Frequently asked clinical questions *about* medical abortion

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"On 1–5 November 2004, in Bellagio, Italy, the UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP), organized a meeting entitled International Consensus Conference on Non-surgical (Medical) Abortion in Early First Trimester on Issues Related to Regimens and Service Delivery (Annex 1). This document is the result of the deliberations of the participants in that meeting, who included highly experienced researchers and clinicians in the area of medical abortion."--Background.

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BACKGROUND

On 1–5 November 2004, in Bellagio, Italy, the UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP), organized a meeting entitled International Consensus Conference on Non-surgical (Medical) Abortion in Early First Trimester on Issues Related to Regimens and Service Delivery (Annex 1). This document is the result of the deliberations of the participants in that meeting, who included highly experienced researchers and clinicians in the area of medical abortion.

Prior to the meeting health-care personnel providing abortion services in various countries were asked to provide a list of the most frequently asked questions about medical abortion. The meeting participants reviewed those questions and compiled answers to them based on the scientific literature and their own clinical experience. The answers are presented in this publication.

INTRODUCTION

Provision of safe abortion to the full extent of the law is an important component of reproductive health services. The development of methods of inducing abortion medically (non-surgically) has created alternative options to make abortion available to women in a variety of health-care settings. The topic has been reviewed extensively in the past five years and a number of evidence-based guidelines have been published *(1-6)*.

It is not the intention here to repeat these guidelines, but rather to provide answers to frequently asked questions, based on a review of available evidence. By focusing on practical issues, the answers should be particularly helpful to health-care personnel who are considering establishing, or already providing, a service for medical abortion in the early first trimester.

Ideally, any method of medical abortion should have an overall efficacy comparable to that of vacuum aspiration, i.e. a rate of complete abortion of more than 95% and an ongoing pregnancy rate of less than 1%.

Other desirable characteristics of a method of medical abortion for the early first trimester are the following:

- it should be effective up to 63 days of gestation;
- it should be easy to administer;
- it should be safe, and have acceptable side-effects;
- blood loss should be similar to, or less than, that associated with vacuum aspiration;
- it should be affordable;
- it should be widely available.

The only regimen that meets the efficacy criteria is a combination of mifepristone and a prostaglandin – either misoprostol or gemeprost. Use of mifepristone or a prostaglandin alone does not meet them. Use of methotrexate in combination with prostaglandin can approach the required efficacy, but is not recommended because it is teratogenic.

The recommendations on medical abortion given here are restricted to early first trimester (up to 63 days since the first day of the last menstrual period – LMP). Although administration of mifepristone followed by a prostaglandin will terminate pregnancy at any stage (and in some countries is licensed for abortion up to 24 weeks), termination of pregnancy when gestational age is >63 days is less common, requires an inpatient setting, and raises separate medical, legal and service issues.

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PRE-ABORTION CARE

1. What counselling is needed by a woman with an unwanted pregnancy who is contemplating abortion?

Every woman with an unwanted pregnancy who is contemplating abortion should receive counselling from a trained health-care professional with comprehensive knowledge and experience of different methods of abortion. Information must be provided to each woman, regardless of her age or circumstances, in a way that she can understand, to allow her to make her own decisions about whether to have an abortion and what method to choose.

Both counselling and abortion procedures should be provided as promptly as possible without undue delay. Nevertheless, clinicians should be sensitive in recognizing that some women require additional time and support in reaching their decision.

Abortion counselling can take place in any health-care setting; ideally, it should be given where the abortion procedure can be initiated. Private interview facilities are essential and each woman should be free to choose to be interviewed alone or with the support of a partner, parent, or friend.

Health-care professionals providing abortion counselling must be familiar with their local legal framework regarding consent by women below the legal age of consent. Each woman should reach her own decision and should not be coerced into involving her parents or partner where there is no legal requirement to do so.

Ideally, pre-abortion counselling should include discussion about future contraceptive needs. In helping the woman choose the most appropriate contraceptive method for the future, it may be useful to explore the circumstances in which the unwanted pregnancy occurred. The goal of contraceptive counselling and provision in the context of abortion care is to begin the chosen method immediately after abortion.

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2. What factors should be taken into account when counselling a woman about her choice between medical and surgical abortion?

There is little, if any, difference between medical and surgical abortion in terms of safety and efficacy. Thus, both methods are similar from a medical point of view and there are only very few situations where a recommendation for one or the other method for medical reasons can be given.

Two studies *(1, 2)* have found that women are more likely to find a method of abortion acceptable if they have chosen it themselves. Being provided with a choice of methods is seen as extremely important by the majority of women undergoing abortion *(2)*. Many studies suggest that women who choose medical abortion find it more acceptable at earlier than later gestations *(1, 3–5)*.

Medical abortion may be preferred:

- if it is the woman's preference;
- in very early gestation; up to 49 days of gestation, medical abortion is considered to be more effective than surgical abortion, especially when clinical practice does not include detailed inspection of aspirated tissue *(6)*;
- if the woman is severely obese (body mass index greater than 30) but does not have other cardiovascular risk factors (see question 3), as surgical treatment may be technically more difficult;
- if the woman has uterine malformations or a fibroid uterus, or has previously had cervical surgery (which may make surgical abortion technically more difficult);
- if the woman wants to avoid a surgical intervention.

Surgical abortion may be preferred:

- if it is the woman's preference, or if she requests concurrent sterilization;
- if she has contraindications to medical abortion (see question 3);
- if time or geographical constraints preclude the follow-up needed to confirm that abortion is complete.

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3. What are the contraindications to medical abortion?

There are very few absolute contraindications to medical abortion. They include:

- previous allergic reaction to one of the drugs involved;
- inherited porphyria;
- chronic adrenal failure;
- known or suspected ectopic pregnancy.

Caution is required in a range of circumstances including:

- if the woman is on long-term corticosteroid therapy (including those with severe, uncontrolled asthma);
- if she has a haemorrhagic disorder;
- if she has severe anaemia;
- if she has pre-existing heart disease or cardiovascular risk factors (e.g. hypertension and smoking).

Further reading

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2. Leighton B et al. Physiological glucocorticoid levels regulate glutamine and insulin-mediated glucose metabolism in skeletal muscle of the rat. Studies with RU 486 (mifepristone). *Biochemistry Journal*, 1991, 274:187–192.

4. Do any other characteristics of the woman need to be taken into account in providing medical abortion?

▶ ***Age***. Neither adolescence nor older age (e.g. over 35 years) should be regarded as a contraindication to medical abortion.

▶ ***Anaemia***. This need not be regarded as a contraindication. However, anaemia detected at the time of abortion should be treated. Average blood loss in medical abortion may be more than that in surgical abortion *(1)*, and the incidence of heavy bleeding may be higher.

▶ ***Breastfeeding***. It is likely that mifepristone passes into breast milk. Studies investigating the endocrine effects of mifepristone on the fetus have found increased levels of adrenocorticotropic hormone and cortisol *(2)*. The clinical implications of these changes are unclear.

Small amounts of misoprostol also enter breast milk soon after administration, but it is not known whether this could have any effect on the infant. As misoprostol levels decline rapidly, it has been recommended that misoprostol should be taken immediately after a feed and the next feed given after four hours in case of oral administration *(3)*. After vaginal administration, misoprostol levels stay high for longer, and the feed should preferably be given more than six hours later. Unfortunately, the available data do not allow a precise recommendation on optimum timing.

▶ ***Insulin-dependent diabetes or thyroid disorder***. There is no evidence that medical abortion causes particular problems in women with these disorders. However, mifepristone has been shown to alter insulin sensitivity *in vitro (4)* and these effects may or may not be reflected in blood sugar and insulin levels.

▶ ***Multiple pregnancy (current gestation)***. There is no evidence that the failure rate of medical abortion is increased or that a different dosage regimen is required in the case of multiple pregnancy.

▶ ***Obesity***. There is no evidence that the failure rate of medical abortion is increased or that a different dosage regimen is required in obese women.

▶ ***Previous Caesarean section***. There is evidence from one study that the safety and efficacy of early medical abortion are unaffected by previous Caesarean section *(5)*.

▶ ***Smoking***. There is no evidence of interaction between the risks of smoking and medical abortion. However, smoking contributes to cardiovascular risk and this factor should be considered when assessing a woman's overall suitability for medical abortion.

▶ ***Uterine malformations, congenital and acquired; previous cervical surgery***. There is no evidence that these represent contraindications.

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5. How should pregnancy be confirmed and gestation estimated?

In most cases, pregnancy can be confirmed and its length estimated on the basis of the woman's history and a physical examination. Occasionally, laboratory tests may be needed when the typical signs of pregnancy are not clearly present and the health-care provider is unsure whether the woman is pregnant.

Ultrasound scanning is not necessary for the provision of early abortion. Where ultrasound equipment is available, a scan can help identify an intrauterine pregnancy and exclude an ectopic one after about six weeks. It also helps determine gestational age and diagnose pathologies or non-viability of a pregnancy.

Further reading

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6. What clinical assessment and laboratory investigations are required prior to medical abortion?

As for any method of abortion, clinical history-taking should serve to identify contraindications (see question 3) and to identify risk factors for complications. History-taking should include: personal and family history of relevant diseases; current use of medications and known allergies; obstetric and gynaecological history, including ectopic pregnancies; any bleeding tendencies; and history of sexually transmitted infections (STIs). Social history should include risk assessment for STIs, taking into account local STI prevalence rates. The clinician must be alert to the possibility of violence or coercion in the context of the unwanted pregnancy.

Basic routine observations (pulse, blood pressure, and temperature) are useful as a baseline.

There are no laboratory tests that are essential before medical abortion. However, tests such as haemoglobin level, blood group and rhesus (Rh) typing, and screening for hepatitis, human immunodeficiency virus (HIV), and STIs, may be offered on the basis of individual risk factors or available resources. Ideally, services should offer testing for pathogens in the lower genital tract, and treat women found positive.

Rhesus status. The prevalence of Rh-negative status varies markedly with ethnicity, being highest among Caucasians. For pregnancies up to 63 days gestation, the theoretical risk of maternal Rh sensitization is very low; there is no evidence that sensitization occurs at this stage of pregnancy. Thus, determination of blood group and Rh status and the offer of anti-D prophylaxis to Rh-negative women are not considered prerequisites for early medical abortion. In settings where the prevalence of Rh-negative status is high, and where resources permit, the offer of Rh typing and anti-D prophylaxis could be worthwhile as precautionary components of medical abortion care.

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7. What steps are necessary to minimize the risk of undiagnosed ectopic pregnancy?

Mifepristone and misoprostol are not treatments for ectopic pregnancy, which, if present, will continue to grow. If medical abortion is contemplated very early in gestation, i.e. before an intrauterine pregnancy can be diagnosed with ultrasound, clinicians must be particularly alert to the possibility of ectopic pregnancy. They should check whether the uterus feels smaller than expected according to the date of the woman's last menstrual period. Women should be told to seek medical advice promptly if they experience symptoms and signs that may indicate ectopic pregnancy, such as abdominal pain on one side. Verification of expulsion in these very early cases can be done only by comparing human chorionic gonadotrophin (hCG) levels prior to the treatment and at follow-up (see question 19).

Where clinical features (e.g. history of ectopic pregnancy or STI, discrepancy between menstrual dates and ultrasound appearance, vaginal bleeding, or pelvic pain) raise suspicion of an ectopic pregnancy, appropriate tests should be done. If ectopic pregnancy is diagnosed or strongly suspected, the woman should be transferred to an appropriate gynaecology service for continuing care.

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REGIMEN FOR MEDICAL ABORTION

8. What is the recommended regimen for medical abortion?

The recommended regimen for medical abortion is 200 mg of mifepristone given orally, followed 36–48 hours later by a prostaglandin – either 0.8 mg of misoprostol or 1 mg of gemeprost – given vaginally *(1, 2)*. This combination results in complete abortion in more than 96% of cases; the rate of continuing pregnancies is less than 1% in gestations up to 63 days' amenorrhoea *(3–5)*.

Misoprostol can also be given orally at a dose of 0.4 mg, but owing to the higher failure rate with dose, it is recommended that oral misoprostol use at this dosage be restricted to very early pregnancy – i.e. < 50 days.

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9. Are other doses of mifepristone possible?

Both mifepristone and prostaglandins, given alone, may lead to abortion; however, they have either a low effectiveness or a high rate of side-effects. In combination, they act synergistically. The challenge, therefore, is to find a regimen combining the lowest doses for both drugs that is highly effective and has few side-effects. In addition, in many parts of the world, cost considerations are important.

In many countries, mifepristone is licensed for use as a single oral dose of 600 mg. However, there is no evidence that a dose of greater than 200 mg is necessary for optimal effect when followed by a suitable prostaglandin *(1–4)*. Some studies have indicated that mifepristone can be given as five or six divided doses of 25 mg over three days, for a total dose of 125–150 mg *(5)*. This regimen is widely used in China and has been shown to

be highly effective up to 49 days of gestation when used in combination with a suitable prostaglandin. However, for service delivery and patient convenience, the single dose of mifepristone is preferred.

A 50 mg dose of mifepristone has been shown to be less effective than a 200 mg dose, when given in combination with gemeprost vaginally *(6)*. Studies are continuing to investigate the minimum effective dose of mifepristone.

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10. Are other doses or routes of administration of the prostaglandin possible?

Vaginal administration of misoprostol is more effective and associated with fewer side-effects than oral administration of the same dose *(1–4)*. However, if the woman prefers to take the drug orally, and the gestational age is less than 50 days LMP, two tablets of 0.2 mg of misoprostol can be taken orally 36–48 hours after the mifepristone dose *(5)*. If the gestational age is 50 days or more LMP, oral administration of misoprostol is not recommended because of its higher failure rate.

In some studies, repeated doses of misoprostol have been used, either routinely for all women or in those with evidence of incomplete abortion *(1, 6, 7)*. Repeated doses are associated with an increased incidence of prostaglandin-related side-effects. There is insufficient evidence at the moment that the overall efficacy is increased by using repeated doses of prostaglandin[1].

Lower vaginal doses and different routes of administration, e.g. buccal and sublingual, of misoprostol are currently under investigation.

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[1] Although not covered in these guidelines, abortion in late first trimester and in the second trimester of pregnancy usually requires repeat administration of prostaglandins.

11. What are the advantages and disadvantages of misoprostol versus gemeprost?

Misoprostol is cheaper than gemeprost and is stable at room temperature. Gemeprost is formulated for use as 1 mg vaginal pessaries and needs to be kept frozen until about half an hour before use. Some studies report that severe pain is more common after gemeprost compared to misoprostol *(1, 2)*. Although misoprostol is formulated for oral use, it is more effective if given vaginally or sublingually *(3–5)*.

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12. Can other prostaglandins be used?

A number of prostaglandins that were used in the past, such as sulprostone and 15-methyl prostaglandin $F_{2\alpha}$, are no longer used because of their adverse side-effects or relative lack of efficacy *(1)*.

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13. Is the interval between administration of mifepristone and prostaglandin crucial?

The licensed and most commonly used interval, of 36–48 hours *(1, 2)*, corresponds to the time when the uterus is most sensitive to prostaglandin after priming with mifepristone; hence the therapeutic dose can be reduced to the minimum. This interval was also found to be the most effective in initial studies when uterine contractility was measured at different times between administration of mifepristone and of prostaglandin *(3)*. It has been shown recently, however, that the interval can be shortened to 24 hours or lengthened to 72 hours, without loss of efficacy, when mifepristone is used in combination with 0.8 mg of vaginally administered misoprostol *(4, 5)*. If misoprostol is given as an oral dose of 0.4 mg, the interval of 36–48 hours should be adhered to. Other time intervals are currently being studied *(6)*.

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14. Can abortion be induced using prostaglandin alone?

It is possible to induce abortion in early pregnancy using prostaglandins alone. However, even the most effective regimens, involving repeated relatively large doses of misoprostol (0.8 mg) or gemeprost (1 mg) vaginally, are less effective and have more side-effects than the combination regimens with mifepristone pretreatment.

There is insufficient evidence to support recommendations on the dose, route of administration and timing of regimens using prostaglandins alone. Reported case series suggest that repeated administration of 0.8 mg of vaginal misoprostol is needed. The only randomized study (yet unpublished), that compared a short (3-hour) and a long (12-hour) interval between vaginal and sublingual doses, demonstrated that if misoprostol is given sublingually, it has to be administered at the shorter interval to have a similar effectiveness as vaginal administration.

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15. What pain relief should be available to women during medical abortion?

Pain is caused both by the abortion process and as a side-effect of the prostaglandin. It is most likely to be felt in the few hours after administration of the prostaglandin, when the gestational sac/embryo is being expelled from the uterus. Studies have shown that women feel less pain if they are older, have been pregnant before or are in the early stages of pregnancy. However, none of these factors is sufficiently predictive to be useful in the management of individual cases.

The perception of pain and request for relief vary greatly from one individual to another and among cultures. In any case, health-care providers should make adequate analgesia easily available to all women who request it during medical abortion. Examples of commonly used preparations are: paracetamol 500–1000 mg or nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen 200 mg. In cases of severe pain, codeine 30–40 mg may be added to either of the above-mentioned treatments.

Further reading

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POSTABORTION CARE

16. If a woman has an incomplete abortion, is it necessary to evacuate the uterus surgically?

On average, vaginal bleeding gradually diminishes over about two weeks after a medical abortion, but in individual cases spotting can last up to 45 days. Generally, bleeding after medical abortion lasts longer than after vacuum aspiration. If the woman is well, neither prolonged bleeding nor the presence of tissue in the uterus (as detected by ultrasound) is an indication for surgical intervention. Remaining products of conception will be expelled during subsequent vaginal bleeding. Surgical evacuation of the uterus may be carried out on the woman's request or if the bleeding is heavy or prolonged, or causes anaemia, or if there is evidence of infection. In the latter case, antibiotic treatment should be initiated (see question 17).

Further reading

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17. How should pelvic infection be diagnosed and treated after abortion?

The genital tract is more susceptible to ascending infection when the cervix is dilated after abortion or childbirth. There are few data on the incidence of clinically significant pelvic infection after medical abortion, but it seems to be rare and probably occurs less often than after vacuum aspiration. Many of the symptoms of pelvic infection, such as pain, are rather nonspecific and hence precise diagnosis is difficult. Women with clinical signs such as pelvic pain, abdominal or adnexal tenderness, vaginal discharge and fever should be treated with broad-spectrum antibiotics.

Rare cases of anaerobic infection without fever have been reported from Canada (one case) and the USA (four cases) following medical termination of pregnancy. No such cases have been reported from China or from Europe. In the reported cases women had little or no fever; variable nausea, vomiting, weakness and some abdominal pain; rapid deterioration within hours or days; tachycardia and refractory hypotension; multiple effusions; elevated haematocrit and elevated leukocyte count, neutrophilia. All five of the women had *Clostridium sordellii*-related toxic shock.

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Further reading

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2. Sitruk-Ware R, Spitz IM. Pharmacological properties of mifepristone: toxicology and safety in animal and human studies. *Contraception*, 2003, 68:409–420.

18. How should the success of medical abortion be confirmed?

For all women who undergo medical abortion, it is important to confirm that the pregnancy has indeed been terminated. If expulsion of the products of conception was confirmed by a qualified person in the hours after administration of the prostaglandin, further follow-up is not absolutely necessary. Otherwise, a follow-up visit should be arranged about two weeks after the administration of mifepristone, at the convenience of the patient.

At the follow-up visit, complete abortion should be confirmed clinically, either by bimanual pelvic examination or, if available, pelvic ultrasound. If serial measurements of human chorionic gonadotrophin (hCG) in blood or urine are used, it should be remembered that in some cases low hCG levels can be detectable for up to four weeks after successful expulsion. Women who continue to have symptoms of pregnancy or who have minimal bleeding are most likely to be still pregnant.

19. How should ectopic pregnancy be identified after medical abortion?

Ectopic pregnancy is a life-threatening condition and a significant cause of maternal mortality. See question 7 for the steps that should be taken before medical abortion to detect ectopic pregnancy.

Even where these steps have been taken, health-care providers should be aware of the possibility of ectopic pregnancy and of the fact that medical abortion may mask its symptoms. Very occasionally, an ectopic pregnancy may co-exist with an intrauterine pregnancy.

If an ectopic pregnancy is clinically suspected (e.g. the woman has continuing symptoms of pregnancy or abdominal pain), further investigations, such as pelvic ultrasound and serial measurement of hCG, should be performed. If this is not possible, the woman should be referred to a specialist centre.

Further reading

1. Kelly AJ, Sowter MC, Trinder J. *The management of tubal pregnancy*. London, Royal College of Obstetricians and Gynaecologists, 2004 (RCOG Guideline No.21).
2. Shannon C et al. Ectopic pregnancy and medical abortion. *Obstetrics and Gynecology*, 2004, 104:161–167.

20. Is there a risk of fetal abnormality after an unsuccessful medical abortion?

Only one anomaly has been reported after the use of mifepristone alone. This case, described as a sirenomelia *(1)*, could not be related to the drug intake. Indeed, this type of anomaly occurs at a very early stage of pregnancy – at about four weeks of embryo development – while the treatment was taken in the fifth week of pregnancy. Thirteen other cases of malformation have been reported: all occurred in pregnancies in which mifepristone was administered at 7–9 weeks of amenorrhoea, followed in eight cases by gemeprost and in five cases by misoprostol. None of the events could be conclusively related to the treatment *(2)*.

It is not possible to determine whether the reported anomalies were caused by the treatment, since the incidence of birth defects in a normal population is around 2 per 100 births *(3)*. Some prostaglandins have been classified as teratogenic, although misoprostol did not induce such effects in embryotoxicology studies *(4)*. Mifepristone is not a teratogenic agent but, when used in combination with a prostaglandin, may induce uterine contraction, which could account for some of the observed defects *(5)*.

Since the available data are limited and inconclusive, there is no need to insist on termination of an exposed pregnancy if the woman wishes to continue it. Women should, nevertheless, be informed that, because of the unknown risk of abortifacient drugs to the fetus, follow-up is important.

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21. Which methods of contraception can a woman use after medical abortion?

Most women who have an induced abortion for an unwanted pregnancy do not want to get pregnant again immediately. In a few cases, there may be medical reasons for avoiding immediate pregnancy. Postabortion family planning is therefore an integral part of comprehensive abortion care *(1, 2)*.

Women who have had an early abortion are almost immediately at risk of becoming pregnant again. Ovulation may occur as early as day 10 (*3)* after a first-trimester abortion; up to 78% of women in one study had ovulated by the time of the six-week follow-up *(4)*.

Women who have had a medical abortion can use any modern method of contraception afterwards. When the woman is counselled about the abortion, the opportunity should be taken to review her contraceptive needs. Ideally, she should be provided with an effective contraceptive method immediately after the abortion.

Combined oral contraceptive pills can be started on the day that misoprostol is administered, when expulsion usually occurs. Two prospective randomized controlled studies evaluated the effects of immediate use of combined oral contraceptive pills versus placebo following medical abortion and found no difference in complete abortion rates, side-effects and duration of bleeding *(5, 6)*. Progestogen-only methods are commonly associated with breakthrough bleeding, which may be confused with an incomplete abortion.

Depot-medroxyprogesterone injections and implants are often associated with amenorrhoea, or irregular bleeding, which may make it difficult to determine whether pregnancy has been terminated. It may therefore be preferable to start using these methods only after it has been confirmed that the pregnancy has been terminated. Sterilization and insertion of an intrauterine device should be deferred until confirmation that the abortion is complete.

Women who choose a contraceptive method that cannot be started immediately should be encouraged to use condoms in the meantime. Other methods, such as caps, sponges, diaphragm, spermicidal foams, jellies and vaginal tablets, can be used as soon as sexual intercourse is resumed, preferably when bleeding has stopped. Methods of natural family planning can be resumed only after the return of regular cycles.

References

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ISSUES RELATED TO PROVISION OF MEDICAL ABORTION SERVICES

Legal and regulatory issues

The practice of abortion is governed by regulations operating within the legal framework of the specific country and/or locality. In most countries, termination of pregnancy is legally permitted for at least one indication, e.g. after rape or to protect the life of the pregnant woman. Legislation in some countries permits abortion for a broad range of indications. Often, the legal framework was established long before medical abortion became available.

The development of methods for medical abortion can raise some uncertainty in the interpretation of existing laws or regulations, as these were generally formulated on the basis of surgical abortion as the prevailing method. For example, in some countries, the law requires that abortions take place in a clinic registered for the purpose. With surgical methods there is no doubt as to where the abortion is performed. But when abortion is induced by medication, is the abortion performed where the drugs are prescribed or where they are administered? Or is it where the products of conception are expelled?

Setting up a medical abortion service

Health-care managers who are contemplating setting up a service to provide medical abortion will first need to find out what is the relevant legal framework in their country with regard to medical abortion. In many countries, there are no specific regulations dealing with medical abortion; in this case, medical abortion is governed by the general abortion regulations. Other countries may have specific regulations relating to the provision of medical abortion.

There may be regulations governing which facilities can provide abortion services. In some countries, the national government may stipulate standards through legislation or through health system norms and regulations. Elsewhere, such regulations may be drawn up at the province, state or local level.

Medical abortion may be provided in health-care settings that do not already provide abortion services. Ideally, it should be integrated into broader reproductive health services. This would allow women who have had a medical abortion easy access to other services – such as family planning – as an important element of comprehensive abortion care.

Emergency care and facilities for surgical intervention should be available locally or through a referral mechanism with established linkages. Back-up services should include uterine evacuation, fluid replacement and blood transfusion.

Obtaining the necessary medicines

Where mifepristone is already licensed for use in medical abortion, the licence will usually specify that it should be used with a specific prostaglandin (usually misoprostol), or simply that a "suitable prostaglandin" should be used. In countries where medical abortion is permitted, mifepristone is available from the physician or clinic. However, it is possible that no prostaglandin appropriate for use in early medical abortion is licensed. When no licensed prostaglandin is available, misoprostol is generally used since it is available in many countries, although it is not specifically licensed for use in abortion.

In many places, licensed medicines can be used for clinical indications that are not covered by the original product registration. Often, physicians have the freedom to use medicines for unlicensed purposes when there is medical evidence to support such use. If a physician uses a drug for purposes other than for which the drug is licensed, the physician must inform the patient about this. Managers considering the introduction of medical abortion should check the situation in their country with regard to this issue. In some reimbursement systems, doctors may prescribe off-label use, but patients may not be able to claim reimbursement for the treatment.

According to the United States Food and Drug Administration, "Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment. If physicians use a product for an indication not in the approved labelling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects."

Further reading

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Annex 1

INTERNATIONAL CONSENSUS CONFERENCE ON NON-SURGICAL (MEDICAL) ABORTION IN EARLY FIRST TRIMESTER ON ISSUES RELATED TO REGIMENS AND SERVICE DELIVERY

Bellagio Conference Center, Bellagio, Italy
1–5 November 2004

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