

early
MEDICAL ABORTION

**A PRACTICAL GUIDE
FOR HEALTHCARE
PROFESSIONALS**

2nd edition

Dr Christian FIALA

Pr Aubert AGOSTINI

Dr Teresa-Alexandra CARMO-BOMBAS

Pr Kristina GEMZELL-DANIELSSON

Dr Roberto LERTXUNDI

Pr Marek LUBUSKY

Dr Mirella PARACHINI

The authors:

- , MD, PhD, gynaecologist/obstetrician, Gynmed Clinic, Vienna, Austria.
- MD, PhD, gynaecologist/obstetrician, La Conception University Hospital, Marseille, France.
- , MD, gynaecologist/obstetrician, Obstetric Unit, Maternidade Dr. Daniel de Matos, Centro Hospitalar e Universitário de Coimbra, Portugal.
- , MD, PhD, gynaecologist/obstetrician, Division of Obstetrics and Gynaecology, Department of Women's and Children's Health, Karolinska Institutet, Karolinska University Hospital, Stockholm, Sweden.
- MD, gynaecologist/obstetrician, Department of Gynaecology and Human Reproduction Clinica Euskalduna Bilbao, Euskadi, Spain.
- MD, PhD, gynaecologist/obstetrician, Department of Obstetrics and Gynaecology, Palacky University Hospital, Olomouc, Czech Republic.
- MD, gynaecologist/obstetrician, Unità Operativa Complessa (U.O.C) Ostetricia e Ginecologia, San Filippo Neri Hospital, Rome, Italy.

Acknowledgements: The authors gratefully acknowledge the contribution of all those who worked on drawing up this practical guide, and in particular, Fabienne PERETZ and Laurence ROUS (Abelia Science).

ISBN: 978-2-9553002-1-3

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This guide can be downloaded free of charge at: <https://abort-report.eu/early-medical-abortion-guide/>.

Editorial

I have had the opportunity to follow from its beginning the slow but successful development of a medical method to terminate early pregnancy.

It started with the identification of prostaglandins and their chemical structure by Professor Sune Bergström and co-workers in 1960, and the development of prostaglandin analogues which strongly stimulated uterine contractility and could, in contrast to primary prostaglandins, be administered by non-invasive routes. Vaginal administration of gemeprost, for example, could effectively terminate early pregnancy. However, the dose needed was high and intense uterine pain and gastro-intestinal side effects were common, limiting treatment acceptance.

The next step towards a medical abortion method was the development of mifepristone by the French scientist Professor Etienne-Emile BAULIEU and co-workers in the early 1980s. Mifepristone is an antiprogestone, blocking the progesterone receptor. Treatment with mifepristone changes the inactive pregnant uterus to an active organ with regular contractions. In addition mifepristone softens the cervix, facilitating the expulsion of the conceptus. However, it was soon found that mifepristone alone was not sufficiently effective to be clinically useful for medical abortion.

The significant breakthrough was our finding that treatment with mifepristone also increased the sensitivity of the myometrium to prostaglandin. Following pretreatment with mifepristone, a low dose of prostaglandin analogue was sufficient to induce effective uterine contractions. **With the combined therapy, the success rate was high and, since a low dose of prostaglandin could be used, the side-effects were kept at an acceptable level.**

The introduction of routine medical abortion has been slow. One reason has been the negative attitude to an “abortion pill” on the part of various groups in society, based on the fear that a simple and effective abortion method would increase the abortion rate. This has not happened and is unlikely to be the result. With medical abortion it is the woman herself who takes the responsibility when she takes the

drugs, and experiences the uterine contractions and the expulsion of the conceptus, in contrast to the alternative (vacuum aspiration) where it is the doctor who performs the abortion. Another reason is the attitude of the doctor. It may seem difficult to understand that women often prefer medical abortion, despite the fact that the alternative is a short, 10-minute surgical procedure with very little discomfort: it is, however, the case. Once medical abortion has been introduced in a country, its acceptability for women always increases. It is possible that the similarity to miscarriage, which is a natural process, makes medical abortion more attractive than the surgical procedure.

Another important aspect of medical abortion during early pregnancy is the simplicity of the treatment. The similarities with miscarriage mean that the clinical events are well known, not only to the doctor but also to many middle-level professionals and to the woman herself. In Sweden, midwives have, with back-up from a doctor, taken over most of the management of medical abortion. Also, in countries with limited medical facilities, the use of trained midwives or nurses in abortion care can increase the availability of abortion services and decrease the risk of unsafe abortion.

Although medical abortion is a simple treatment, **detailed knowledge of all aspects is essential for safe outcome. This clinical guide, prepared by very skilled and experienced scientists in the field, gives all the information needed to perform a safe medical abortion during early pregnancy.**

Marc BYGDEMAN

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HOW IS ABORTION REGULATED IN EUROPE?

The legal situation regarding abortion varies considerably between European countries^{a,b}.

Few countries in Europe give women unrestricted access. Most require some conditions to be fulfilled:

- Waiting periods of various length.
- Obligatory “counselling”.
- Signature of two doctors.
- Written statement by the woman that she is in distress...

In practice, these restrictions do not prevent women from getting abortion on request but may result in an unsafe abortion or in delaying the abortion procedure.

European countries where abortion is in practice not accessible on request in the first trimester are the following:

- Andorra,
- Liechtenstein,
- Malta,
- Monaco,
- Poland,

and parts of the United Kingdom (Northern Ireland, Isle of Man) and of Denmark (Faroe Islands).

Abortion has been legalised in December 2018 in the Republic of Ireland, after a referendum showed overwhelming support.

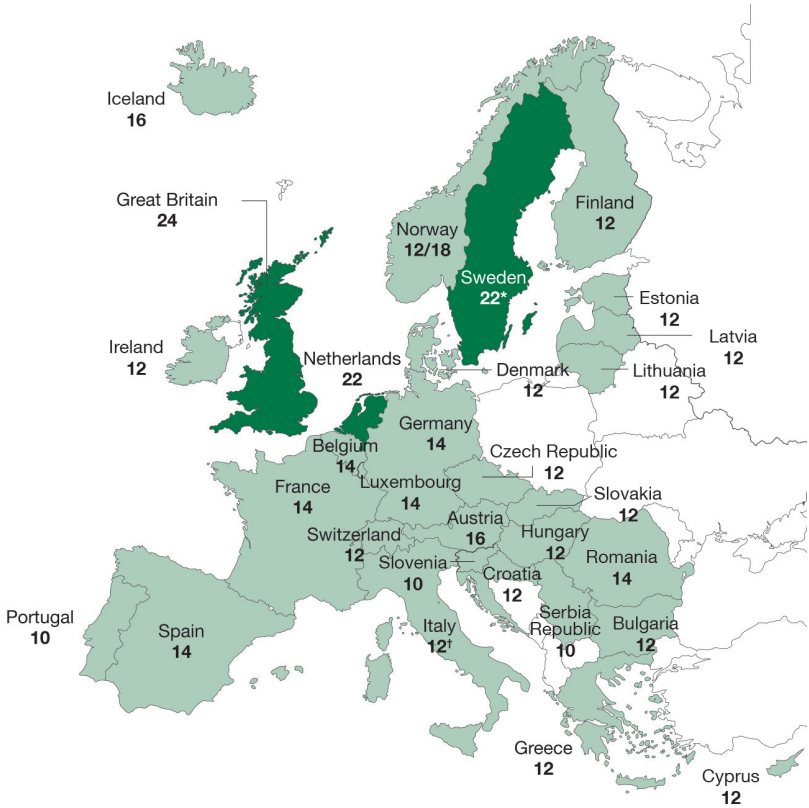


Mirella PARACHINI: “In Italy, the law does not allow abortion on request^a. However, it provides such broad grounds on which abortion is permitted that it has been interpreted by some as allowing abortion on request. In addition, it is the woman herself who attests that she is in one of the situations described by the law and the primary role of the physician is to certify the existence of a pregnancy”.

<http://www.un.org/esa/population/publications/abortion/profiles.htm>.

Where abortion is in practice authorised on request in Europe, the upper time limit ranges between 10 and 24 weeks of amenorrhoea (Fig.1). In addition, all countries have legal provisions for later abortion in cases of medical indication for the woman or the foetus.

Fig.1 Legal time limit for performing abortion by European country (in weeks of amenorrhoea)^a.



* No fixed upper limit but defined by "potential to survive" (21 weeks + 6 days in practice)

† 90 days (i.e., 12 weeks + 6 days)

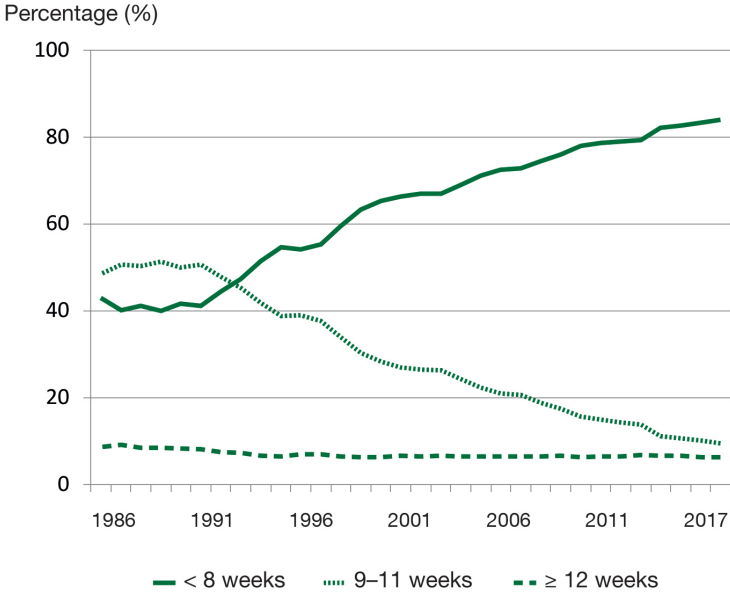
The vast majority of women with an unwanted pregnancy want to terminate it as soon as possible. The gestational age at abortion is independent of the upper gestational limit and mainly reflects women's legal ease or difficulty in gaining access to abortion in their country. The proportion of women in some European countries having an abortion in the first 9 weeks of amenorrhea is shown in Tab.1.

Tab.1 Percentage of abortions before the 9th week of amenorrhea in certain European countries^a.

Country	(legal limit)	Percentage of abortions before Week 9 (year)
Sweden	(22 weeks*)	84% (2017)
England & Wales	(24 weeks)	80% (2016)
Finland	(12 weeks)	78% (2017)
Norway	(12 weeks)	77% (2016)
Czech Republic	(12 weeks)	76% (2013)
Germany	(14 weeks)	73% (2017)
France	(12 weeks)	66% (2013)
Netherlands	(22 weeks)	65% (2016)

In recent years, there has been a significant trend in most countries for abortions to be performed earlier, as shown, for example, in Sweden (Fig.2).

Fig.2 Impact of the introduction of medical abortion on gestational age at abortion in Sweden from 1986 to 2017^a.



MEDICAL ABORTION

In the early 1980s, Etienne-Emile BAULIEU and colleagues, from the French national institute INSERM (Institut National de la Santé et de la Recherche) and the pharmaceutical company Roussel-Uclaf, developed mifepristone (initially known as RU-486). For medical abortion, mifepristone used alone has a maximal effectiveness of 80%, which is insufficient for routine clinical use. The final breakthrough came with the discovery by Marc BYGDEMAN, a leading gynaecologist at the Karolinska Hospital in Stockholm, that mifepristone increased the sensitivity of the pregnant uterus to prostaglandins and that combined treatment significantly increased efficacy. This led to the development of the currently used combined treatment.

In Europe, medical abortion with mifepristone and prostaglandin was first approved in 1988 in France (originally only up to 7 weeks of amenorrhoea), followed by approvals in 1991 in the United Kingdom and in 1992 in Sweden (up to 9 weeks of amenorrhoea). However, it was not until 1999 that medical abortion with mifepristone and prostaglandin was approved in several other European countries (Tab.2). Mifepristone is subject to significant and sometimes highly unusual restrictions in all European countries, where it is available. For example it cannot be bought in pharmacies, except in Bulgaria.

Tab.2 List of mifepristone approval^a.

1988 China France	2000 Alaska Norway Puerto Rico Taiwan Tunisia US	2003 Estonia	2008 Romania Nepal	2013 Azerbaijan Bulgaria Czech Republic Slovenia Uganda Uruguay
1991 UK	2001 New Zealand South Africa Ukraine	2004 Guyana Moldova	2009 Cambodia Italy	2014 Thailand
1992 Sweden	2002 Belarus Georgia India Latvia Serbia Vietnam	2005 Albania Hungary Mongolia Uzbekistan	2010 Zambia	2015 Canada
1999 Austria Belgium Denmark Finland Germany Greece Iceland Israel Luxembourg Netherlands Russia Spain Switzerland	2006 Kazakhstan	2006 Kazakhstan	2011 Ghana Mexico Mozambique	2017 Benin Colombia Nigeria Togo
	2007 Armenia Kyrgyzstan Portugal Tajikistan	2007 Armenia Kyrgyzstan Portugal Tajikistan	2012 Australia Bangladesh Ethiopia Kenya	2019



In 2005, the World Health Organisation (WHO) included the combination of mifepristone and misoprostol for use in medical abortion in its Essential Medicine List^a.

Today, women in most European countries have access to the two drugs which are used in combination for early medical abortion:

- **Mifepristone** is authorised in 22 European countries for use in medical abortion under several brand names (Mifegyne[®], Mifepristone Linepharma, Miffée[®]) (Tab.2). According to one of the distributors of mifepristone (Exelgyn, Paris, commercialising Mifegyne[®]), more than 8 million procedures have so far been achieved with mifepristone in Europe since it was first introduced in 1988.
- **Misoprostol**, an E1 prostaglandin, has been used off-label since the introduction of mifepristone. A new product (Gymiso[®]) has been only registered in France in the 2000s. Since 2012-2014, other products have been approved for use in medical abortion in several European countries, and have recently been marketed (MisoOne[®], Topogyne[®], Mispregno[®]). Misoprostol is used for abortion in association with mifepristone.



Misoprostol marketed as Cytotec[®], registered for use to prevent gastric ulcers in most European countries, is also used off-label for medical abortion. However, it is progressively replaced by specifically approved products mentioned above.



Gemeprost, another E1 prostaglandin, was formerly used in medical abortion. However, it has been replaced by misoprostol because the latter is at least as effective, allows flexible dosage, has fewer side effects, is easier to dose, can be stored at room temperature, and is significantly cheaper.

In European countries, up to 97% of women choose medical abortion when available. Medical abortion is currently^a:

- The commonest method of abortion in Finland (97%), Sweden (93%), Norway (88%), Switzerland (75%), Portugal (72%), and Denmark (70%).
- Commonly used in France (67%), Iceland (67%), and the United Kingdom (England & Wales, 64%).
- Uncommon in Spain (36%), the Netherlands (24%), Belgium (21%), Germany (21%), and Italy (20%).

Latest official national statistics for Belgium, France, Germany, Portugal, Spain, 2015-2017) for Denmark, Finland, Iceland, Norway, and Sweden.

Introduction of medical abortion has been slow in most European countries, **although it is the preferred method of many women ifoy w.05 c (Fig.3).ntriesCS0viceC.8 0 0 0 1**

HOW DOES MEDICAL ABORTION WORK? HOW DO THE TWO MEDICATIONS WORK?

Abortion can be performed with either mifepristone or a prostaglandin alone, but single drug treatment has lower efficacy and a high rate of side effects. The combination of mifepristone and a prostaglandin (commonly misoprostol) has a synergistic effect which allows a lower dose to be used, reduces side effects and increases efficacy.

The combined action of mifepristone and prostaglandin on the decidua and cervix results in detachment and expulsion of the pregnancy, which is very similar to a spontaneous miscarriage due to corpus luteum insufficiency.



Mifepristone and misoprostol act synergistically.

From a medical point of view, spontaneous and medically induced abortions are similar processes.

MIFEPRISTONE

Mifepristone is a synthetic hormone, which competitively blocks the progesterone receptors (Fig.4).

Mifepristone has a higher binding affinity to the progesterone-receptor than progesterone. This leads to a competitive blockage of the progesterone receptors by mifepristone. This blockage is fully reversible^{a,b}. The clinical effects last for 3 days following single intake.

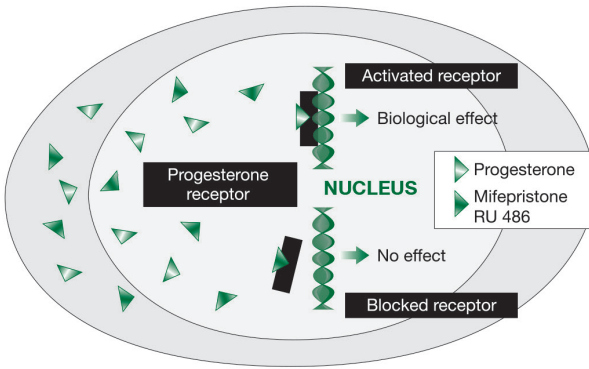
Oral absorption of mifepristone is rapid with peak concentrations occurring approximately 90 min after ingestion and a half-life of 20-40 h.

There are three main metabolites of mifepristone, which also have an affinity to the progesterone-receptor, although lower than mifepristone. Data on pharmacokinetics and binding affinity suggest that these metabolites may contribute to a significant extent (23-33%) to the anti-progestagenic effects of mifepristone^c.

Mogulewsky M, Philibert D. Biochemical profile of RU 486. In: Baulieu EE, Segal

Fiala C, Gemzel-Danielsson K. Review of medical abortion using mifepristone in

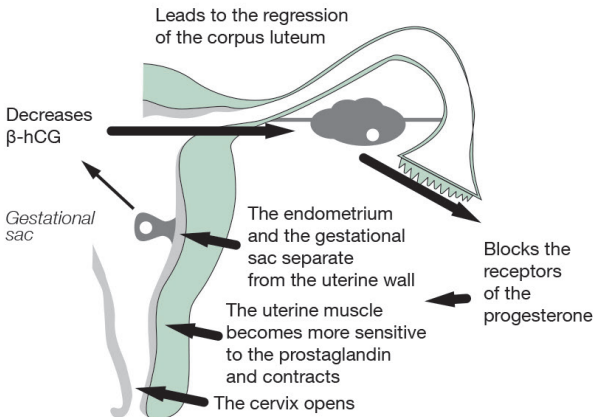
Fig.4 Mifepristone's action in the cell.



with a higher affinity, thereby blocking the effects of the progesterone.

At tissue level, mifepristone increases the contractility of the uterus by its sensitization of the myometrium to prostaglandin. The effect begins 12-24 hours after mifepristone administration and is maximal at 36-48 hours. **Mifepristone also causes the cervix to soften and ripen** and results in a release of endogenous prostaglandins from the decidua (Fig.5).

Fig.5 Mifepristone's action at tissue level.



MISOPROSTOL

Misoprostol is a prostaglandin E1 analogue. It induces contractions of the uterus and expulsion of the pregnancy.

Where approved in Europe, misoprostol is licensed as **tablets for oral use**. However, misoprostol is recommended in clinical guidelines and widely used in practice in early medical abortion:

- Via oral route* in pregnancy ≤ 7 weeks of amenorrhea.
- Via other routes (vaginal, sublingual, or buccal)* in pregnancy ≤ 9 weeks of amenorrhea. However, these non-oral routes are not included in approved labels.

The peak plasma level of the active metabolite (misoprostol acid) occurs after less than 30 minutes when administered orally. Absorption after vaginal administration is slower and more variable: peak plasma level is occurring at 80 minutes. The plasma elimination half-life of misoprostol acid is 20-40 minutes.



Mifepristone is effective throughout pregnancy. There is thus no upper gestational limit to when medical abortion is effective, but there are specific protocols according to gestational age. **The present practical guide, however, focuses on early medical abortion: i.e., for pregnancies ≤ 9 weeks of amenorrhea.**

WHAT IS THE SUCCESS RATE OF MEDICAL ABORTION?

In clinical trials, success rates are between 92.5% and 98% depending on gestational age, the time-interval between mifepristone and prostaglandin administration, the type of prostaglandin used, and the prostaglandin administration route. Failures occur in 1.3% to 7.5% of cases, including 0 to 1.5% ongoing pregnancies, 1.3% to 4.6% incomplete abortion, and 0 to 1.4% excessive bleeding/haemorrhage.

The following factors affect success rates:

- **Gestational age of pregnancy**
Medical abortion is less effective as gestational age increases. More contractions are needed, thus more prostaglandin needs to be given. Beyond 24 weeks of amenorrhea, the dose of the prostaglandin needs to be reduced because of the risk of uterine rupture.
- **Mifepristone-prostaglandin regimen**
Regimens vary in terms of dose, timing and administration route.
- **Healthcare professional**
Inexperienced clinicians may have lower levels of success with medical abortion as they tend to intervene surgically at early stages of the process (e.g., in the mistaken belief that termination is not complete). **Surgical evacuation of the uterus after a medical abortion is only indicated if there is a clinical indication such as heavy or prolonged bleeding, ongoing pregnancy and/or if the woman wishes intervention** (for further details, please see “Post-abortion care”, p. 83).
- **Follow-up visit**
Many women want to know as soon as possible if the abortion has been complete, and an early follow-up consultation may increase satisfaction. On the other hand, at early follow-up human chorionic gonadotropin (hCG) levels are still high and the uterine cavity may contain more blood, which is sometimes misdiagnosed by inexperienced professionals as incomplete abortion, possibly leading to repeated follow-up visits or unnecessary surgery (for further details, please see “Post-abortion care”, p. 83).

WHAT ARE THE DIFFERENT STEPS IN EARLY MEDICAL ABORTION?

Treatment regimen details vary from one country to another and according to the healthcare professional's experience and national guidelines. For further protocols and details, please see: "What are the recommended protocols in early pregnancy?", p. 69.



Each professional should first consult the legal product information applied in his/her country.

Treatment always follows 4 steps (Fig.6).

Fig.6 Medical abortion: a 4-step method.



Some of the treatment steps can be done at home, depending on the local situation and national legal regulations. The number of visits therefore ranges between 1 and 4.

CONCLUSION

1. The law on abortion and the administrative regulations vary considerably from one European country to another. Nevertheless, **abortion in the first trimester is accessible on request in most European countries.**
2. Medical abortion was introduced in Europe in 1988. Since this date, it has been increasingly used.
3. **Early medical abortion (≤ 9 weeks of amenorrhea) with mifepristone and a prostaglandin (commonly misoprostol) has been shown to be a highly effective and safe method. It is the preferred method for most women, when they have a free choice. The procedure is very similar to miscarriage.**
4. **Early medical abortion is always a 4-step method:**
 - Confirmation of pregnancy (intrauterine).
 - Intake of mifepristone.
 - Intake of the prostaglandin.
 - Verification of successful abortion.
5. **The details of the treatment regimen used in early medical abortion and the protocol followed are variable.** They depend on gestational age, country and the healthcare professional.

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- *Delivering information in a confidential, respectful and non-*

WHAT IS COUNSELLING?

The aims of abortion counselling are:

- To help the woman to understand her situation, her options, to come to a self-determined clear decision and to implement her decision.
- To assist her in controlling her future fertility.

Counselling must be able to offer active listening to what the woman has to say and practical information about abortion methods and contraception.

Counselling is probably the most variable step of medical abortion. Depending on the country, it can be performed by a doctor, a midwife, a social worker or a trained counsellor. It can be voluntary or made mandatory by law. It can take place either in the institution where the abortion is to be carried out or in another place.



Healthcare professionals should refer to their national law and/or local regulations about counselling.

The following chapter focuses on information on abortion (surgical or medical abortion) and future contraception that must be provided by all healthcare professionals to all women who have taken the decision to terminate their pregnancy. **Information should be accurate, impartial and easy to understand.**

Before starting the treatment, the healthcare professional may ask the woman to sign an informed consent form or information form.



Christian FIALA: “Examples of templates of an information card and informed consent form for medical abortion are presented in Fig.7 and Fig.8 and online at www.mifegyne.info.”

Fig.7 Example of template of an information card for medical abortion.

Information on Early Medical Abortion

You have decided to terminate your pregnancy medically.

The medical method is carried out 3 steps and consists of taking 2 drugs:

HOW TO RECEIVE WOMEN WHO COME FOR AN ABORTION?

Woman requesting an abortion should be reassured that the consultation is confidential and that the information she provides is available only to other healthcare professionals directly involved in her care.

The woman's personal details must not be shared with anyone else, unless she has expressly given permission to do so, or in certain specific cases regulated by local law (child abuse, domestic violence, etc.) and special attention has to be given to the needs of adolescents regarding appropriate protection of confidentiality.

Ideally, the reception area, toilets and examination rooms should be separate from those provided for women coming to the same facility for antenatal care and delivery.



Mirella PARACHINI: “Conversations are best held with the woman sitting up rather than lying down, and with the healthcare professional seated at the same level as the woman. This corresponds to an attitude of respect and support and can help ease anxiety.”

There is no evidence of a causative association between abortion and mental health problems^{a,b}. However, it can be helpful for the woman to hear during counselling that:

- To feel upset in such a situation is normal.
- Many kinds of experience can be traumatic (e.g., divorce, job loss).
- Approximately a third or more of women of reproductive age have had or will have an abortion (which is likely to include someone that she knows).
- On TV and in magazines, abortion is often dramatized as a political issue that people have to take sides on: it is quite a different matter what real women actually experience.
- A lot of women think that choosing an abortion makes it seem like they don't care about children; but in reality it often means that they care so much about children that they want to be sure they have them only when they can take the responsibility and provide for all their needs.
- Pregnancy confirms current fertility of both partners.
- Abortion has no effect on future fertility^c.
- Abortion does not increase the risk of breast cancer^{d,e}.

Munk-Olsen T, et al. Induced first-trimester abortion and risk of mental disorder. N Engl

HOW TO HELP THE WOMEN TO CHOOSE BETWEEN THE TWO ABORTION METHODS?

Both methods are effective and safe for abortion within the first trimester of pregnancy:

- Vacuum aspiration (manual or electrical) under anaesthesia (local or general).
- Mifepristone followed by prostaglandin (commonly misoprostol).

For each method, women must be given information on:

- What will be done during and after the procedure.
- What effects and side effects they are likely to experience (e.g., menstrual-like cramps, pain and bleeding).
- How long the procedure will take.
- What kinds of pain management can be made available.
- What risks and complications are associated with the method.
- Follow-up care.
- Start/initiation of contraception or switch to more effective or adapted method of contraception.



Christian FIALA: “The following website contains detailed information about abortion in many languages: www.gynmed.org. I recommend it for women with an unwanted pregnancy.”

WHAT INFORMATION SHOULD BE GIVEN ABOUT SURGICAL ABORTION?

Vacuum aspiration involves evacuating the contents of the uterus through a plastic cannula connected to a vacuum source.

The plastic cannula is inserted into the uterus with or without prior dilation by mechanical dilators, alone or in combination with prostaglandin. The size of the cannula varies according to gestational age. Electrical vacuum aspiration uses an electrical vacuum pump; in manual vacuum aspiration, a vacuum is created using a hand-held 60 ml plastic syringe.

The procedure usually takes place in an operating theatre or outpatient clinic room. It takes between 3 and 10 minutes to complete.

The procedure can be performed on an outpatient basis, using local or general anaesthesia. The woman should be given the choice between local or general anaesthesia.

After the procedure under local anaesthesia, most women feel well enough to leave the healthcare facility after about 30 minutes' observation in a recovery room. Longer recovery periods are generally needed when sedation or general anaesthesia has been used.



If the products of conception are not identified during aspiration, an ultrasound scan (if available) should be taken immediately after the aspiration to check that the uterine cavity has been emptied.

A follow-up visit is not needed if the evacuation of the uterus has been confirmed during the abortion procedure.

The method is very effective. Electrical and manual vacuum techniques are equally good, **with complete abortion rates ranging between 95% and 100%.**

The vacuum aspiration method is a very safe procedure when performed in a safe environment by a skilled professional in a well equipped facility.

Common side-effects can be: abdominal cramping, pain and menstrual-like bleeding.

Complications (pelvic infection and excessive bleeding) are rare. The following other complications are very rare: cervical injury, incomplete evacuation, perforation of the uterus, anaesthesia-related complications, and ongoing pregnancy.

All women should be offered presurgical priming of the cervix with mifepristone^a (200 mg given orally 24 to 48 hours before the intervention) or misoprostol (400 µg given either sublingually 1 hour before the intervention or vaginally 3 hours before the intervention) as it has been shown to facilitate transcervical procedures and to reduce side-effects^{b,c}.



For **very early gestations** (< 6 weeks of amenorrhea), surgical may be less effective than medical abortion (possibility of missing the gestational sac during aspiration).

On the contrary, medical abortion is equally effective for very early gestations and early gestations^d.

Meirik O, et al. Complications of first-trimester abortion by vacuum aspiration after

Bizjak I, et al. Efficacy and safety of very early medical termination of pregnancy: a cohort

WHAT INFORMATION SHOULD BE GIVEN ABOUT MEDICAL ABORTION?

Women should be advised that this method involves taking **two different medications consecutively**: an antiprogesterone (mifepristone) and then a prostaglandin (commonly misoprostol). Mifepristone and misoprostol induce uterine contractions leading to the expulsion of the pregnancy. For further details, please see “How does medical abortion work? How do the two medications work?”, p. 19.

The procedure includes 4 steps (counselling incl.), but depending on the country and the healthcare professional between 1 and 4 visits are necessary.

First, mifepristone is taken orally as a single dose. Then, misoprostol is taken 1 to 2 days later according to the chosen protocol. This may be via oral route for early medical abortion ≤ 7 weeks of amenorrhea, or vaginal, sublingual or buccal route for early medical abortion ≤ 9 weeks of amenorrhea. Finally, 1 to 3 weeks after the treatment, successful expulsion should be confirmed.

Women need to know that intake of mifepristone starts a process which is irreversible and cannot be stopped^a.

For further details, please see: “How should mifepristone and misoprostol be taken?”, p. 71 and “How to exclude an ongoing pregnancy?”, p. 86.

MIFEPRISTONE INTAKE

Usually, women take **mifepristone** under clinical supervision and leave the facility without further delay, but it can be also safely taken at home if permitted by local regulations.

The woman should be informed about what to expect, including that in some cases (3%) the pregnancy can get expelled at home before she has taken the prostaglandin. She should also be informed of the possibility of bleeding ($< 5\%$ of cases).



The occurrence of bleeding after taking mifepristone does not mean that the pregnancy has been terminated. The woman still needs to take the prostaglandin.

Grossman D, et al. Continuing pregnancy after mifepristone and "reversal" of first-

At this step, the woman should either be given an appointment for misoprostol administration or receive the tablets to be taken at home (if permitted by local regulations). In the latter case, she will be provided with the prostaglandin and information on how to take it. She should be informed about what to expect, including side-effects. In addition, **pain treatment should be discussed, and the woman should receive sufficient pain medication.**



Expulsion usually occurs shortly (3-6 hours) after misoprostol intake; it is crucial for the woman to plan the best time for her to take the prostaglandin.

MISOPROSTOL INTAKE



Some women start heavy bleeding before planned misoprostol intake. In this case, women can immediately take 2 tablets orally, even if they were advised to take 4 tablets vaginally. For these women, treatment is finished earlier; no further misoprostol intake is needed.

There is clear evidence that it is safe for women to take **misoprostol** at home instead of coming to the healthcare facility^a. They should therefore be given a free choice as to where to take the misoprostol assuming that this is legally permitted in the country.

If a woman chooses to come to the healthcare facility, then she will usually remain for a few hours under observation, during which abortion occurs in around 70% of cases.

A few countries have a legal requirement for women to come to the healthcare centre to take the prostaglandin. In these countries, in case of early pregnancy (≤ 9 weeks of amenorrhea), women may choose to go home soon after administration of the prostaglandin and expel the pregnancy at home^a.

Most women will start bleeding shortly after misoprostol intake and expel the pregnancy within a few hours. However, there are huge individual variations:

- Pregnancy can be expelled before the misoprostol intake.
- A small proportion of women expel the gestational sac more than 24 hours after misoprostol intake.

During this period, most women require medication to relieve pain due to cramps. Pain medication should be made available.

Women should be advised that even after expelling the pregnancy, they may expect to have bleeding which may be heavier or longer than a menstrual period. They should be given clear verbal and written information on how to reach a healthcare professional in case of abnormal bleeding or other adverse events. **A 24-hour telephone hotline should be available for all women under treatment, to answer questions or direct patients in the rare case of an emergency situation.**

For further details, please see "What are the main adverse events associated with medical abortion? How should they be managed?", p. 72.



Absence of bleeding is a sign of treatment failure.

But the occurrence of bleeding is not in itself a sign of successful abortion.

Cameron S, et al. Women's experiences of the final stage of early medical abortion at home: results of a pilot survey. J Fam Plann Reprod Health Care 2010;36(4):213-6.

FOLLOW-UP

Successful expulsion should be diagnosed 1 to 3 weeks after the treatment, either during a follow-up visit with a skilled practitioner or with an hCG test (urinary pregnancy test at home, or serum test in a medical laboratory).



Low sensitivity urinary pregnancy tests (LSUP) can be used by women themselves to assess the outcome of medical abortion. However, normal pregnancy tests can remain positive for up to 6 weeks after a successful abortion, as hCG is excreted only slowly.

The efficacy of the method is high (95%-98%). However, between 2% to 5% of women will require further medical treatment or surgery for incomplete abortion, to terminate a continuing pregnancy, or to control bleeding.

For further details, please see “How to manage failure of medical abortion?”, p. 92.

The method is very safe when used as recommended. The side-effects of medical abortion are similar to those found with miscarriage: cramping and prolonged menstrual-like bleeding. Bleeding occurs for about 2 weeks on average. Side-effects may also include nausea, stomach cramps, vomiting and diarrhoea.

For further details, please see “What are the main adverse events associated with medical abortion? How should they be managed?”, p. 72.

WHAT ARE THE ADVANTAGES AND DISADVANTAGES OF MEDICAL ABORTION?

The main advantages of the **medical method** are the following:

- Medical abortion can be performed at a very early stage (before 6 weeks of amenorrhoea), without surgery or anaesthesia.
- Complications are very rare.
- The success of the method is not dependent on the skill of the surgeon.
- Women may feel this method is more natural and leaves them more in control than with surgery.

Its disadvantages are possible stronger pain (which can be successfully treated) and bleeding. In addition, the overall procedure takes time (for further information, please see Tab.3).

The main advantages of the **surgical method** are that the procedure is very fast, and complications are very rare when performed in a safe environment by a skilled professional in a well-equipped facility. The procedure is also highly predictable, and women can know what to expect. Some women may feel the use of anaesthesia and the loss of control as disadvantages.



Medical abortion has no effect on fertility and does not increase the risk of future miscarriage.

Tab.3 Comparison of medical and surgical abortions^a.

Method	Medical abortion	Surgical abortion/aspiration
Performed by	- The patient, who takes the tablet independently. - More responsibility for the woman.	- A trained professional (usually a doctor). - The professional takes the responsibility.
When	- 4 to 9 weeks* of amenorrhoea.	- 6 to 14 weeks of amenorrhoea.
Duration	- Several days.	- 3 to 10 minutes.
Visits	- 1 to 4 visits (counselling incl.) depending on the country or the professional. - Possible to plan according to patient's preference.	- 1 to 3 visits (counselling incl.) depending on the country or the professional. - Planned according to clinic schedule.
Additional medication	Painkillers in most cases.	Local or general anaesthesia. Painkillers.
Bleeding	More difficult to predict and control. Usually a bit stronger and longer than menstruation (i.e., 80 ml).	Same total blood loss as medical, but fewer days of bleeding after the procedure.
Side-effects	Cramp-like pain (frequent), nausea and (rarely) vomiting or diarrhoea.	Sometimes short cramp-like pain, nausea and vomiting after surgery.
Complications (very rare)	Heavy bleeding, ongoing pregnancy, and infection.	Injury to the uterus, infection, problems of anaesthesia.
Effects on fertility	None.	None if correctly performed and without complications.
Contraception	Effective method needed immediately.	Effective method needed immediately.

* This limit may be extended according to the country regulations

WHAT ARE THE REASONS LEADING WOMEN TO EXPRESS A PREFERENCE BETWEEN MEDICAL AND SURGICAL ABORTION?

The most common reasons for choosing medical abortion are^{a-c}:

- Avoidance of surgery or general anaesthesia.
- Greater privacy and autonomy than surgical abortion.
- Greater flexibility with planning, no need to consider availability of operating doctor.
- Perception that the procedure is safer and more natural than surgery.

Women tend to choose surgical abortion if they prefer to be asleep (general anaesthesia) and do not want to be aware of the procedure.



Women who choose medical abortion find it more acceptable at earlier than at later gestational ages^{d-f}. However, women who wish to use a particular method should be allowed their choice, regardless of gestation^d.

Winikoff B. Acceptability of medical abortion in early pregnancy. Family Planning

Honkanen H, von Hertzen H. Users' perspectives on medical abortion in Finland.

WHAT ARE THE REASONS WHY HEALTHCARE PROFESSIONALS MIGHT PREFER TO OFFER MEDICAL OR SURGICAL ABORTION?

Medical abortion should be preferred by healthcare professionals if:

- It is the **woman's preference**.
- The **woman is severely obese** (body mass index > 30 kg/m²), as this may make surgical treatment more difficult technically.
- The woman has a **uterine anomaly** (such as bicornuate uterus), or has previously had **cervical surgery** such as conisation which may make surgical abortion technically more difficult.

Surgical abortion should be preferred if:

- It is the woman's preference.
- The woman has contraindications to medical abortion (exceptional).
- The woman has a psychological/psychiatric problem making it difficult for her to go through the process of medical abortion.



Roberto LERTXUNDI: “Both abortion methods, medical and surgical, are effective and safe. The most important is women’s free choice after appropriated counselling, considering the eligibility criteria.”

WHY AND HOW SHOULD CONTRACEPTION METHODS BE PRESENTED DURING THE COUNSELLING VISIT?

The present unwanted pregnancy is the consequence of the absence of contraception or a failure in the contraception method. It confirms fertility in both partners.

The healthcare professional should therefore discuss with the woman (and her partner if present) what she/they had been using for contraception and how they could avoid another unwanted pregnancy in the future.

Information on contraception should be given from the first contact with the patient and an effective method can be started immediately after the abortion, because:

- Lack or failure of contraception is the main reason for an unwanted pregnancy.
- Abortion as a backup method is an integral part of comprehensive family planning. In countries where abortion is legal and widely available, abortion rates are low if effective contraception is widely used.
- Women coming for an abortion are emotionally preoccupied with the decision about the abortion and have usually spent little time thinking about future contraception.
- Fertility resumes immediately, with the next ovulation taking place 10 to 14 days after abortion.
- Most women requesting abortion do not want to get pregnant again immediately.



The woman's acceptance of an effective contraceptive method must not be made a precondition for providing her with abortion services.

Post-abortion contraception is an integral part of comprehensive abortion care: abortion and contraceptive counselling and services should be provided together. For further details, please see "Which methods of contraception can a woman use after medical abortion?", p. 80.

GOOD PRACTICE POINTS

1. Legal requirements for counselling vary from country to country. **Healthcare professionals need to refer to their national law and local regulations.**
2. Women requesting an abortion should be treated with respect and understanding, ensuring confidentiality and privacy.
3. **The choice of the abortion method involves both the woman and the healthcare professional**, and will depend on several factors, including:
 - Patient preference.
 - Gestational age.
 - Patient's medical history.
 - Current national or local legislation and regulations.
4. Healthcare professionals should provide women with clear and complete verbal and written information on abortion and contraception methods. Women should be provided with information about symptoms that may indicate a complication and that would necessitate urgent medical consultation, and also about symptoms suggestive of ongoing pregnancy.
5. **A woman who chooses medical abortion needs to realise that this method involves her active participation:**
 - She needs to take the two drugs.
 - She needs to attend a check-up or perform it herself 1 to 3 weeks after taking mifepristone.
 - In some rare cases, expulsion and bleeding can occur before she takes the prostaglandin.
 - She should contact her doctor immediately in case of heavy bleeding. She should recognise signs and symptoms that may indicate a complication and for which she should seek urgent medical advice.
6. Medical abortion using combined mifepristone and prostaglandin is highly effective, but in rare cases (2% to 5%), she will require further treatment or surgery to complete the treatment.

Pre-abortion care

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- *Provide a-checklist of clinical, laboratory and ultrasound red flags*

WHAT INFORMATION NEEDS TO BE COLLECTED IN HISTORY-TAKING?

History-taking looks for contra-indications to the abortion method, screens for risk factors for complications, and looks for contra-indications to contraceptive methods.

Social history should include risk assessment for sexually transmissible infections, taking account of local prevalence rates.

Clinical history-taking should include:

- Personal and family history of relevant diseases, including bleeding tendencies.
- Current use of medication, and known allergies.
- Obstetric and gynaecological history, including ectopic pregnancies and adverse events or complications that occurred during previous abortions.



Teresa-Alexandra CARMO-BOMBAS: “From a clinical point of view, presence of HIV infection in a woman undergoing abortion requires the same precautions as it does in any other medical or surgical intervention.”

HOW TO CHECK GESTATIONAL AGE?

CLINICAL EXAMINATION AND PREGNANCY HISTORY-TAKING

It is **difficult or sometimes impossible to diagnose early pregnancy reliably** on the basis of the woman's history and a physical examination alone.

However, history should always be taken, including:

- First day of the woman's last menstrual period.
- Whether the menses were regular.
- Any pregnancy-related symptoms: i.e., breast tenderness, nausea, vomiting, fatigue, and changes in appetite or frequency of urination. A bimanual pelvic examination can be performed to determine uterine enlargement. However, it must be kept in mind that diagnosis of gestational length by **clinical examination is not reliable in early gestation** (Tab.4) and bimanual pelvic examination is an invasive method.

Tab.4 Possible causes of discordant uterus size in a pregnant woman.

Size of the uterus (pregnant woman)	Causes
Smaller than expected	Pregnancy less advanced than estimated Ectopic pregnancy Missed abortion
Larger than expected	Pregnancy more advanced than estimated Multiple pregnancy Presence of uterine fibroids Molar pregnancy



In case of discrepancy between uterus size on pelvic examination and gestational age, ultrasound examination should be performed.

Basic routine observations (pulse, blood pressure and temperature) are optional. They are not essential for medical abortion.

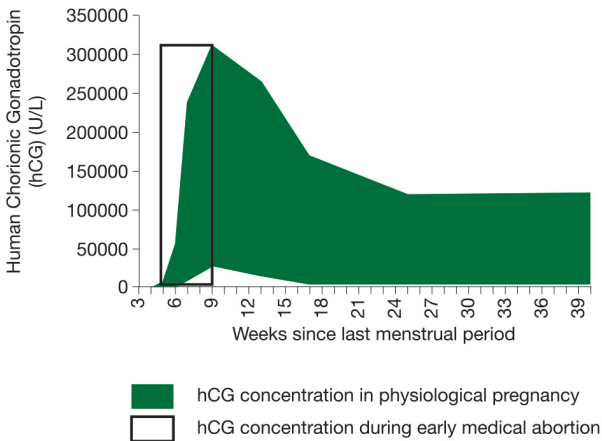
HUMAN CHORIONIC GONADOTROPIN (URINE OR SERUM)

A urinary pregnancy test that detects hCG should be made to confirm pregnancy if ultrasound is not part of the routine examination or if the pregnancy is too early to be seen on ultrasound.

In a normal pregnancy, hCG levels double every 2-3 days between weeks 4 and 8. It is important to keep in mind the huge individual variations in hCG concentration, which prevent reliable diagnosis of gestational age based on hCG level alone. However, **hCG is positive in 98% of pregnant women at 4 weeks of amenorrhea.**

Fig.9 presents serum hCG concentration.

Fig.9 Serum hCG concentration in physiological pregnancy and during early medical abortion - Adapted from Montagnana^a.



The earlier the gestational age, at which medical abortion is performed, the less will be the pain and bleeding. Early diagnosis of pregnancy is therefore crucial. However, **medical abortion should not be delayed just to wait for hCG results.**

ULTRASOUND

Ultrasound scan increases the standard of care. However, it is not always easily available, and **medical abortion can be safely performed without ultrasound.**



Ultrasound scan is a very useful diagnostic tool that helps to increase the standard of care. But it **is not a prerequisite for medical abortion^a**, and lack of ultrasound should not prevent professionals from offering this method.

Where available, ultrasound can be performed to confirm viable intrauterine pregnancy and date the gestational age except for very early pregnancy (too small to be visualised).



Christian FIALA: “Abdominal/suprapubic ultrasound is preferred by patients because it is less invasive. It is sufficient in the vast majority of cases to diagnose the size and viability of a pregnancy. Vaginal ultrasound should be available for specific issues.”

Ultrasound is not required between mifepristone and prostaglandin administration.

Where ultrasound is used, the facility should ideally provide areas where women seeking abortion can be scanned, separate from those for women receiving antenatal care.



Kristina GEMZELL-DANIELSSON: “Women should be allowed to choose whether they want to view the ultrasound image or not^{a,b}.”

Definitive diagnosis of intrauterine pregnancy by ultrasound scan requires detection of:

- **Gestational sac**

It is visible (6 to 10 mm diameter) from around 35 days of amenorrhea (5 weeks). An excentric location and decidual reaction may differentiate a true gestational sac from a pseudo-sac (often central, with no decidual reaction), although this sign alone is not always sufficient.

- **Yolk sac**

It is visible (diameter 3 to 8 mm) from around 38 days of amenorrhea and should be visible. Its presence is proof of intrauterine pregnancy.

- **Embryo**

It appears at 42 days of amenorrhea (6 weeks). Cardiac activity can be detected in a 2-3 mm embryo and is systematically detected in a 5 mm embryo.

Diagnosis of intrauterine pregnancy does not necessarily exclude presence of ectopic pregnancy. Heterotopic pregnancy (with one intrauterine and one ectopic gestation) can occur, but is extremely rare in women not using assisted reproduction technologies.



A gestational sac with a yolk sac is proof of intrauterine pregnancy.

A gestational sac of 16 mm diameter or more normally contains a viable embryo.

An embryo of 5 mm diameter or more normally has cardiac activity.

Gestational age can be determined by measuring the gestational sac or the longest axis (crown-rump length, CRL) of the embryo, when visible:

Training in ultrasound in abortion care can be helpful. An e-learning course (Ultrasound in Abortion Care, by Deutchman M et al.^a) can be recommended.

CORRELATION BETWEEN ULTRASOUND FINDINGS AND SERUM hCG LEVELS

Many studies have evaluated data to determine at which hCG threshold a gestational sac has to be visualized. The authors were surprised by the huge individual variation. This let them to conclude that “the threshold level at which an intrauterine gestational sac should always be seen is not known”^a. Consequently “using an arbitrary discriminatory zone as a basis to manage these women is not recommended on the basis of this study”^b. Correlation between ultrasound findings and serum hCG levels in early pregnancy are presented in Tab.5. Nevertheless, an 80% decrease between serum hCG level before treatment and at follow-up (6-18 days after treatment) is effective to confirm a successfully medically induced abortion in pregnancy up to 7 weeks of amenorrhea.^c

Tab.5 Correlation between ultrasound findings and serum hCG level in early pregnancy - Adapted from Fiala^c.

Ultrasound finding	Serum hCG level (mU/ml)
No gestational sac	28–1,752 (median 558)
Gestational sac, no yolk sac	802–54,443 (median 4,072)
Yolk sac	2,700–107,400 (median 17,295)
CRL > 2 mm	22,900–190,750 (median 63,600)

SHOULD ANTI-D PROPHYLAXIS BE ADMINISTERED TO RH-NEGATIVE WOMEN?

Most clinical guidelines recommend RhD-immunisation in RhD-negative women, without specifying a lowest gestational age.

For pregnancies ≤ 9 weeks of amenorrhea, there is no evidence that maternal RhD-sensitisation occurs during spontaneous or induced abortion. However, it is difficult to prove that RhD-immunisation is not necessary, even when the theoretical risk is very low.

In countries where the prevalence of RhD-negative status is high (e.g., in Caucasian women), and if resources permit, maternal RhD-typing and anti-D prophylaxis might be offered as precautionary components of complete medical abortion care. In that case, it is recommended to administer a dose of 50 μg (250 IU) anti-D immunoglobulin G (IgG)^a. This dose can neutralise more than 2 ml of foetal blood in the maternal circulation. The RhD-immunoglobulin can be given on the same day that mifepristone or misoprostol is administered^b.

Fiala C, et al. Rh-prophylaxis in early abortion. Acta Obstet Gynecol Scand

WHAT OTHER TESTS OR EXAMINATIONS SHOULD BE PERFORMED?

The following tests or examinations should be performed only if there are clear clinical indications.

- **Cervical cytology**

Cervical cytology is not necessary before medical abortion, but can be performed without problem.

Unscheduled cervical screening is not justified if the woman is less than 25 years of age or has undergone screening within the previous 3 to 5 years, unless the previous screening test was abnormal.

If a woman has been called for routine screening and she is pregnant and coming for an abortion, the test will be deferred until after the medical abortion unless there is a specific indication^a.



Teresa-Alexandra CARMO-BOMBAS: “In women that were not regular attendees of Reproductive and Sexual Health Care Services, the appointment for medical abortion can be an opportunity for cervical screening.”

- **Laboratory testing for reproductive tract infection**

If clinical signs indicate infection, the woman must be treated with antibiotics immediately. However, this should not delay the beginning of medical abortion treatment.

- **Other laboratory tests**

There is no indication for:

- Routine coagulation tests in low-risk asymptomatic women with no personal or family history of excessive bleeding.
- Haemoglobin and haematocrit assays in the absence of clinical signs of anaemia.

NHS Cervical Screening Programme. 3rd edition. Sheffield: NHS Cancer Screening system/uploads/attachment_data/file/515817/NHSCSP_colposcopy_management.pdf.

WHAT ARE THE CONTRAINDICATIONS AND PRECAUTIONS FOR USE FOR MEDICAL ABORTION?

Medical abortion is a very safe treatment with extremely few contraindications. However, **pregnancy has to be confirmed by ultrasound scan or biological tests prior to the treatment.**

Medical abortion **is not to be given** in women with^a:

- Adrenal failure.
- Allergy (hypersensitivity) to the active substance (mifepristone) or any of the excipients of the products.
- Allergy (hypersensitivity) to the chosen prostaglandin.
- Severe asthma uncontrolled by therapy.
- Inherited porphyria.
- Diagnosed ectopic pregnancy or specific signs or symptoms suggesting ectopic pregnancy.



Medical abortion is not effective in ectopic pregnancies.

Medical abortion **is not recommended** in women suffering from:

- Renal failure.
- Hepatic failure.
- Malnutrition.
- Any illness or treatment that negatively affects blood clotting.
- Severe anaemia.
- Uncontrolled epilepsy.

Medical abortion with E1-prostaglandins (such as misoprostol) **is not contraindicated** in women with controlled asthma, cardiovascular history or a risk factor for heart disease, such as high blood pressure or high blood cholesterol level. This is in contrast to E2-prostaglandins (dinoprostone, marketed as Cervidil[®], Prostin E2[®], Propess[®], Glandin[®]), which are contraindicated in these situations.

The following medications may decrease the efficacy of medical abortion, as they decrease the serum level of mifepristone: phenytoin, phenobarbital or carbamazepine. Conversely, mifepristone reduces the activity of rifampicin, dexamethasone and St John's wort

The following situations are not contraindications for medical abortion: age, diabetes, thyroid disorder, multiple pregnancy, obesity, previous caesarean section, smoking, uterine malformation and previous cervical surgery. For further details, please see, "Are there specific measures to apply in case of ...?", p. 98.

The levels of **mifepristone** found in mother's breast milk are low and not expected to be of clinical relevance^a. **Misoprostol** is rapidly metabolised to misoprostol acid, which is biologically active and excreted in breast milk. The level of misoprostol acid is low in breast milk and rapidly declines after a single dose of 400 µg or 800 µg. No clinical effects are expected at such low doses in case of breastfeeding. **Based on available evidence, the doses of mifepristone and misoprostol used in medical abortion allow nursing to be safely continued without interruption.**

IS PREGNANCY LOCATION REQUIRED IN VERY EARLY PREGNANCY? HOW CAN ECTOPIC PREGNANCY BE DIAGNOSED?

More and more women are self-diagnosing their pregnancy very early and presenting for abortion as soon as they miss a period or shortly thereafter. In these cases, the location of the pregnancy cannot be diagnosed, due to its small size.

Although ectopic pregnancy cannot be ruled out, medical abortion can be started without delay if close follow-up (i.e., pre- and post-hCG assay) **after 1 week can be scheduled.** Indeed, side-effects such as pain and bleeding are at their lowest when abortion is performed in very early pregnancy, and increase with gestational age. Furthermore, it has been shown that an existing ectopic pregnancy is diagnosed earlier in women who are given very early medical abortion compared to women with a delayed treatment^a.



There is no need to delay the treatment until a yolk sac or foetal cardiac activity can be seen on ultrasound.

ECTOPIC PREGNANCY

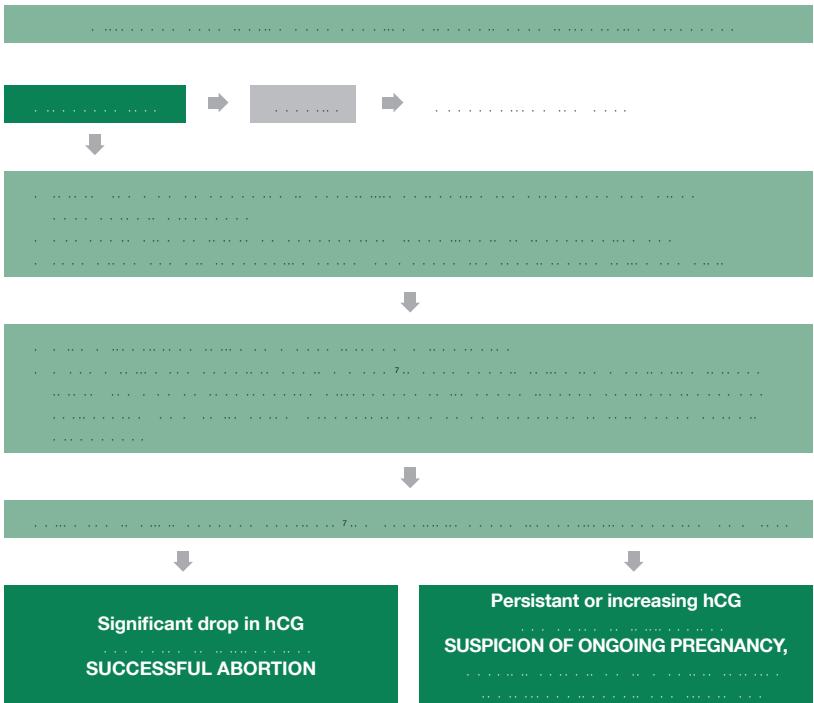
Ectopic/extrauterine pregnancy is a rare but potentially life-threatening event. Failing to detect it in patients coming for abortion in very early pregnancy is therefore one of the main worries of healthcare professionals. **Women with specific signs and symptoms of ectopic pregnancy should be referred to an appropriate gynaecological facility without delay.**

Diagnosis can be difficult, and is actually impossible in very early gestation. Therefore a specific procedure should be used in all facilities, so as to ensure against overlooking any ectopic pregnancy. If this can be implemented, then women in very early pregnancy should be given the option of starting treatment without delay.

Fig.10 shows a model flow-chart for patients presenting very early for abortion.

Bizjak I, et al. Efficacy and safety of very early medical termination of pregnancy: a cohort

Fig.10 Procedure for patients presenting very early for an abortion.



Risks factors for ectopic pregnancy are the following:

- Previous ectopic pregnancy.
- Previous fallopian tube surgery including sterilisation.
- Documented fallopian tube pathology.
- diethylstilbestrol (DES) exposure.
- Previous genital infection (chlamydia, gonorrhoea, pelvic inflammatory disease).
- Infertility.



If ectopic pregnancy is suspected based on specific symptoms, diagnosis must be confirmed and treatment initiated immediately.

Clinical diagnosis of ectopic pregnancy by clinical examination alone is difficult or impossible.

The following signs are possible red flags:

- Constant lower abdominal pain on one side, especially if accompanied by vaginal bleeding and spotting, dizziness or fainting, pallor and, in some women, an adnexal mass touching the uterus.
- Uterine size smaller than expected for the estimated duration of pregnancy.
- Peritoneal irritation signs and pain on moving the uterus.



If medical abortion has been started without prior confirmation that the pregnancy is intrauterine, and the woman has constant severe and increasing pain in the lower abdomen during or after the procedure (with increase in hCG level), ectopic pregnancy must be suspected and appropriate tests performed without delay.

The most reliable way to diagnose ectopic pregnancy is by repeat serum hCG and ultrasound imaging.

A discrepancy between serum hCG levels and ultrasound findings can be suggestive of ectopic pregnancy, even in the absence of clinical symptoms.

However, serum hCG levels are subject to huge individual variations. Published correlations between hCG and ultrasound are therefore only indicative and can diverge significantly between individual patients. The threshold at which an intrauterine gestational sac should always be seen is not known^a.

However, an hCG level above 6,500 mIU/ml (Fig.9, p. 53) with absence of intrauterine gestational sac on vaginal probe can be suggestive of ectopic pregnancy^b.

HCG curves redefined. Obstet Gynecol 2004;104(1):50-5.

GOOD PRACTICE POINTS

1. Pregnancy must be diagnosed with reliable methods such as ultrasound and/or hCG.
 - **Ultrasound** has the advantage allowing reliable dating and diagnosis of associated conditions.
 - **hCG** has the advantage of also being reliable in very early pregnancy.
 - **Gynaecological examination** is not reliable in early pregnancy but can be useful in settings where other forms of diagnosis are not readily available.
2. Where ultrasound scan is used, the facility should, if possible, provide areas where women seeking abortion can be scanned, separate from those for women coming for antenatal care. Abdominal ultrasound should be performed as first-line procedure, and vaginal ultrasound as backup.
3. **Medical abortion should be performed as soon as the patient has made up her mind and ongoing pregnancy has been diagnosed.**
5. In countries where the prevalence of Rh-negative status is high, and in settings with resources, **Rh-typing and anti-D prophylaxis may be offered** as precautionary measures, even though there is no evidence of maternal Rh sensitisation in abortion during the first 9 weeks of amenorrhea.
6. Unless there are specific indications, **cervical cytology and other laboratory tests are not necessary before medical abortion** and the procedure should not be delayed awaiting laboratory or other results unless they are important for the safety of the procedure.

Medical abortion treatment

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WHAT ARE THE RECOMMENDED PROTOCOLS IN EARLY PREGNANCY?

Medical termination of pregnancy using mifepristone followed by misoprostol is a highly effective method (for further information, please see “How does medical abortion work? How do the two medications work?”, p. 19).

The two drugs are to be taken in sequence to be effective in expelling the pregnancy. Simultaneous intake of the two medications is considerably less effective than sequential.



Respect of a time-interval between mifepristone and the prostaglandin is important. Myometrium sensitisation to prostaglandin is maximal with a 36-48 hour interval. When this time-interval is not convenient for the woman or the service organisation, it can be shortened to 24 hours.

For the first trimester of pregnancy, there are numerous protocols according to gestational age and setting. Recommendations usually distinguish very early pregnancy (before 7 weeks of amenorrhoea) from later gestational bands (7 to 9 weeks of amenorrhoea). Although dose and administration route differ between guidelines, the efficacy, safety and acceptability of medical abortion are extremely high in all cases.



Implementation of the medical abortion method must be in accordance with national legislation.

Tab.6 and Tab.7 show the different recommended regimens for early medical abortion, before 7 weeks and between 7 and 9 weeks of amenorrhoea, respectively. All are evidence-based efficacy and safety protocols. The most recent one, from the WHO^a was developed to be cost-effective and allow safe abortion, especially in countries where induced abortion is “legally highly restricted and/or unavailable” and has become “the privilege of the rich”.

Tab.6 Various recommendations for early medical abortion before 7 weeks of amenorrhoea.

Recommendations (Year)		Mifepristone* Dose	Prostaglandin Product, Route (Dose)		Time interval (Hours)
EMA HAS	2007 2018	600 mg	Misoprostol	Oral (400 µg)	36-48
EMA	2007	600 mg	Gemeprost	Vaginal (1 mg)	36-48
		200 mg	Gemeprost	Vaginal (1 mg)	36-48
HAS	2018	600 mg	Gemeprost	Vaginal (1 mg)	36-48
RCOG WHO	2011 2012	200 mg	Misoprostol	Vaginal/ Sublingual/ Buccal (800 µg)	24-48
				Oral (400 µg)	24-48

Tab.7 Various recommendations for early medical abortion between 7 and 9 weeks of amenorrhoea.

Recommendations (Year)		Mifepristone* Dose	Prostaglandin Product, Route (Dose)		Time interval (Hours)
EMA HAS	2007 2018	600 mg	Gemeprost	Vaginal (1 mg)	36-48
EMA HAS	2007 2018	200 mg	Gemeprost	Vaginal (1 mg)	36-48
		200 mg	Misoprostol	Vaginal/Buccal/ Sublingual (800 µg)	24-48

* Oral route.

EMA: European Medicine Agency; HAS: Haute Autorité de Santé (France); RCOG: Royal College of Obstetricians and Gynaecologists (UK); WHO: World Health Organisation.

The following protocol is widely used for pregnancies up to 7 weeks of amenorrhoea: 3 tablets of mifepristone taken orally (200 mg/tablet, total dose: 600 mg), followed 36 to 48 hours later by 2 tablets of misoprostol taken orally (200 µg/tablet, total dose: 400 µg).

The following protocol is widely used for pregnancies up to 9 weeks of amenorrhoea: 1 tablet of mifepristone taken orally (200 mg/tablet, total dose: 200 mg) followed 24 to 48 hours later by 4 tablets of misoprostol inserted vaginally or taken buccally or sublingually (200 µg/tablet, total dose: 800 µg).

HOW SHOULD MIFEPRISTONE AND MISOPROSTOL BE TAKEN?

The following protocol concerns early medical abortion with mifepristone and misoprostol. The different protocols are shown in Tab.6 and Tab.7. For further details on each step of the medical abortion procedure, please see “What information should be given about medical abortion?”, p. 37.

MIFEPRISTONE INTAKE

Mifepristone is taken orally in a single dose. Usually, it is taken in the presence of a healthcare professional, but could be taken safely at home if permitted by local legislation. When mifepristone is taken in the healthcare setting, the woman may leave the facility without further delay.



For pregnancies that have occurred despite an intrauterine device, the device should be removed prior to administering mifepristone.

MISOPROSTOL INTAKE

Misoprostol can be taken at home or in the healthcare facility.



Special caution must be taken in delivering misoprostol tablets. If the blister has been damaged, the misoprostol tablet is not to be taken (loss of efficacy due to humidity in the air)^a.

In women with severe vomiting in early pregnancy, it is preferable to administer the prostaglandin vaginally rather than orally. Another dose of misoprostol can be taken again if bleeding does not start in a menstrual-like way 3 hours after the first dose.



When they can choose, women usually prefer the oral route^b.

WHAT ARE THE MAIN ADVERSE EVENTS ASSOCIATED WITH MEDICAL ABORTION? HOW SHOULD THEY BE MANAGED?

When performed by skilled healthcare professionals with proper equipment, correct technique and standards, abortion is one of the safest medical procedures.



The most frequently reported adverse events in medical abortion are **pain** (caused by uterine contractions) and **vaginal bleeding**.

Diarrhoea, headache, malaise and a rise in body-temperature, which may occur, usually with prostaglandin, are dose-dependent and less frequently reported.

PAIN

Pain is caused both by uterus contractions due to the prostaglandin and by the expulsion of the gestational sac. It is usually greatest in the first few hours after administration of the prostaglandin, and decreases after the pregnancy has been expelled from the uterus.

Pain increases with pregnancy size. It may be milder for earlier pregnancies, in older women and women who have been pregnant before.



Severe constant pain still felt several days after administration of the prostaglandin requires careful attention, as it may be related to infection.

Non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen 600 mg, can be taken systematically following misoprostol^a. Acetaminophen (paracetamol) can also be used but it is less effective than ibuprofen^b. In rare cases of severe pain, codeine (50-60 mg) may be added.

Dawood MY, Khan-Dawood FS. Clinical efficacy and differential inhibition of menstrual fluid prostaglandin F2alpha in a randomized, double-blind, crossover treatment with



Kristina GEMZELL-DANIELSSON: “We always offer ‘prophylactic pain medication’ -that is, NSAIDs- before administration of misoprostol. Reducing pain helps women to relax and thus leads to a shorter induction-to-expulsion interval.”

Abdominal massage, a hot-water bottle or heating pad, sitting or lying comfortably and support from friends and family can all help to relieve pain.



Women should be instructed to take painkillers at the same time as the prostaglandin analogue.

BLEEDING

Bleeding usually occurs a few hours after prostaglandin administration. It is usually heavy, with clots, and lasts for 2 to 4 hours. It then decreases, and slight bleeding continues for an average of about 2 weeks. In some cases, bleeding can continue up to the next menstrual bleeding. Bleeding duration and volume increase with pregnancy duration and are greater after 7 weeks of amenorrhea than in very early pregnancy.

Bleeding can best be managed if women are counselled on what to expect and when to seek treatment if bleeding becomes very heavy or persists for a long time. In addition, women should have adequate access to emergency back-up facilities and healthcare professionals on a 24 hour-basis in case of excessive bleeding (for further details, please see “Haemorrhage”, p. 76).



Christian FIALA: “Prolonged slight bleeding does not increase the risk of infection and is not a medical indication to abstain from sexual intercourse.”

The following questions can help the healthcare professional to determine bleeding severity:

- “Did you take mifepristone?”; “Did you take misoprostol?”
- “Did you take other medicines?”
- “How many sanitary towels did you use during the last 2 or 3 hours?”
- “Did you see clots?”; “Did you see the pregnancy?”
- “Is the bleeding continuous or episodic?”
- “Do you have other clinical signs (malaise, faintness or weakness)?”

Excessive bleeding is considered as soaking more than 2 or 3 sanitary pads per hour for more than 2 or 3 hours.

In the vast majority of cases, no treatment is needed. However, in case of signs of severe bleeding the woman should be given uterotonic medicine or be transferred to a hospital.

GASTROINTESTINAL SIDE-EFFECTS

Nausea and vomiting are frequent pregnancy-related symptoms. In some cases they may become worse with treatment. Diarrhoea can be caused by the action of prostaglandin on the intestinal muscle fibres. **Gastrointestinal side-effects are transient and dose-related.** They usually occur within the hour following administration and last for 1 to 2 hours.

In case of severe symptoms, anti-emetic and anti-diarrhoeic drug treatments should be provided.

OTHER CLINICAL SIGNS

Transient (1 to 3 hours) rise in **body temperature** may occur after prostaglandin administration. Symptomatic treatment and reassurance can be provided.



Any body temperature of 38°C or higher lasting for more than 3 hours or occurring more than 12 hours after prostaglandin administration must be explored (possible infection).

Shivering, hypothermia, malaise and abnormal vaginal discharge may be associated with infection, and are indications that the woman requires medical attention.

Transient headache occurs in approximately a quarter of women undergoing medical abortion. Reassurance, and analgesia if needed, may be provided.

WHAT ARE THE POSSIBLE COMPLICATIONS OF MEDICAL ABORTION? HOW ARE COMPLICATIONS TO BE PREVENTED AND MANAGED?

Complications after medical abortion are rare, and include severe haemorrhage and infection (continuing pregnancy being counted rather as treatment failure).

Before prescribing mifepristone, women must therefore be informed about the low risk of these events. **Women have to know whom to call and what to do** (including going to an Emergency Department if none of the provided contact-persons are reachable) **if they experience sustained fever, shivering, severe abdominal pain, prolonged heavy bleeding, or fainting.**

HAEMORRHAGE

Prolonged or heavier than menstrual bleeding is an expected effect of medical abortion. **Bleeding excessive enough to warrant either blood transfusion or back-up curettage (aspiration) is extremely rare** (0%-0.2% and 0.3%-2.6% of cases, respectively).

Every facility must be able to stabilise and treat women with haemorrhage, or refer them elsewhere, as quickly as possible.

- If there is evidence of haemodynamic shock, intravenous fluids should be administered.
- If bleeding is particularly profuse or prolonged, surgical intervention may be required.
- Transfusion should be performed only if clearly medically required.

Women should be advised to seek immediate medical attention if they experience prolonged heavy vaginal bleeding, as it may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed.

INFECTION

The genital tract is more susceptible to ascending infection when the cervix is dilated after abortion or childbirth. Infection (endometritis, pelvic inflammatory disease, PID) is a rare complication but depends on individual risk factors. While the risk in medical abortion is lower than in the surgical method, it still exists and is similar to that found in spontaneous abortion. Infection has been reported in less than 5% of women after medical abortion.

Common symptoms of infection include fever or chills, foul-smelling vaginal or cervical discharge, persistent abdominal or pelvic pain, prolonged vaginal bleeding or spotting, and uterine tenderness.



Severe pain after completed expulsion can be related to infection and requires careful attention, even in the absence of fever.

When infection is suspected and/or diagnosed, antibiotics should be administered and, if retained products of conception are a likely cause of the infection, the uterus should be evacuated and antibiotics administered. Hospital admission may be necessary in case of severe infection.

Antibiotic prophylaxis is prescribed in some countries (e.g., the UK), for reasons based on cost-effectiveness and local frequency of infection.

Routine use of prophylactic antibiotics is not recommended^a.



Aubert AGOSTINI: “Complications following medical abortion are rare but potentially serious. In order to diagnose and treat them as soon as possible, women should be informed on three issues before beginning medical abortion:

- For which symptoms they must contact the centre (fever, haemorrhage...)?
- Who can they contact during medical abortion?
- Where they must go if they need medical support?”

OTHER COMPLICATIONS

The vast majority of women who have a medical abortion will not suffer any long-term effects on their general or reproductive health. On the contrary, the present pregnancy confirms fertility and the next ovulation usually occurs 10-14 days after medical abortion.

WHAT MUST THE WOMEN KNOW BEFORE TAKING THE FIRST DRUG?

Women should be aware of:

- The irreversibility of the process that cannot be stopped; most women (60-80%) will expel the pregnancy even if they do not take the prostaglandin.
- The dates of the forthcoming visits.
- The possibility (< 5% of cases) of bleeding after taking mifepristone.
- The possibility of expulsion (3%) after taking mifepristone.
- How to take the prostaglandin (if to be taken at home) and repeated doses.
- The amount of bleeding and pain they can expect (which may be significantly stronger than normal menstrual cramps).
- The usefulness of ibuprofen or acetaminophen/paracetamol to relieve pain.
- How and when to seek urgent medical attention.
- The use of sanitary pads to manage bleeding.
- When to start contraception, and with which method.
- How the success of abortion will be checked.

In very rare cases medical abortion is not effective and the pregnancy continues. The teratogenic risk to the foetus in these situations is at present unknown; the woman should therefore be aware that if medical abortion fails and she has an ongoing pregnancy:

- Then termination should be completed by either medical or surgical abortion.
- If she wishes to continue with the pregnancy, careful ultrasound monitoring is advised, as malformation risk cannot be ruled out (For further details, please see “Is there a risk of foetal abnormality after unsuccessful medical abortion?”, p. 93).

Women should be aware that mifepristone and misoprostol are absorbed rapidly when taken orally. Consequently, if vomiting occurs 1.5 hours or more after taking either drug, there is no need to take the drug again.

Finally women must be aware that **fertility resumes immediately after medical abortion**. It has been shown that ovulation may occur as early as 10 days after a first-trimester abortion and, in one study, up to 78% of women had ovulated by 6 weeks. Consequently, they are able to become pregnant again almost immediately.

WHICH METHODS OF CONTRACEPTION CAN A WOMAN USE AFTER MEDICAL ABORTION?

The woman should be provided with accurate information to assist her in choosing the most appropriate contraceptive method to meet her needs. However, the final choice must be her own.



Contraception should be started immediately after medical abortion. Women who do not start a contraceptive method immediately should be encouraged to use condoms and receive information (or a prescription in some countries) for emergency contraception.

Women may start:

- Hormonal contraception on the day of prostaglandin intake or the day after.
- Intrauterine device use immediately after expulsion or during the follow-up visit, which should be done as early as possible after the abortion.
- Caps, sponges, diaphragms, spermicidal foams, jellies or vaginal tablets as soon as sexual intercourse is resumed.
- Methods based on fertility awareness once regular menstrual cycles have resumed.

For further details, please see “When should contraception be started after abortion?”, p. 89.

GOOD PRACTICE POINTS

1. **Medical abortion using mifepristone followed by misoprostol is a highly effective medical procedure.** Oral misoprostol is effective before 7 weeks of amenorrhoea. Beyond 7 weeks, misoprostol should be taken via another route (vaginal, sublingual, or buccal).
2. **Medical abortion is a very safe medical procedure:** serious adverse events (haemorrhage or infection) are rare and the most common adverse events (pain, bleeding and gastrointestinal disorders) directly related to abortion and/or prostaglandin effects are the same as those found in case of miscarriage.
3. **Women must be informed of the risk of severe adverse events, be able to identify clinical signs that help to diagnose these complications, and know what to do in these cases.**
4. Very rare cases of fatal toxic shock caused by *Clostridium sordellii* endometritis presenting without fever or other obvious symptoms of infection have been reported in different situations such as delivery and spontaneous abortions as well as with medical abortion.
5. **Analgesic drugs** (ibuprofen or acetaminophen/paracetamol) as well as such simple techniques as a hot water bottle, abdominal massage, etc. **can be used to relieve pain.** Prophylactic antibiotics are not routinely required for medical abortion.
6. Medical abortion drugs (mifepristone or misoprostol) should be taken again in case of vomiting within 1.5 hours of intake.

Post-abortion care

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WHAT IS THE PURPOSE OF FOLLOW-UP AFTER MEDICAL ABORTION?

The purpose of follow-up after medical abortion is to confirm that the pregnancy has been successfully terminated.

Further goals are:

- To ensure that effective contraception has been commenced.
- To detect, treat, and follow up any complications.
- To provide psychological support.

However, rather than waiting for a follow-up visit before starting contraception, women should be advised to begin immediately after the medical abortion.

Furthermore, complications such as haemorrhage or infection may occur before a scheduled follow-up visit. Women should therefore be given clear advice about signs and symptoms that may indicate a complication, and be advised to seek prompt medical advice.

Only a minority of women experience ongoing psychological difficulties after an abortion. Rather than a routine follow-up visit, women should be provided with information about where they can seek advice and support after the abortion if they do experience ongoing grief or sadness.



If the woman has expelled the pregnancy on hospital/clinic premises and passage of products of conception has been confirmed by an experienced clinician, then no routine follow-up is necessary unless bleeding (heavier than regular menses) persists for more than 9 days.

HOW TO EXCLUDE AN ONGOING PREGNANCY?

ULTRASOUND

An ultrasound scan will reliably exclude ongoing pregnancy if an intrauterine pregnancy was visible on ultrasound before treatment. Blood clots or thick endometrium are common ultrasound findings in the uterine cavity, and are not usually clinically relevant.

Ultrasound can increase the standard of care and facilitate medical abortion, but can be expensive and is therefore not always available. Ultrasound can lead inexperienced clinicians to carry out unnecessary interventions (evacuation of the uterus) due to the presence of ultrasonically visible but clinically unimportant blood clots^{a-f}.



Christian FIALA: “A frequent mistake is to misdiagnose the intrauterine blood clots as residual products of conception. Indications for back-up curettage should therefore be based on clinical signs instead of ultrasound findings, except in the case of ongoing pregnancy”.



In the case of a very early pregnancy, ultrasound is not useful to confirm expulsion. Follow-up should be based on hCG measurement.

a

Reeves MF, et al. Endometrial thickness following medical abortion is not predictive of

Fiala C, et al. Verifying the effectiveness of medical abortion; ultrasound versus hCG

HCG TESTING COMBINED WITH INTERVIEW ABOUT BLEEDING AND PREGNANCY SYMPTOMS

Within 24 hours of misoprostol intake, there is a marked decrease (70%) in serum hCG level, followed by a more gradual decline. By 2 weeks after medical abortion, hCG levels are reduced by 99%^a. It takes about 7 to 8 weeks for hCG to become undetectable^b.

Serum measurements of hCG before and after medical abortion have been used to exclude ongoing pregnancy^b. In a study of women at less than 7 weeks of amenorrhea, a fall in hCG of less than 20% of the initial value had a positive predictive value of 95%. However, serum hCG testing is time-consuming and serum hCG level correlates very well with urine concentrations^c.

Although the usual urine pregnancy tests on their own are not a sufficiently reliable method for detecting ongoing pregnancy, low-sensitivity urine pregnancy tests (LSUP) can, in combination with a series of questions about bleeding and presence of pregnancy symptoms, be used to screen for ongoing pregnancy^{d-f}.

a

^b *Fiala C, et al. Verifying the effectiveness of medical abortion; ultrasound versus hCG*

c

d

^e *Perriera LK, et al. Feasibility of telephone follow-up after medical abortion. Contraception*

f

Women who screen positive on the basis either of a positive LSUP or of minimal bleeding during the treatment or ongoing pregnancy symptoms at follow-up require a confirmatory ultrasound or serum hCG testing.



The urine pregnancy test can be performed by the woman herself at home or, if preferred, in the facility. Special low sensitivity urinary pregnancy tests (LSUP) should be used, as normal pregnancy tests can remain positive for up to 6 weeks after a successful abortion.

An LSUP that detects urine hCG levels of 1,000 IU has been used at 2 weeks after medical abortion, in combination with questions about bleeding and symptoms, to screen for ongoing pregnancy^a.

The high-sensitivity urine pregnancy test (HSUP), which detects lower levels of urine hCG (in the region of 25 IU), usually found in pharmacies cannot be used until 4 weeks after medical abortion^b.

This method of follow-up can be conducted via a telephone call to the woman (if she is at home), together with a self-performed LSUP at 2 weeks (or HSUP at 4 weeks).



Marek LUBUSKY: “The main goal of follow-up after medical abortion is to exclude ongoing pregnancy. Women should be informed in detail about the potential risks and solutions; their informed consent should be obtained.”

WHEN SHOULD CONTRACEPTION BE STARTED AFTER ABORTION?

Medical abortion has no adverse effects on fertility or the outcome of a subsequent pregnancy. Ovulation may return as early as 8 to 10 days after an induced abortion with no difference between medical and surgical abortion, and 83% of women have ovulation during the first cycle after abortion^{a,b}. In addition, more than 50% of women have been found to reinstate sexual activity within two weeks after the induced abortion^c.



Contraception should be started immediately after medical abortion.

A significant proportion of abortions are repeat abortions. Postponing contraception is associated with the highest rate of repeat abortion^d. Women who start using an intrauterine method immediately after their abortion have a significantly lower rate of repeat abortions.

The WHO's Medical Eligibility Criteria and Selected Practice Recommendations for Contraceptive Use (WHOMECS and WHOSPR, respectively) provide evidence-based recommendations on eligibility for methods and on maximising effective contraceptive use. The WHOSPR advises that all hormonal methods (pills, injectables, implants, patches, rings) can be started on the same day as misoprostol administration.

Commencing a combined hormonal pill does not affect the number of days of bleeding or measured blood loss after early medical abortion^e. While there is no direct evidence, it seems likely that this is also the case for combined hormonal contraceptives by other routes (transdermal, vaginal).

Boesen HC, et al. Sexual behavior during the first eight weeks after legal termination of

WHEN TO INSERT AN INTRAUTERINE DEVICE? WHEN TO INSERT AN IMPLANT?

INTRAUTERINE DEVICE

Early insertion of the copper intrauterine device (IUD) or levonorgestrel intrauterine system (IUS) is safe, well-tolerated, and is not associated with an increased risk of expulsion or complication. Women are more likely to return for IUD/IUS fitting and less likely to have had prior unprotected intercourse if fitting is scheduled soon after the abortion. Early fitting should be routinely suggested for women undergoing first-trimester medical abortion^{a,b}.

Intrauterine contraceptives (IUD/IUS) can be inserted immediately after expulsion or during the follow-up visit, which should be done as early as possible after the abortion. Endometrial thickness, residual intrauterine material or elevated hCG levels do not predict IUD/IUS expulsion. Women who postpone IUD/IUS insertion to follow-up at 3-4 weeks after the abortion are at higher risk of a new unplanned pregnancy^c.

Women who choose to have an IUS after abortion have significantly fewer days of heavy bleeding after the procedure^d.

If insertion of an IUD/IUS has to be delayed, then the woman should be provided with an interim method of contraception to use after the abortion, until the IUD/IUS can be inserted.

IMPLANTS

They should be inserted on the day of mifepristone intake. Early insertion will have no negative impact on the abortion process but results in significantly lower risk for repeated unplanned pregnancy within the year after the abortion^e.

WHAT PSYCHOLOGICAL ROLE CAN THE FOLLOW-UP VISIT PLAY?

Although general support and reassurance after an abortion may be appreciated by some women, studies show that most adult women who terminate a pregnancy do not experience mental health problems^a.

Indeed, according to the American Psychological Association

In the same way, a population-based cohort study involving 84,620 Danish girls and women showed that the risk of mental disorders was not increased after a first-time first-trimester induced abortion^c. Moreover, in adult women with unplanned pregnancy,

single elective first-trimester abortion or deliver that pregnancy”

Studies have shown that for most women stress levels fall after the abortion, since it is a solution to the stress caused by the unwanted pregnancy^{d,e}. **Women should, however, be provided with information about where they can seek advice and support after the abortion if they experience ongoing grief or sadness.**

Women with risk factors for psychological problems after abortion (including lack of social support, ambivalence about the abortion, and membership of a cultural/religious group that considers abortion to be morally wrong) should be identified prior to the abortion, and offered additional counselling after the procedure.

American Psychological Association. APA Task Force finds abortion not a threat

Munk-Olsen T, et al. Induced first-trimester abortion and risk of mental disorder. N Engl J Med 2011;364(4):332-9.

HOW TO MANAGE FAILURE OF MEDICAL ABORTION?

HOW TO MANAGE CONTINUING PREGNANCY?

Medical abortion fails in about 0 to 1.5% of cases^{a,b}.

If the pregnancy is ongoing, mifepristone and misoprostol can be administered again if the patient is still within the legal gestational limit for medical abortion or surgical termination can be conducted.

HOW TO MANAGE INCOMPLETE ABORTION?

Blood clots, thick endometrium or residual products of conception are common findings on ultrasound performed within a few weeks of medical abortion, and are not usually clinically relevant.

If bleeding is not troublesome or heavy, and there are no signs of infection, then expectant management (i.e., waiting for the next menstruation to be passed) can be adopted.

Alternatively, the woman may choose to have further medical treatment with a single dose of misoprostol (600 µg oral or 400 µg sublingual)^c. However, a further medical treatment with misoprostol alone is usually not effective without sensitization of the myometrium with mifepristone. Then, for missed abortion, a new course of medical abortion should be performed: a dose of mifepristone (200 mg oral) followed 24h later by a dose of misoprostol (800 µg vaginal)^d.



Surgical evacuation of the uterus may be carried out only if clinical symptoms are present (mainly heavy or persisting bleeding) or at the woman's request, not on the basis of an abnormal ultrasound finding in the area of uterine cavity or cervical canal.

Morris JL, et al. FIGO's updated recommendations for misoprostol used alone in

In the general population, the incidence of spontaneous malformations is around 2-3%.^{a,b}

If a woman does change her mind:

1. After mifepristone intake, there is no evidence that would justify a medical indication for termination.
2. After misoprostol intake, the woman needs to be informed that:
 - Misoprostol is a teratogen agent.
 - Detecting an ongoing pregnancy is important, because of the increased risk of foetus malformation associated with the medical abortion drugs.

To conclude, if the pregnancy is ongoing and the woman finally decides to continue with the pregnancy, she should be informed in detail about the potential risk of abnormal foetus development (damage to central nervous system and/or extremities have been reported). Antenatal monitoring with a detailed foetal anomaly scan by ultrasound is recommended (cerebellum, limb, central nervous system and facial mass). The pregnancy should be closely followed in specialised centres.

De Vigan C, Khoshnood B, Lhomme A, Vodovar V, Goujard J, Goffinet F. Prevalence and

GOOD PRACTICE POINTS

1. **Verification of successful expulsion is necessary after medical abortion.** This can be done:

- In the facility, using ultrasound or hCG testing, or
- At home, with low-sensitivity hCG urinary tests in combination with assessment of bleeding and the absence of pregnancy symptoms.

There is no need for further follow-up when successful abortion was confirmed in the facility at the time of misoprostol intake.

2. The main goal of follow-up is to exclude ongoing pregnancy. Women should be informed in detail about the potential risks and solutions.
3. Clinicians should be aware that, when ultrasound is carried out routinely after medical abortion, blood clots or thick endometrium are common findings. They are not an indication for evacuation of the uterus. **The decision to perform an evacuation of the uterus should only be undertaken on the basis of clinical signs or symptoms (mainly bleeding or persisting bleeding) and NOT on ultrasound findings alone.**
4. Rather than attending a clinic for follow-up, it may be considered appropriate for women (depending on how far they live from the facility, and on their preference) to have telephone follow-up. This would enquire about post-abortion bleeding and pregnancy symptoms, the results of a self-performed low-sensitivity urine pregnancy test, as well as contraceptive use.
5. **If medical abortion fails and the woman wishes to continue with an ongoing pregnancy,** she should be informed that **regular antenatal monitoring and repeated ultrasound scans** are important, because of the potential harmful effects on the foetus associated with the medical abortion drugs.
6. Contraception should not be delayed and should be commenced at the time of abortion, since fertility resumes immediately after medical abortion.

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ARE THERE SPECIFIC MEASURES TO APPLY IN CASE OF ...?

Q1. MULTIPLE PREGNANCY (CURRENT GESTATION)

The same medical abortion drug and dosage regimen can be used to treat multiple pregnancy.

Q2. PREVIOUS CAESAREAN SECTION(S)

The safety and efficacy of early medical abortion are unaffected by previous caesarean section(s) when conducted up to 9 weeks of amenorrhea. If the woman chooses medical abortion, it should be performed as usual. Cases of uterine rupture (rare) have only been reported at later stages.

Q3. UTERINE MALFORMATION (CONGENITAL OR ACQUIRED) OR PREVIOUS CERVICAL SURGERY

When medical abortion is conducted up to 9 weeks of amenorrhea, there is no evidence that uterine malformation (congenital or acquired) or previous cervical surgery represent contraindications, except malformation without possibility of vaginal access which requires abdominal surgery (rudimentary uterine horn). If the woman chooses medical abortion, it should be performed as recommended.

Q4. BREASTFEEDING WOMEN

In practice, in medical abortion, the dosage of mifepristone and misoprostol allows nursing to be safely continued without interruption. (For further information, please see: "What are the contraindications and precautions for use for medical abortion?", p. 60).

Q5. OVERWEIGHT WOMEN

The same medical abortion drug and dosage regimen can be used in women who are overweight or obese.

If the woman chooses medical abortion, it should be performed as recommended.

Q6. WOMEN WITH VERY LOW BODY WEIGHT

The same medical abortion drug and dosage regimen can be used in women who are underweight. Both products have very wide safety margins.

If the woman chooses medical abortion, it should be performed as usual.

Q7. ALLERGY TO GLUTEN, CHICKEN PROTEIN, MILK PROTEIN

There is no evidence of cross-allergies. Neither mifepristone (Mifegyne[®], Mifepristone Linepharma, Miffee[®]) nor the widely used misoprostol (Cytotec[®]/Cyprostol[®], MisoOne[®], Topogyne[®], Mispregmol[®], and Gymiso[®]) products contain any lactosis. If the woman chooses medical abortion, it should be performed as usual.

Q8. CONTROLLED ASTHMA

Mifepristone has antiglucocorticoid effects. The efficacy of long-term corticosteroid therapy, including inhaled corticosteroids in asthma patients, may therefore be diminished during the 3 to 4 days following intake of mifepristone. Asthma therapy should be adjusted^a.

It is recommended to double the dose inhaled for 2 days after mifepristone intake.

Q9. HIGH PLATELET COUNT

Women with high platelet count can have medical abortion; however, the cause should be ascertained.

Determination of the cause should not delay treatment.

Q10. LOW PLATELET COUNT

Caution and clinical judgement are required in cases of women with low platelet count. The risk of bleeding must be discussed.

Q11. ANTICOAGULANT THERAPY

Anticoagulant therapy is not a contraindication to medical abortion; however, as bleeding may be increased, medical abortion should be avoided in women under anti-coagulant therapy.

Q12. DIABETES

There is no evidence that a different dosage regimen is required in diabetes, whether insulin- or non-insulin dependent. If the woman chooses medical abortion, it should be performed as usual. However, insulin-dependent women may need therapy adjustment due to termination of the pregnancy and the possibly associated stress of the procedure.

Q13. CONTROLLED THYROID GLAND DISEASE

No interaction has been shown. Because treatment is limited (one dose of mifepristone and one dose of prostaglandin), it has in theory no effect on thyroid hormone.

If a woman with controlled thyroid gland disease chooses medical abortion, it should be performed as recommended.

Q14. EPILEPSY

Epilepsy is not a contraindication to medical abortion. Drug interactions with anti-epileptics are unknown. However, although specific drug or food interactions with mifepristone have not been studied, its metabolism by CYP 3A4 makes it possible that certain anticonvulsants (phenytoin, phenobarbital, carbamazepine) may induce mifepristone metabolism (lowering the serum level).

If the woman chooses medical abortion, it should be performed as recommended.

Q15. WOMEN TAKING DRUGS FOR PSYCHOLOGICAL/PSYCHIATRIC DISORDER

There is no pharmacological problem in carrying out medical abortion in women under treatment for psychological/psychiatric disorder, although no interaction studies have been conducted.

However, the process takes several days and the woman needs to comply with the complete process, which may pose a problem in some cases.

WHAT DO THE WOMEN WANT TO KNOW?

Q1. WHAT ARE THE ADVANTAGES OF MEDICAL ABORTION?

The major advantage of medical abortion is that the termination can be carried out very early in gestation and neither surgery nor anaesthesia is necessary. The treatment can be done at home, which increases privacy and flexibility.

Q2. WHICH IS THE BEST METHOD? "WHICH WOULD YOU CHOOSE?"

There is no "best method", and also no worst method. All methods are highly effective and safe, and there is ample experience with all of them. The decision is yours, taken according to your own situation and preferences.

Q3. WHICH IS THE NATURAL METHOD?

Induced abortion is not a natural event; however, the medical method may be perceived by many women as being "more natural" than surgery because the clinical presentation and course are indistinguishable from spontaneous abortion or miscarriage.

Q4. IS MEDICAL ABORTION SAFE AND CAN I STILL HAVE CHILDREN AFTERWARDS?

Both of the medical abortion drugs have been extensively studied and are known to be safe. Possible complications, which are rare, are described in the patient information notice. Future fertility and childbearing are not affected.

Q5. ARE REPEATED ABORTIONS DANGEROUS?

A single abortion has no negative effect and does not leave any trace. Consequently, there is no reason to believe that repeated medical abortion has any adverse effects on a woman's physical or psychological health. Contraception is the best way to prevent unwanted pregnancies.

Q6. IS ABORTION PAINFUL FOR THE EMBRYO?

There is no feeling and no perception of pain felt by an embryo at that stage of pregnancy.

Q7. I'M WORRIED THE TREATMENT WON'T WORK. CAN MEDICAL ABORTION FAIL?

Medical abortion has very high efficacy: > 95%. There are few other treatments in medicine with such a high efficacy.

Ongoing pregnancy occurs in only about 1 in 100 cases.

Q8. IF THE TREATMENT FAILS, COULD I REPEAT?

Medical abortion has very high efficacy, but can fail in rare cases. It is safe to repeat the treatment.

Q9. IS IT SAFE TO USE THE SECOND DRUG, MISOPROSTOL, AT HOME?

The use of misoprotol at home is safe, and is the standard in many countries. There is no increased risk with home use.

Most women prefer the home use because it is more comfortable and protects their privacy.

Q10. I HAVE HAD A MEDICAL ABORTION 2 WEEKS AGO, I WAS WORRIED THE TREATMENT WOULDN'T WORK AND I CARRIED OUT A PREGNANCY TEST TO BE REASSURED. MY PREGNANCY TEST IS POSITIVE: WHAT SHOULD I DO?

A positive test some days after abortion is normal. Most chemical tests for pregnancy look for the presence of the pregnancy hormone hCG in urine, and after abortion the hCG level decreases only slowly. Usually 4 to 6 weeks are required to have a negative hCG test.

Other signs or clinical symptoms that you may still be pregnant are:

- You have had little or no bleeding after the treatment (< 4 days).
- You still feel pregnant.
- You have not had your next period as expected after treatment (Fig.11, p.103).

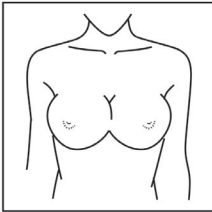
This may indicate that the pregnancy is ongoing, and you should consult your abortion care professional immediately.

Fig.11 Example of an information form helping women to know if they are still pregnant.

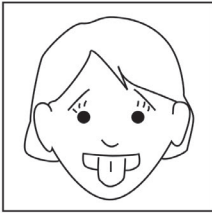
Please remember you might still be pregnant after a medical abortion treatment if you have any of the following:



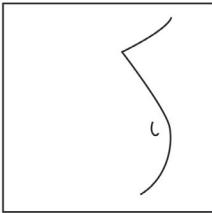
Please contact us if you have not bled within 24 hours of treatment or if you have less than 4 days of bleeding, or:



Tender breasts, or:



Feeling sick, or:



Tummy growing, or:



You do not have a period by 1 month after treatment.

Q11. HOW LONG DO I HAVE TO BE OFF WORK/SCHOOL?

Frequently, there is heavy bleeding and pelvic pain for a few hours after taking the prostaglandin; we recommend women not to work during that time. Most women return to work or school the day after the prostaglandin intake.

Q12. I'M A WORKING WOMAN, AND IT IS VERY DIFFICULT FOR ME TO RETURN TO THE HOSPITAL/CLINIC MANY TIMES. CAN I DO THE FOLLOW-UP MYSELF, WITHOUT WASTING MORE TIME?

Yes, you can use a low-sensitivity urine pregnancy (LSUP) test such as ToP®.

Q13. HOW LONG AFTER MEDICAL ABORTION CAN I USE THE LSUP TEST?

After 10-28 days post-abortion. This is only possible for intrauterine pregnancies.

Q14. HOW LONG AFTER MEDICAL ABORTION CAN I RESUME SEXUAL INTERCOURSE?

As soon as you want. There have been no studies of the question.

Q15. WHEN IS THE NEXT CYCLE AFTER MEDICAL ABORTION?

Your body starts a new cycle immediately after medical abortion. Consequently, most women will ovulate 2 weeks later and have their next period in 4 weeks. After medical abortion, the next menstruation may be slightly heavier than normal.

Q16. HOW MUCH WILL I BLEED?

Heavy bleeding and passing clots is common in medical abortion during the first days. Afterwards, lighter bleeding is common for an average of 14 days. If the bleeding continues to be heavier than your usual menses for more than 5 days, consult your healthcare professional.

Q17. HOW WOULD I KNOW THAT I HAVE TO VISIT A HEALTHCARE PROFESSIONAL IF THERE'S A PROBLEM?

You will have to contact and possibly consult a healthcare professional in case of:

- Heavy bleeding (more than 2 or 3 pads used every hour for more than 2 or 3 hours).
- Prolonged heavy bleeding (heavier than your usual menses for more than 5 days).
- Severe abdominal pain after expulsion.
- Sustained fever.
- Abdominal pain or discomfort or general malaise (including weakness, nausea, vomiting or diarrhoea) more than 24 hours after taking misoprostol.

Q18. HOW PAINFUL IS IT? I'M AFRAID OF PAIN.

There are huge differences in pain from women to women. Medical abortion causes mild to very strong cramping throughout and after the termination process. Cramping is usually worse for about 4-8 hours after prostaglandin, especially while the pregnancy is being expelled. Milder cramps may continue for several days to 2 weeks.

Fear of pain is understandable. Many women experience cramps and lower abdominal pain, usually after taking prostaglandin. But some women do not experience any pain.

Painkillers will be prescribed to you and you can take them 30 minutes before misoprostol intake and repeat during the procedure if you have pain. The painkillers used during medical abortion are highly effective and safe.

If you are afraid of pain, you may discuss staying in hospital/clinic for a few hours or choose surgical abortion.

Q19. WILL I SEE THE FOETUS?

—

HAT DOL INEED TO BRING TO THEHOSPITAL/ABORTION ?

Q22. CAN I USE TAMPONS DURING OR AFTER MEDICAL ABORTION?

During the first day following prostaglandin intake, you are advised not to use tampons, because the gestational sac cannot be absorbed by the tampon. No increased risk of infection has been found if a tampon is used.

Q23. CAN I TAKE SHOWERS AFTER MEDICAL ABORTION? CAN I HAVE A BATH?

You can take a shower at any time. During the first 2 days following medical abortion, it is preferable not to have a bath or to swim.

Q24. IS THERE A DIFFERENCE BETWEEN MEDICAL ABORTION AND EMERGENCY CONTRACEPTION (ALSO KNOWN AS THE "MORNING AFTER" PILL)?

Yes, medical abortion and emergency contraception are totally different. Medically, the beginning of pregnancy is defined as the implantation of a fertilised egg in the lining of the uterus. This begins 5 to 7 days after fertilisation and is complete several days later.

Emergency contraceptives work before fertilisation takes place and prevent ovulation. If a woman takes emergency contraception when she is already pregnant, it will not make any difference to the pregnancy and will not induce abortion.

Q25. WHY MUST I START CONTRACEPTION IMMEDIATELY AFTER ABORTION?

Your current pregnancy confirms that you are fertile. Abortion has no impact on your fertility. Most women are fertile immediately after the abortion. The risk of pregnancy is just the same after abortion. Contraception is the best method to avoid unwanted pregnancy. You should discuss with your physician/midwife/nurse which is the best method for you. Combined hormonal contraception (pill, ring and patch) and oral progestins could be started on the day of misoprostol intake; injection and implant could be started on the day of mifepristone intake and intrauterine contraceptives (hormonal and non-hormonal) could be inserted immediately after expulsion or at follow-up visit (see more details on p. 90).

WHERE CAN FURTHER INFORMATION BE FOUND?

- ABORT report (<https://abort-report.eu>).
- Abortion Clinics in Europe (www.abortion-clinics.eu).
- Abortion Info – Everything about abortion (<http://abortinfo.com>).
- Fiala C, Gemzel-Danielsson K. Review of medical abortion using mifepristone in combination with a prostaglandin analogue. *Contraception* 2006;74(1):66-86.
- Fiala C. Schwangerschaftsabbruch mit Mifepriston und Misoprostol. Fachinformation für Frauenärztinnen und Beraterinnen. Frankfurt am Main, May 2008.
- Gynuity Health Project. Providing medical abortion in low-resource settings: an introductory guidebook. 2nd ed. New York 2009, 70 pages.
- Haute Autorité de Santé. Interruption volontaire de grossesse par méthode médicamenteuse. Recommandations de bonne pratique. Décembre 2010 [In French] (https://www.has-sante.fr/portail/jcms/c_961137/fr/interruption-volontaire-de-grossesse-par-methode-medicamenteuse). (https://www.has-sante.fr/portail/jcms/c_961137/fr/interruption-volontaire-de-grossesse-par-methode-medicamenteuse).
- Medical abortion. Gynmed Clinic for Abortion and Family Planning (www.gynmed.at/en/abortion/medical).
- Ministère de la Santé, de la Jeunesse et des Sports. Interruption volontaire de grossesse. Dossier-guide. 2010, 44 pages.
- Mifegyne. La pilule d'avortement (<http://mifegyne.info>).
- misoprostol.org. Safe usage guide for Obstetrics and Gynaecology (<http://www.misoprostol.org/>).
- MToP Passeport (<http://exelgyn.com/widget>).
- Paul M, Stewart FH, Weitz TA, et al. Early abortion training workbook. UCSF Center for Reproductive Health Research and Policy, San Francisco, CA (2003) (<http://www.teachtraining.org/trainingworkbook/earlyabortiontrainingworkbook.pdf>).
- RCOG Royal College of Obstetricians and Gynaecologists. The care of women requesting induced abortion. Evidence-based clinical guideline number 7, November 2011 (https://www.rcog.org.uk/globalassets/documents/guidelines/abortion-guideline_web_1.pdf).
- World Health Organization (WHO). Medical Management of Abortion. WHO 2018, 54 pages (<https://www.who.int/reproductivehealth/publications/medical-management-abortion/en>).
- World Health Organization (WHO). Safe abortion: technical and policy guidance for health systems. WHO Geneva, Switzerland 2012, 124 pages (<http://www.who.int/reproductivehealth/publications/unsafe-abortion/9789241548434/en/index.html>).