Sublingual | Every 3 hours for a maximum of 3 doses     |  |  |  |

# Appendix B: Illustration of 8-9 week embryo to scale



## Appendix C: Additional medical abortion questions and answers

#### General information

• How does medical abortion (MA) differ from emergency contraception (EC)?

MA stops an implanted pregnancy from growing and causes expulsion of the pregnancy, but EC prevents a pregnancy from occurring in the first place, most often by inhibiting ovulation. EC must be taken within 120 hours (5 days) of unprotected sex (but the sooner, the better), whereas MA can be used to abort a pregnancy in the first and second trimester. In summary, EC is not abortion and it must be taken within a few days of unprotected sex to prevent a pregnancy, whereas MA is an abortion of an existing pregnancy.

• Who can provide MA?

Any trained clinician can provide MA as long as she or he can estimate gestational age, determine if a woman is eligible and provide follow-up in case of an emergency. MA providers do not have to provide vacuum aspiration services, but must be able to manage or refer in the unusual case of an MA failure in the rare case that a complication occurs.

### Eligibility

• Is MA safe and effective for adolescents?

Yes, MA is safe and effective in adolescents (Phelps 2001) and has been found to be even more effective in women who have never given birth (see below).

• Is MA less effective for women who have never had children (nulliparous women)?

MA is effective in women of any parity, especially in nulliparous women. In a retrospective study of MA up to 49 days, it was found that the success rate was higher for nulliparous women than for those women who have previously given birth (parous women) (Lefebvre 2008, Chien 2009).

• Can the MA regimen using only misoprostol be used in obese women and if so, do you need to increase the dose?

A retrospective study showed that MA with mifepristone and misoprostol in obese women has the same efficacy rates as non-obese women and that no increased dose is needed (Strafford 2009). It is fair to assume that the dosage does not need to be changed with misoprostol-only abortions, but there are no studies to confirm this.

• Are there any precautions for women who have had prior cesarean-sections when using MA before 13 weeks?

No. Women with prior cesarean-sections (c-sections) are eligible for MA. One study of MA up to 56 days since LMP found that women who had previous c-sections had higher failure rates (Chien 2009). This study was conducted using the less effective oral route of 400µg of misoprostol. There is little data on safety of MA for women with prior c-sections before 13 weeks, but a recent review of second-trimester abortion (up to 26 weeks) with misoprostol found the risk of uterine rupture to be less than 0.3 percent (similar to vaginal delivery after c-section) (Goyal 2009), so one can assume that the risk of uterine rupture is far lower in abortions before 13 weeks. MA can be recommended for women with prior c-sections at this gestational age.

If a woman has had a MA before, will subsequent MA be less effective?

Previous induced abortion is not a risk factor for MA failure (Haimov, 2007). A woman who has had an MA before may choose to have an MA again at any time if she is eligible.

• Do women need to have access to a telephone in order to use MA?

No. MA has been provided for women in communities where there are no phones at all; in these cases, a woman would be taken by vehicle to a medical facility if a serious problem arose.

#### Practical advice

• Does the mifepristone dose need to be repeated if a woman vomits?

If the woman has kept down the mifepristone for 30 minutes, she doesn't need a repeat dose of mifepristone. If she vomits within 30 minutes, she should be given a repeat mifepristone 200mg pill. If a woman is known to have a problem with frequent vomiting with pregnancy, to prevent her from vomiting the mifepristone, it may be helpful to give an anti-emetic or a light snack (toast or crackers) to settle her stomach prior to giving mifepristone.

• What practical advice can help women preparing to have MA?

Giving women clear expectations about pain and bleeding are important when providing MA. Providers report that women who are well-hydrated feel better and endure the side effects of misoprostol better. Encourage women who are having MA to drink plenty of non-alcoholic beverages throughout the entire process.

• Is it necessary for a woman to have an adult stay with her on the day she takes misoprostol? Having a friend, partner or family member in the home or close by on the day the woman takes misoprostol is ideal. However, some women prefer to be alone and do not want others with them after they take misoprostol or go through the process of expelling the pregnancy. If a woman is alone, it is highly recommended that she has access to a telephone if she needs help—or at least has someone checking in on her throughout the day.

• Can women undergoing MA use tampons?

Once the heavier bleeding has subsided a day or two after using misoprostol, she may use tampons. Basically, she can use tampons when she's comfortable doing so, but during the day she uses misoprostol, it's easier to assess the amount of bleeding if she does not use tampons.

• Can women undergoing MA take a bath?

Women can bathe during the MA, but should not insert the misoprostol vaginally while in the bathtub.

• Should certain foods be avoided while using MA?

Any foods that the woman is comfortable eating and do not cause nausea or vomiting are safe to eat while using MA and will not interfere with the medications.

• *Is there a right or wrong place to insert the misoprostol vaginally?* 

The medication in misoprostol will be absorbed if it is placed anywhere in the vagina. After placing the pills in the vagina it is recommended that the woman lie down for 30 minutes so the pills do not fall out. See "Vaginal Use of Misoprostol" in Module Two A or Two B.

• What if the woman inserts misoprostol vaginally, or buccally or sublingually and the pills don't dissolve?

Women need to be reassured that the active medicine within misoprostol will absorb within 30 minutes. The active ingredient of misoprostol will absorb from the pill through the mucus membrane of the vagina, cheek or under the tongue into the woman's bloodstream. The outer shell casing of the pill may not dissolve; that is not a problem. If the woman inserted the misoprostol vaginally, as long as the misoprostol has been in the vagina for 30 minutes, the active medicine has absorbed. If she gets up and urinates, for example, and the pill casings come out, she doesn't need to put them back in the vagina. Similarly, if she places the misoprostol in the cheek (buccal) or under the tongue (sublingual), even if the pills haven't dissolved, the active medicine has absorbed, and she should swallow the remaining pill fragments 30 minutes later.

• How much time does the woman need to rest after using misoprostol?

This will depend on the woman and her other responsibilities and any underlying medical conditions (such as anemia). Typically, women can resume normal activities as early as the day after using misoprostol, although she will likely be bleeding for several days or weeks. She should not engage in heavy physical activity (such as heavy lifting or vigorous exercise) for about a week after MA.

• Some women tell their family members that they are having a miscarriage, not an abortion. Will the family members be able to tell the difference?

MA is basically a miscarriage induced with medicines. Unless a woman reveals that she's taken medicines, family members or others will not be able to tell the difference between a miscarriage and a medical abortion. Women may want to consider that when the vaginal route of administration is used, remnants of the medicines may remain.

• Can young women use MA?

MA is safe and effective in adolescents. It may even be slightly more effective in women who have not given birth before, which is the case for many young women.

• Is it possible for an adolescent or woman to just tell others that she is having a heavy period (so that family members won't know she was pregnant)?

A woman who doesn't want to tell her family that she is having a medical abortion may explain that she is having a heavy period. Some young women living with their families have had a medical abortion and told their families they are having a heavy menstrual period—if they say anything at all—so family members won't know they were pregnant. They should be counseled, however, that their plan to keep the abortion and pregnancy secret may not work if they experience very heavy bleeding that requires emergency treatment, which is not common but can occur.

If bleeding is considerably heavier than a menstrual period, it may be difficult for a woman to keep this from family members—particularly if she only has access to communal sanitary facilities. If someone notices the excessive bleeding, a married woman may still be able to say she is having an early miscarriage, but an adolescent or unmarried woman may wish—or even need, for her own safety—to avoid any acknowledgement of pregnancy. For this reason, women should be informed in advance of the possibility of heavy bleeding so they can plan accordingly.

• Can a woman use MA if she is pregnant with twins?

Yes. A woman who is pregnant with twins or other multiple gestations may take mifepristone and misoprostol using the standard dosages of medications. The success rate is similar to the success rate for singleton pregnancies.

#### Follow-up

• Why is routine follow-up of MA no longer recommended?

Routine follow-up is no longer recommended because the success of the mifepristone and misoprostol regimen is so high. Most women are able to determine whether their abortion was successful. However, routine follow-up may be offered if a woman wants reassurance that she has passed her pregnancy. Follow-up must be available for women who experience complications or have a failed MA. For providers using misoprostol only, follow-up is recommended as the success rates are significantly lower.

• For those doing ultrasound at follow-up, what if an empty sac (not an ongoing pregnancy) is seen at the follow-up visit?

If an empty gestational sac is seen on follow-up ultrasound, expectant management (waiting and watching) can be used or an additional dose of misoprostol can be offered. A small study of 800µg of misoprostol vaginally for MA up to 63 days since LMP found that more than half of women expelled the gestational sac 1 week after the repeat dose of misoprostol (Reeves 2008). Women's wishes to avoid surgery and instrumentation should be considered. Uterine aspiration may be necessary if the woman is symptomatic for bleeding problems.

• If the woman is still pregnant at the follow-up visit, can the dose of mifepristone and misoprostol be repeated?

If the woman is still pregnant at the follow-up visit, this is considered a MA failure and standard practice is to refer her for uterine aspiration. A repeat dose of misoprostol 1 week after the MA for ongoing pregnancies has been studied and found to have limited success (about 30 percent) but is another option that can be considered to avoid uterine aspiration (Reeves 2008). Repeating the entire regimen of mifepristone and misoprostol has not been studied and is not recommended.

• When will menstruation return after MA?

A study found that menses typically return about 33 days after MA (Dayis 2000).

• Will clinicians receive a lot of after-hour phone calls when providing MA?

Clinicians receive fewer after-hours calls as they gain experience with MA. This is simply because they learn how to communicate more clearly and effectively with women about what to expect with the MA process. The amount of calls received after hours will depend on the quality of the counseling and advance guidance given to women at the initial visit for MA. Women's questions will lead providers to improve counseling by remembering to answer these concerns during subsequent clinic visits.

 What if a woman has an ongoing pregnancy at the follow-up visit and refuses to terminate the pregnancy?

Clinicians cannot force women to terminate a pregnancy, but should inform women of the potential risk of birth defects should that pregnancy continue. At the initial visit, part of the counseling is to assess whether the woman is committed to the steps necessary to terminate the pregnancy, including vacuum aspiration if necessary. See "Potential Birth Defects" in Module Four.

• What if clinicians observe repeated failures of MA?

The first step in evaluating what is perceived to be a high failure rate with MA is to determine what the actual failure rate is over time and also to determine whether failure is truly due to ongoing pregnancy or if providers are intervening for other reasons.

One type of failure occurs when the woman is no longer pregnant, but in the clinician's judgment, uterine evacuation is still advised. If this occurs frequently, a quality assurance review should be done to determine if these interventions were medically necessary. The intervention rates of different providers (with ongoing pregnancy separated out) can be compared to see if there is wide variation in intervention rates, and then to determine why the intervention rate of one clinician is higher than the others. In a group of experienced clinicians using a highly effective regimen, the intervention rate, not including intervention for ongoing pregnancy, is about 1 to 2 percent (Fjerstad 2009, Raghavan 2009). Clinicians who are inexperienced with MA tend to intervene more at first because they are not confident in the method, not comfortable with the amount of time a woman may bleed after MA or simply because they believe a uterine evacuation would resolve any potential problems. As clinicians gain experience and confidence with MA, success rates rise and unnecessary interventions decrease (Borgatta 2000, Suhonen 2003). Basically, intervention is not needed as long as the woman feels well and does not have a viable (growing) pregnancy.

If it is determined that there is a higher-than-expected rate of ongoing pregnancy (which is a biologic outcome and is not dependent on clinician judgment or the possibility of over-intervention), then a different analysis and response is needed. The ongoing pregnancies may be just coincidence, or it is possible that the batch of medicines is faulty or expired, or that the medicines were not taken properly. Review the expiration dates, the storage conditions for misoprostol and assure that the medicines were taken as directed and contact the manufacturer with any concerns.

Mifepristone is a very stable medicine with a long shelf life. There have been many anecdotal reports about batches of misoprostol that resulted in high failure rates. Because misoprostol is hygroscopic (that is, it attracts moisture), it can become ineffective if it remains in opened bottles for a long time, especially in moist, humid or hot environments. Providers have reported unexpected groups of failures; but when they used a new lot or a new bottle of misoprostol, failure rates returned to the usual low baseline rates. Misoprostol should always be stored in a cool dry area of the clinic.

#### • What are the psychological after-effects of MA?

The research on mental health after abortion is controversial as it is often politically motivated and prone to bias. In 2008, after extensive review of the evidence, the American Psychological Association concluded that in general, women who terminate an unplanned, undesired pregnancy are at no increased risk of mental health problems compared to other women. Individual women, however, may be at greater risk of mental health problems afterwards, particularly women who suffer from stigma, abuse, low social support, or pre-existing depression or anxiety. These women should be supported throughout and after their abortion (Major et al 2009).

## Appendix D: Medical eligibility for contraceptive use after MA

In general, all modern contraceptive methods can be used immediately following first-trimester MA provided that there are no contraindications.

| When to start contraception after MA                   |  |  |  |  |
|--|--|--|--|--|
| Contraceptive method                                   | Initiation timing  |  |  |  |
| Oral contraceptive pills, contraceptive ring and patch | Day 1 of the MA regimen  |  |  |  |
| Implant  | Day 1 of the MA regimen  |  |  |  |
| Injection  | Day 1 of the MA regimen  |  |  |  |
| IUD  | As soon as reasonably sure woman is no longer pregnant                         |  |  |  |
| Sterilization  | As soon as reasonably sure woman is no longer pregnant                         |  |  |  |
| Natural family planning                                | Following one postabortion menses in a woman with a history of regular periods |  |  |  |

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