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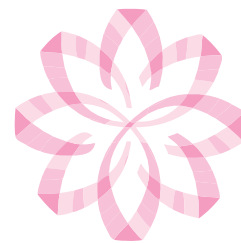
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Medabon

**Medabon**<sup>®</sup>  
medical abortion

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Medical and Service  
Delivery Guidelines



# Medabon®: Medical and Service Delivery Guidelines

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These guidelines represent a consensus view of three agencies for the Medabon® product that may differ from their own general medical abortion protocols.

This document can be found online at [www.medabon.info](http://www.medabon.info). To request additional copies, please contact Concept Foundation at [medabon@conceptfoundation.org](mailto:medabon@conceptfoundation.org).

Medabon® is a combination therapy for medical abortion in pregnancies through nine weeks, or up to and including 63 days since a woman's last menstrual period (LMP). Medical abortion refers to the process of ending a pregnancy by taking medication, rather than through surgical intervention.\* It may also be referred to as medication abortion, the abortion pill, non-aspiration abortion, or non-surgical abortion. The term "medical abortion" does not mean that a physician needs to be involved or that the procedure is performed out of medical necessity.

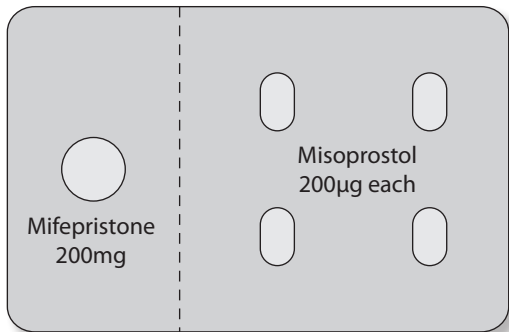
Medical abortion has been used by millions of women throughout the world. In 2006, the World Health Organization (WHO) released updated recommendations on medical abortion based on available evidence.<sup>1</sup> According to these recommendations, medical abortion through nine weeks' gestation is safe and effective. The most effective and safest medical abortion regimen requires the use of two drugs, mifepristone and misoprostol. Medabon® packages contain mifepristone and misoprostol together.

This document on Medabon® has four sections that roughly correspond to the medical abortion process from a health worker's perspective: background information, screening, administration, and follow-up. The protocol on page 9 provides an overview of the medical abortion process using Medabon®. This document was developed for an audience with a moderate amount of medical expertise. The level of technical detail and language may be adapted for the health providers who will be implementing services in a specific setting.

\* The term "surgical abortion" is often used to refer to procedures such as vacuum aspiration (electric or manual) and sharp curettage, also known as dilatation and curettage (D&C).

# 1 Background information on Medabon®

Mifepristone and misoprostol are licensed separately in many countries. Medabon® offers the benefit of the drugs being licensed and packaged together in one medical abortion product.



Mifepristone acts by blocking progesterone receptors, leading to changes in the endometrial lining so that it ceases to support pregnancy, softening and dilation of the cervix, and increased uterine sensitivity to prostaglandins (such as misoprostol).<sup>2</sup>

Misoprostol is the preferred prostaglandin analog for use with mifepristone because of its efficacy, safety, low cost, and wide availability.<sup>3</sup> Misoprostol softens the cervix and increases uterine contractility, and the contractions expel the pregnancy.

## Dosing and regimen

The Medabon® regimen consists of one 200-mg tablet of mifepristone given orally, followed one to two days (24 to 48 hours) later by four 200-µg tablets of misoprostol. This is the regimen recommended by WHO as a safe and effective method for medical abortion.<sup>1</sup>

### Misoprostol administration

Women have options in terms of when and how they can take misoprostol.\* Providers should discuss these options with each woman taking Medabon® so that she can choose the regimen most optimal to her needs and preferences.

#### MISOPROSTOL administration

(Day 1 is mifepristone day)

Route	Timing
Vaginal (800 µg)	Day 2 or 3 (24–48 hours after mifepristone)
Sublingual (800 µg)	

Medabon® is registered for vaginal and sublingual use of misoprostol. See page 8 for complete instructions regarding administration of misoprostol, including through vaginal and sublingual routes. There is additional evidence that buccal use of misoprostol (i.e., inserting pills between the cheek and the gum) is also effective and is widely used in some countries,<sup>8–10</sup> but Medabon® is not currently labeled for this route.

Medical abortion with Medabon® generally requires three steps:

- 1 Administration of mifepristone.
- 2 Administration of misoprostol one to two days later.
- 3 A follow-up assessment one to two weeks (generally 10–14 days) after mifepristone administration to confirm completion of abortion.

\* The initial registrations and labeling for Medabon® recommended that misoprostol be used vaginally 36–48 hours after mifepristone. Since then, Concept Foundation has gained access to data showing that misoprostol can be administered safely and effectively by the sublingual route,<sup>4,5</sup> and misoprostol can be administered by both the vaginal and sublingual routes 24–48 hours post-mifepristone.<sup>6,7</sup> These changes are being made to regulatory submissions and eventually to packaging materials. Despite this original labeling, providers may wish to comply with the new evidence-based regimens stated in these guidelines.

## Effectiveness

An effective medical abortion is generally defined as a pregnancy terminated without need for another uterine evacuation method, such as vacuum aspiration or curettage. The Medabon® regimen has been shown to achieve complete abortion in about 98 percent of cases, and less than 1 percent of women using this regimen experience ongoing, viable pregnancies.<sup>5,11</sup>

The rate of complete abortion for the Medabon® regimen can vary by provider. As provider experience increases, they are likely to be more comfortable with the method and less likely to perform unnecessary interventions. Following the regimen outlined in these guidelines will help ensure the highest rates of success. For example, adhering to the suggested interval between administration of misoprostol and a follow-up visit will help ensure that a woman's abortion has had time to complete and will make unnecessary intervention less common. Of course, women should seek follow-up care sooner if they have problems or concerns.

## Expected effects

Vaginal bleeding and cramping are normal and expected. The medical abortion process may feel like an intense, crampy, and long menstrual period, or similar to a spontaneous miscarriage.

Vaginal bleeding, often accompanied by the passage of clots, is usually heavier than a menstrual period. Bleeding sometimes begins after taking mifepristone, but most often starts one to three hours after misoprostol is taken. The amount and duration of bleeding varies: bleeding is generally heaviest for a few hours during the actual abortion and has the general pattern of diminishing over time, often lasting up to two to three weeks. Cramping is typically strongest in the hours after misoprostol is taken, then eases off after the pregnancy is expelled.<sup>12</sup>

After the pregnancy passes, which the woman may not be able to differentiate from other blood and/or clots, she will likely experience a persistent decrease of bleeding and cramps until the bleeding ends.

## Side effects

Uterine contractions can be painful, and some women will experience side effects—including nausea, vomiting, diarrhea, headache, chills, shivering, and transient fever lasting less than a day. There are no long-term health effects of Medabon®, nor will the medication impact any future pregnancies.<sup>13</sup>

### Medabon® key facts

- Medabon® consists of two medicines: mifepristone and misoprostol.
- The Medabon® regimen is in line with current (as of June 2009) WHO recommendations for medical abortion!: one 200-mg tablet of mifepristone given orally, followed 24–48 hours later by four 200-µg tablets of misoprostol. The four misoprostol tablets can be administered vaginally or sublingually.
- Medabon® is registered for use in pregnancies through nine weeks (63 days) since a woman's LMP.
- Medical abortion with mifepristone and misoprostol has been shown to be 98 percent effective when used through nine weeks (63 days) since LMP.<sup>5</sup>

## 2 Screening for Medabon®

### Contraindications

There are very few situations that absolutely exclude a woman from taking Medabon®.

#### Women cannot take Medabon® if they:

- Are allergic to any of the drugs involved (mifepristone, misoprostol, or another prostaglandin).
- Have inherited porphyria, a rare blood disorder.<sup>14</sup>
- Have a hemorrhagic disorder or are on concurrent anticoagulant therapy, unless transfusion services are available (there is very limited evidence describing provision of medical abortion in such cases).
- Have a known or suspected ectopic pregnancy.

### Precautions

#### Women with these conditions should be treated with caution specific to their situation:

- Currently taking long-term systemic corticosteroid therapy for asthma or other conditions.<sup>15,16</sup> By contrast, the medicines in asthma inhalers are not systemically absorbed and women taking these medicines may use Medabon®.
- Chronic adrenal failure. It is possible that women with chronic adrenal failure may acutely develop dehydration, low blood pressure, or shock after taking mifepristone. Women with chronic adrenal failure should take an increased dose of glucocorticoids when using mifepristone and should be carefully monitored for signs and symptoms of shock.<sup>15,16</sup>

**Note:** Women with multiple gestation<sup>17</sup> and obese women<sup>18</sup> may be given Medabon® in the same doses as other women. Additionally, women who have used Medabon® in the past may use it again with no decrease in efficacy.

### Special considerations

There is little evidence on the use of medical abortion in women with the following conditions: severe anemia (hemoglobin level < 9 g/dL), clinical illness or unstable health problems, or sepsis. Whether to administer medical abortion to women with these conditions will depend on the available options for safe abortion care, referrals, and clinical judgment.

The following women can take Medabon®, but may require additional information or clinical care:

- **Women who are breastfeeding.** Misoprostol enters breast milk soon after administration, and it is likely that mifepristone does as well. There is no evidence to suggest that either medication is harmful to infants. Women who are concerned about the effects of misoprostol on infants can take the medication immediately after nursing.<sup>19</sup>
- **Women with an intrauterine device (IUD).** Women with an IUD can be treated with Medabon® as long as the IUD is removed beforehand. See page 11 for information on reinitiating contraception after taking Medabon®.
- **Women with sexually transmitted infections (STIs).** Women with a confirmed STI should be treated concurrently with the initiation of medical abortion. Women with a suspected STI should be evaluated or referred and treated as appropriate for the health care setting; however, treatment of suspected STIs should not delay the abortion.

Given that Medabon® is only licensed for pregnancies through nine weeks, the likelihood of Rh-sensitization is very low. There is currently not enough evidence to recommend for or against Rh screening through nine weeks since LMP.<sup>20</sup> Depending on the prevalence of RhD-negative blood in the population and the ability to offer Rh-immune globulin, the country standard should be followed.

## Confirming pregnancy and timing

Medabon® is licensed for women with pregnancies through nine weeks: in other words, a woman can take Medabon® through 63 days after the first day of her LMP.

Duration of pregnancy can generally be confirmed by taking the woman's history and with a physical examination. If signs of pregnancy are not clearly present, a blood or urine test confirming pregnancy may be required. Ultrasound is not necessary and should not be a prerequisite for abortion in settings where it is unavailable or makes the procedure overly expensive.<sup>1,21</sup> Where ultrasound is available, it may help to determine the length of pregnancy in cases of a discrepancy in dating, or to confirm an intrauterine pregnancy.

## Choosing medical abortion or vacuum aspiration

Both medical abortion and vacuum aspiration have been found to be acceptable methods to women.<sup>22,23,24</sup> Women are more likely to find a method acceptable if they have chosen it themselves.<sup>25,26</sup>

Women choose medical abortion or vacuum aspiration for a variety of reasons that reflect a woman's specific circumstances and cultural context. Factors women consider in choosing between available methods include the length of gestation, the duration of the abortion process, where the abortion will occur, and what they are likely to experience.<sup>23</sup>

Both medical abortion and vacuum aspiration are safe and effective methods with low complication rates.<sup>11,27</sup> There are, therefore, very few situations where a clear medical preference for either method exists.

### Undiagnosed ectopic pregnancy

An ectopic pregnancy is a pregnancy located outside the uterine cavity. Medabon® does not treat ectopic pregnancy, a preexisting condition rather than a complication of the abortion procedure. Therefore, ectopic pregnancy may be diagnosed when a woman seeking a medical abortion undergoes clinical assessment before the procedure. However, ectopic pregnancy can go undetected during clinical assessment and even remain undetected after a medical abortion is performed. A woman may still experience bleeding and cramping after taking Medabon®, even if she has an ectopic pregnancy, and a provider is unlikely to examine the expelled tissue to confirm termination of pregnancy. Therefore, diagnosis and treatment of ectopic pregnancy may take place in the course of follow-up.

Typical symptoms of ectopic pregnancy are abdominal or pelvic pain—often one-sided—and vaginal bleeding. Pain and bleeding may be persistent or erratic and variable and, in some cases,

absent.<sup>28</sup> High-risk factors for ectopic pregnancy are tubal surgery, tubal sterilization, previous ectopic pregnancy, in utero exposure to diethylstilbestrol, use of intrauterine device (IUD)\*, and documented tubal disease.<sup>30</sup>

Ectopic pregnancy can sometimes be confirmed with an ultrasound, but often an ultrasound can only confirm the absence of an intrauterine pregnancy. With serial  $\beta$ -hCG measurements *and* ultrasound showing an empty uterine cavity in an asymptomatic patient, ectopic pregnancy can be strongly suspected. It is rare to actually see the ectopic pregnancy on ultrasound, unless a very good unit, a transvaginal probe, or a highly skilled sonographer is available and the patient's pelvic anatomy and location of the ectopic pregnancy permit visualization. If ultrasound is not available and ectopic pregnancy is suspected, or if the woman is symptomatic for ectopic pregnancy, she should be referred to an appropriate gynecology service for urgent treatment.

\* Women with an IUD in place and those who have had tubal ligation are more likely to have an ectopic than intrauterine pregnancy if conception does occur, but their baseline risk of pregnancy is far lower than that of women not using contraception.<sup>29</sup>

Possible reasons to recommend **medical abortion**:

- Severe obesity. A surgical procedure may be more technically challenging.<sup>1</sup>
- Uterine malformations, a fibroid uterus, or previous cervical stenosis.
- A wish to avoid an invasive procedure.

Possible reasons to recommend **surgical abortion** (usually vacuum aspiration):

- Contraindications to medical abortion.
- Time or geographical constraints preclude follow-up to confirm that medical abortion is complete.
- A woman has made the free and informed choice that she would like to be sterilized or have an IUD inserted, and the procedures can be carried out at the same time.
- Suspected ectopic pregnancy (so tissue can be examined to verify complete abortion).

Each woman who chooses medical abortion should be clearly informed:

- What will be done at each visit and what she will experience or do at home.
- What the medical abortion may feel like.
- What the common side effects are.
- How long the process may take.
- What the potential risks and complications are.
- What pain medications are available and how to use them.
- That she must plan to complete the abortion process once she starts it.
- When she will be able to resume her normal activities, including sexual intercourse.
- When she needs to seek medical attention.
- What contraceptive methods are available and how to get/start them.



# 3 Prescribing and administering Medabon®

## Scheduling medical abortion with Medabon®

The full medical abortion process should be taken into consideration when health providers and women schedule clinic visits. For most women, expulsion will happen within four to six hours of taking misoprostol.<sup>31</sup> Bleeding and cramping will likely be heaviest at this time. If misoprostol is administered in a clinic setting, it is advisable that a woman stays in the clinic until she feels comfortable and able to return home. Women should be informed of this in advance so that they can plan for misoprostol administration around travel time, work and family needs, and the ability to have someone there with her if she chooses.

Women should have access to emergency care during the medical abortion process. Providers and women should make a plan for where to seek emergency care in the rare event of a serious complication.

## Medabon® administration

**Step 1.** Woman swallows one mifepristone pill.

If a woman vomits within 30 minutes of taking mifepristone, she will need to take another mifepristone pill.

**Step 2.** Four 200-µg misoprostol tablets are administered one or two days (24–48 hours) later (see box “Misoprostol administration,” page 3).

*Vaginal administration:* The woman or health worker should use their finger to push the four tablets one at a time into the vagina as far as they are able.

Health workers who administer misoprostol vaginally should follow the instructions on the package insert and wear clean gloves. If women administer misoprostol vaginally themselves, either at home or in the clinic, they should be advised to wash their hands first.

*Sublingual administration:* Women should place two tablets of misoprostol under their tongue and wait for them to dissolve. As soon as they have dissolved, two more tablets can be taken in the same way. If the first two tablets have not dissolved after 20 minutes, women can swallow any remaining fragments and take the final two tablets.

Some women may prefer to take all four tablets at once. In that case, women should place all four tablets under the tongue and wait for them to dissolve. If they have not dissolved after 20 minutes, women can swallow any remaining fragments.

Swallowing the tablets whole (oral administration) is less effective than placing them under the tongue until they dissolve or for 20 minutes.<sup>5</sup>

More information on **Step 3**, the follow-up visit, is provided on page 12.

## Resuming normal activities

Women should have clear expectations regarding when they will or can resume normal activities. For example:

- Showering and bathing are fine at any time in the medical abortion process. Vaginal douching is not recommended.<sup>32</sup>
- Women may ask when they are able to resume sexual activity. There is no evidence base to suggest ideal timing, but women should be encouraged to wait until they feel comfortable and ready (see below).
- Women can ovulate, and therefore get pregnant, before menstruation returns to normal. Women who want to prevent pregnancy should use a contraceptive method during sexual relations after taking Medabon®. Women have been found to ovulate as early as ten days following abortion. See page 11 for more information about contraceptive options.
- The return of menses following medical abortion will generally occur after about five weeks.<sup>33</sup>

# Medabon® Clinic Visits and Protocol

## STEP 1 Initial clinic visit and mifepristone administration

- Confirm pregnancy and length of pregnancy.
- Counsel woman on pregnancy/abortion options.
- Complete physical exam and medical history.
- Screen for contraindications and risk factors.
- Rule out ectopic pregnancy.

For women who choose Medabon® and will take misoprostol **in the clinic**:

- Counsel woman on what to expect.
- Create schedule of Medabon® visits.
- Create plan for emergency follow-up care.
- Provide suggestions for dealing with side effects.
- Woman takes mifepristone orally.

For women who choose Medabon® and will take misoprostol **at home**:

- Counsel woman on how to administer misoprostol vaginally or sublingually, using visual aids as appropriate.
- Review signs of serious complications and confirm woman has printed materials.
- Create plan for emergency follow-up care.
- Provide suggestions for dealing with side effects and make pain medication available.
- Schedule follow-up visit.
- Provide misoprostol tablets to take home.
- Woman takes mifepristone orally.

## STEP 2 Misoprostol administration (24–48 hours later)

### In the clinic:

- Administer misoprostol vaginally or sublingually.
- Make pain medication available.
- Review signs of serious complications and confirm woman has printed materials.
- Review plans for follow-up visit.
- Review side effects and management.

### At home:

- Woman administers misoprostol vaginally or sublingually.

## Contraception

Discuss contraceptive options early in the process.

The woman's choice of method will determine when contraception is provided.

## STEP 3 Follow-up visit (10–14 days after mifepristone administration)

- Confirm that abortion is successful (most women will be in this category).
- If the woman is experiencing problematic bleeding (see page 12 for more detail), treatment options include:
  - Waiting longer for bleeding to stop.
  - An additional dose of misoprostol.
  - Uterine evacuation.
- In the case of continuing pregnancy, uterine evacuation is recommended.

## Managing effects of the abortion

### Bleeding

Bleeding can be managed similarly to a very heavy menstrual period or a spontaneous miscarriage (e.g., with sanitary pads or cotton wool). It will be heaviest after taking misoprostol—often during expulsion of the products of conception—and light bleeding may last two weeks or longer. It is not uncommon for bleeding to stop and then start again. Some women, up to 20 percent in one study, may continue to have bleeding or spotting 35–42 days after the initiation of a medical abortion.<sup>34</sup> If bleeding is heavy, prolonged, or causes anemia (or symptoms of anemia, such as dizziness, faintness, or significant loss of energy), then vacuum aspiration, fluid replacement, or transfusion might be required. The risk of bleeding requiring intervention (transfusion and/or aspiration) ranges from 0.02 to 1.8 percent.<sup>35–37</sup>

### Cramping and pain

Women are most likely to feel pain in the first few hours after administration of misoprostol.<sup>1</sup> Women should receive medicines (or where they are unavailable, prescriptions or recommendations for medicines) to manage pain and have the pain medicine available when taking the misoprostol. Nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen (400–800 mg) have been shown to be more effective than paracetamol (500–1,000 mg)<sup>38</sup> and can be taken at the same time as misoprostol, but not before. If possible, women should have access to or at least a prescription for a narcotic pain medicine in the event they need it; codeine 30–40 mg may be added to either NSAIDs or paracetamol. Women should be advised of other comfort measures, such as use of hot water bottles.

## Seeking care for possible complications

When educating women about the use of Medabon®, it is important to stress that serious complications are rare, but that they should be on the look-out for the following signs and symptoms, and seek help (ideally from their original provider) if they experience:

- Persistent, heavy bleeding to the point where they feel sick or weak, or if they soak more than two pads per hour for more than two consecutive hours.
- Fever of 38°C/100.4°F or higher continuing for more than the day following misoprostol use.
- Persistent vomiting or diarrhea for more than the day on which misoprostol was administered.
- Very severe, continuous, or increasing abdominal pain that is unrelieved by medication, rest, a hot water bottle, or a heating pad.

Little to no bleeding 24–48 hours following misoprostol is not an emergency, but is cause for seeking follow-up care as it may be a sign of continued pregnancy.

Infection after medical abortion procedures is rare. Women should, however, be informed of the symptoms of infection and encouraged to seek follow-up care should symptoms of infection occur. The severity of the infection should determine what treatment is provided; oral antibiotics are used for most treatment of infection or presumed infection.<sup>39</sup>

Women should always be given printed information on signs of complications to take home (see the sample patient brochure in these materials). As noted previously, providers and women should discuss a plan for emergency care prior to the medical abortion process. Ideally, women should seek care for complications from their original providers. If the original provider is not available, accessible, or cannot provide the necessary follow-up, providers should work with women to identify an alternative in advance. Women should be encouraged to take their informational materials with them if they seek emergency care elsewhere, in case the facility is unfamiliar with medical abortion and associated complications.

Most back-up care is similar to that needed by women having a spontaneous abortion, and many communities have a health care facility already in place to provide such care. In rare cases, serious complications do occur that require emergency follow-up (see the “Medical Guidelines for Providers of Emergency Care” included in this packet).

## Contraceptive counseling and services

Women taking Medabon® should be offered contraception. Women can become pregnant within ten days of the abortion if they are not using an effective method of contraception.<sup>40</sup> Evidence supports the use of any modern contraceptive method after an uncomplicated abortion.<sup>41,42</sup>

Women can begin taking hormonal methods, whether combined (estrogen and progestin) or progestin-only, on the same day as misoprostol administration, when expulsion of the products of conception generally occurs.<sup>43</sup> These methods include oral contraceptives,<sup>44–46</sup> injectable methods, implants, and the contraceptive patch. For women taking the misoprostol at home, they can be given any patient-initiated hormonal methods and told to start them on the day they take misoprostol. They may see a provider for injectable contraception or implants. The vaginal contraceptive ring can be started when bleeding slows down after expulsion of the pregnancy.

Condoms, spermicides, the cervical cap, and the diaphragm can be used as soon as women start having sex again.<sup>1</sup> If a woman would like to have an IUD inserted or undergo sterilization, these procedures should be performed after an assessment confirms that the woman is no longer pregnant and the products of conception have been expelled.

Natural family planning or fertility-awareness methods cannot be initiated until a woman’s regular cycles have resumed, and she may need to use a barrier method—like a condom or a diaphragm—in the meantime.



## 4 Following up

A follow-up visit is desirable approximately two weeks (10–14 days) after taking Medabon®. During this visit, the clinician confirms that the woman is no longer pregnant and that bleeding patterns are within the expected range, ensures contraception is provided if desired, and answers her questions. Confirmation that the pregnancy has been terminated is possible by pelvic examination, bleeding and symptom history, or by ultrasound, if necessary.

The following scenarios represent the most likely situations encountered at the follow-up visit:

### Successful medical abortion

The woman reports she no longer feels pregnant, has taken the medications as instructed, and had bleeding and cramping consistent with a successful medical abortion. This is the most common outcome.

### Problematic bleeding

Problematic bleeding encompasses a range of bleeding patterns that may be tiresome or problematic for the woman, or, in rare cases, are true emergencies. In the case of problematic bleeding, the pregnancy is not growing, but the woman's bleeding pattern is not gradually diminishing. The pelvic exam is consistent with a small or non-pregnant uterus. Treatment options, unless indicated otherwise below, are: 1) waiting longer for bleeding to stop; 2) an additional dose of misoprostol, which may help the uterus contract and expel residual tissue or a persistent empty sac; or 3) uterine evacuation.

Various patterns of problematic bleeding requiring specific interventions are:

- **Persistently heavy bleeding.** The woman may have been bleeding continuously—like during a heavy menstrual period—since she took misoprostol. If the woman feels weak from bleeding, a uterine aspiration is recommended. If she is clinically stable and feels well, a repeat dose of misoprostol may be offered as long as the woman is willing and able to return two days to one week later, depending on the duration and amount of problematic bleeding, to assess whether bleeding

is diminishing.<sup>45</sup> Although providing a second dose of misoprostol is a practice used by some providers to increase uterine contractility and expel residual tissue, its use has been studied for expulsion of a persistent sac or unexpelled embryo<sup>47</sup>; providing a repeat dose of misoprostol has not been studied for alleviation of problematic bleeding.

- **Erratic bleeding.** Some women have days of very little bleeding, no bleeding, or spotting, and erratically experience very heavy, gushing bleeding. If a woman is symptomatic for anemia, perform uterine aspiration.
- **Hemorrhage.** Hemorrhage causing hemodynamic instability is an emergency and is treated with an immediate uterine evacuation to empty the uterus. If the hemorrhage has been very serious, blood or fluid transfusion should be considered. If transfusion services are not available, the woman should be transported to the nearest facility providing these services.

### Continued pregnancy

The woman reports continued pregnancy symptoms and the uterus is larger than on previous exam. Uterine evacuation is recommended at this time.

### Possible birth defects if pregnancy continues

Evidence on birth defects associated with mifepristone or misoprostol are inconclusive. From an estimated two million procedures performed between 1987 and 2008 in countries where Exelgyn Laboratories holds marketing authorization for a mifepristone product—Mifegyne®—a total of 26 malformations have been reported in cases where the combined treatment failed or the woman changed her mind about the procedure after taking the mifepristone.<sup>48</sup> Six cases of malformation have been reported after use of mifepristone alone, and twenty other cases have been reported after use of mifepristone and a prostaglandin. According to these authors, none of the events have been conclusively related to the treatment.

Women who choose to carry a pregnancy to term should be counseled on the possibility of birth defects and encouraged to seek active follow-up care throughout pregnancy.

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