MEDICAL MANAGEMENT OF EARLY PREGNANCY LOSS

TRAINEE REFERENCE GUIDE

Version 0.1

WomanCare GLOBAL | academy

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Acknowledgements

This Reference guide has been adapted from the following sources

RCOG, Ectopic Pregnancy and miscarriage: diagnosis and initial management NICE Guideline [NG126] Last Updated 23 August 2023

Clinical practice handbook for quality abortion care. Geneva: World Health Organization; 2023.
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Abortion care guideline. Geneva: World Health Organization; 2022..
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Best Practice in Post Abortion Contraception Royal College of Obstetricians and Gynaecologists, September 2022
https://www.rcog.org.uk/media/53fhrbz2/post-abortion-contraception-best-practice-paper-2022.pdf

Best Practice in Abortion Care, Royal College of Obstetricians and Gynaecologists, April 2022
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https://www.ipas.org/resource/abortion-care-videos/

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World Health Organization Department of Reproductive Health and Research (WHO/RHR) and Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP), Knowledge for Health Project. Family Planning: A Global Handbook for Providers (2018 update). Baltimore and Geneva: CCP and WHO, 2018.
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CONTENTS

INTRODUCTION

Welcome to the Dkt WomanCare Global Reference Guide for Medical Management of Early Pregnancy Loss. This has been developed as part of our standardised training program for abortion and family planning services.

The Medical management of early pregnancy loss training programme has three components:

- This reference guide, which serves as a background for the course and an introduction to Dkt products for management of induced abortion and early pregnancy loss.
- A Trainer Guide – group training reference guide and slide pack
- A knowledge test which is not assessed

Additionally, Dkt WomanCare has a separate Reference Guide, Trainer Guide and Slide pack to support safe and effective use of medical abortion drugs for early pregnancy loss only.

These programmes are based on evidence-based recommendations for provision of Medical Management of Early Pregnancy Loss services up to 12 weeks gestation.

Who is this guide for?

This content is designed for all individuals who are involved in provision of care of women seeking abortion services. This includes:

- Clinical staff: mid-level providers, nurses, midwives, pharmacists.
- Non-clinical team members such as managers, sales teams, distributors, as well as those from the public sector and other NGOs to ensure services provided are safe, effective, and patient-centred care and of the highest quality as per organisational mission and vision.

RIGHTS-BASED APPROACH

Reproductive health services including post abortion care should be available on the request of woman or girl. Dkt WomanCare Global is committed to the principles of right's based, person-centred care delivered in an enabling environment where there is respect for human rights, a supportive framework of law and policy, availability and accessibility of information within a supportive health system.

Box 1: General Principles of Right's based Abortion Provision. WHO, Abortion Care Guidelines 2022

- Sexual and reproductive health and rights are grounded in a range of human rights recognized and guaranteed in national and international law
- States have a duty under international human rights law to ensure that the regulation of abortion does not cause women and girls to resort to unsafe abortions
- States must provide essential medicines listed under WHO's Action Programme on Essential Drugs
- Treaty monitoring bodies have called for the decriminalization of abortion in all circumstances
- Regardless of whether abortion is legal or restricted, States are required to ensure access to post-abortion care

Overview of Medical Management of Early Pregnancy Loss

Comprehensive abortion care (CAC) services are an essential component of sexual and reproductive health services. CAC includes the provision of information, abortion management (including induced abortion, and care related to pregnancy loss/spontaneous abortion and post-abortion care. Strengthening access to comprehensive abortion care within the health system is fundamental to meeting the Sustainable Development Goals (SDGs) relating to good health and well-being (SDG3) and gender equality (SDG5). [1]

Drugs such as mifepristone and misoprostol provide an alternative to surgical uterine evacuation for women experiencing early pregnancy loss. It is safe and effective for women who take the pills in a health care facility or self-administer at home up to 12 weeks in the first trimester. The option of self-administration means that the woman can opt for privacy and convenience by taking the medication at a time that suits her. This can increase patient satisfaction with the service without reducing safety or effectiveness.

Principles of MA (Medical Abortion) Service Provision

- Any method of abortion should be initiated with no delay to reduce risks as pregnancy gestation increases and to increase patient satisfaction. This means that services should be accessible, available, and affordable.
- Care should be focused on the patient and her needs in a welcoming de-medicalized environment which respect auditory and visual privacy.
- Providers should be trained in counselling and be able to provide information in a non-judgmental manner. There must be complete assurance of patient confidentiality
- Counselling should ensure that the patient is able to make an informed choice without coercion. It should include information on the choice of abortion method, possible complications and need for follow-up especially if complications arise.
- There should be well established referral networks to other sexual health services if these are not provided on site
- All aspects of service provision should be documented
- Providers should achieve basic competencies during training and be aware of the limits of their training especially with respect to gestation of pregnancy and refer to other providers where appropriate

[1] Abortion care guideline. Geneva: World Health Organization; 2022. https://iris.who.int/bitstream/handle/10665/349316/9789240039483-eng.pdf?sequence=1

Definition of Terms

Partly derived from Abortion Care Guidelines, WHO 2022

Medical abortion is the use of pharmacological agents to terminate pregnancy - most commonly mifepristone and misoprostol in combination, or misoprostol alone. These medications can be used for management of induced, spontaneous or incomplete abortion.

Mifepristone blocks the effects of progesterone which is essential for the pregnancy to continue. It also as cervical ripening effects and increases sensitivity of the uterus to contractions.

Misoprostol is a synthetic prostaglandin E1 analogue which has a cervical ripening effect and induces uterine contractions.

Induced abortion is the termination of an ongoing pregnancy using drugs or uterine aspiration.

Spontaneous abortion is the non-induced loss of a pregnancy before 24 weeks gestation. The term miscarriage is used interchangeably with abortion.

Missed abortion: The demise of a pregnancy where the fetus/embryo remain in the uterus and the cervical os remains closed. Symptoms may include pain and/or bleeding, or there may be no symptoms at all.

Incomplete abortion occurs when uterine contents not fully expelled or removed after spontaneous abortion or induced abortion by clinical presence of an open cervical os.

"Unsafe abortion" refers to abortion when it is carried out by a person lacking the necessary skills or in an environment that does not conform to minimal medical standards, or both.

Post-abortion care is defined as the provision of services after an abortion, such as contraceptive services and linkage to other needed services in the community or beyond. It includes optional follow up as requested by the woman. It can also include management of complications after any type of abortion. It should always be provided regardless of whether abortion is restricted in a particular setting.

Telemedicine: A mode of health service delivery where providers and clients, or providers and consultants, are separated by distance. This can include real time on line or phone interactions and follow up of message left by phone/email/SMS. This service delivery approach should be an option offered as alternative to person to person interactions.

Self-management: Self-management of the entire process of medical abortion or one or more of its component steps, such as self-assessment of eligibility for medical abortion, self administration of medicines without the direct supervision of a health worker, and self-assessment of the success of the abortion process.

Surgical aspiration. This involves evacuation of the contents of the uterus through a cannula, attached to a vacuum source. Electronic vacuum aspiration (EVA) requires a power supply and manual vacuum aspiration (MVA) in the form of a hand held syringe.

Gestational age: The number of days or weeks since the first day of the woman's last menstrual period in women with regular cycle. For women with irregular cycles or when last menstrual period (LMP) is unknown, gestational age is the size of the uterus, estimated in weeks, based on clinical examination or ultrasound, that corresponds to a pregnant uterus of the same gestational age dated by LMP.

Comparison of uterine evacuation methods in the first trimester

There is no one method of uterine evacuation that is superior. Medical and surgical evacuation each have advantages and disadvantages, and it is up to the woman to decide what is best for her, given the local clinical context, resources available and gestation. A comparison of medical and surgical procedures is shown in Figure 1.

Figure 1: Comparison of abortion methods and contraindications (from Clinical practice handbook for quality abortion care, WHO 2023)

<12 WEEKS OF GESTATION	
MEDICAL	**VACCUUM ASPIRATION**
• Avoids surgery • Mimics the process of spontaneous miscarriage • Controlled by the woman and may take place at home • Takes time (hours or days) to achieve successful abortion, and the timing may not be predictable • Women experience bleeding and cramping, and potentially some other side-effects (nausea, vomiting) • May require more clinic visits or surveillance than vacuum aspiration *May be preferred in the following situations:* • For severely obese women • In the presence of uterine malformations or fibroids • Prior cervical surgery • For women who want to avoid surgical intervention • If a pelvic exam is not feasible or not wanted	• Quick procedure and completed in a predictable time • Takes place in a health-care facility • Successful abortion easily verified by evaluation of aspirated uterine contents • Sterilization or placement of an intrauterine device (IUD) may be performed at the same time as the procedure • Very small risk of uterine or cervical injury • Requires instrumentation of the uterus • Timing of abortion controlled by the facility and health worker • Can be performed under sedation *May be preferred in the following situations:* • If there are contraindications to medical abortion drugs • If there are time constraints for the abortion
CONTRAINDICATIONS	
• Previous allergic reaction to one of the drugs involved • Inherited porphyria • Chronic adrenal failure • Known or suspected ectopic pregnancy (neither misoprostol nor mifepristone will treat ectopic pregnancy) *Caution and clinical judgement are required in cases of:* • Long-term corticosteroid therapy (including those with severe uncontrolled asthma) • Haemorrhagic disorder • Severe anaemia • Pre-existing heart disease or cardiovascular risk factors • An IUD in place (remove before beginning the regimen)	• There are no known absolute contraindications *Caution and clinical judgement are required in cases of:* • An IUD in place (remove before beginning the procedure)

For women experiencing missed abortion, or for those women presenting with incomplete abortion, expectant management can also be offered. It is important that any woman considering this is counselled that expulsion time may be prolonged, and that there is an increased chance of an incomplete expulsion, meaning a surgical procedure may be required. The success rates of medical, surgical and expectant management of early pregnancy loss are summarised in Figure 2. It is critical that clinical condition is also assessed before embarking on conservative treatment options, for example if there are signs of haemorrhage or infection, expectant management may not be appropriate.

Figure 2: Comparison of method for managing early pregnancy loss
(from Clinical practice handbook for quality abortion care WHO 2023)

METHOD	POTENTIAL ADVANTAGES	POTENTIAL DISADVANTAGES	EFFICACY (%) MISSED ABORTION	EFFICACY (%) INCOMPLETE ABORTION
Expectant management	• May minimize visits • Avoids side-effects and complications of other methods • Avoids intrauterine instrumentation	• Unpredictable time frame • May still require follow-up vacuum aspiration if not successful	16 – 75%	82 – 100%
Medical management	• Avoids intrauterine instrumentation	• May cause more bleeding and need for follow- up than vacuum aspiration • Short-term side- effects from misoprostol	77 – 89%	61 – 100%
Surgical management (vacuum aspiration)	• Quick resolution	• Surgical procedure	96 – 100%	96 – 100%

Provision of Medical Management of EPL services

Healthcare workers providing uterine evacuation services should have training in three key components of service provision:

1. Assessing eligibility (how to assess the woman who requests medical abortion)
2. Administering the medications with full instructions, managing side effects and the procedure
3. Providing information on what happens after the abortion process including how to determine whether it has been successful.

Healthcare workers are eligible to provide medical management of early pregnancy loss services or part of the service range from community health workers, pharmacists, auxiliary nurses, nurses midwives and doctors depending on local regulations.

In some settings, women may be able to administer their own medications at home and some elements of the process themselves – 'self-management'. These elements are:

- self-assessment of eligibility
- self-administration of medicines, and
- self-assessment of the success of the abortion.

Self-management requires provision of the highest quality information on what to expect and where follow up may be required.

Remote support can be provided via telemedicine as well as with healthcare workers in person.

Self-management of the uterine evacuation process should be offered wherever possible for women who would prefer to be at home rather than be treated in a healthcare facility.

Medical abortion >14 weeks gestational age should only be done by an appropriately qualified generalist doctor or specialist.

Assessing eligibility for treatment

Before the medical abortion procedure it is essential to assess eligibility for treatment. The key components are:

Diagnosing the pregnancy

Determining gestational age. This is essential to ensure that the gestation is accurate so that the woman receives the correct doses of medication.

- Medical uterine evacuation at later gestations should be performed in a healthcare facility because of increased risk of bleeding.
- This can be reasonably estimated in most cases as the number of weeks and days from the first day of the last normal menstrual period (LMP)
- Routine ultrasound examination is not necessary unless there is uncertainty about gestational age. request for an ultrasound can also delay the procedure. An ultrasound should be performed however if there is suspicion as an ectopic pregnancy.
- Gestational age can also be estimated with a physical examination with a trained provider where there is further doubt about duration of pregnancy and/or ultrasound is not available

Excluding medical conditions which may be contraindications for treatment.

- These include a known or suspected ectopic pregnancy* and a previous allergic reaction to mifepristone and misoprostol, inherited porphyria and chronic adrenal failure
- Women who have severe uncontrolled asthma, adrenal failure or an inherited porphyria should not use mifepristone
- Women who have bleeding disorders, severe anaemia, or takeblood thinning agents will need careful assessment about the location of procedure and whether medications should be stopped
- An intrauterine device (IUD) must be removed before starting the medical abortion process

The following are *not* routinely required before medical abortion:

- Estimation of haemoglobin unless the woman has symptomatic anaemia.
- Physical examinations including breast examination or cervical cancer screening
- Blood pressure measurement.
- STI screening.
- Prophylactic antibiotics.
- Anti D for women <12 weeks gestation.

* An ectopic pregnancy is where the embryo develops outside the womb. This will typically be in a fallopian tube or, less commonly, in the abdominal cavity, ovary or cervix.

COUNSELLING AND INFORMED CONSENT

Any information provided to the patient, either written or verbal, must comply with the human rights principles of counselling set out in Box 3.

Box 3: Key considerations relevant to the provision of information (developed from WHO Abortion Care guidelines 2022)

KEY HUMAN RIGHTS CONSIDERATIONS RELEVANT TO THE PROVISION OF INFORMATION	
Informed consent requires the provision of complete and accurate, evidence-based information.	
Accurate information on abortion must be available to individuals in a way that respects privacy and confidentiality.	
The right to refuse such information when offered must be respected.	
Abortion information should be available to all persons without the consent or authorization of a third party. This includes abortion information being available to adolescents without the consent or authorization of a parent, guardian or other authority.	
Information must be non-discriminatory and non-biased and presented in a respectful manner. It should not fuel stigma or discrimination and bed and in a manner understandable to/tailored to the individual.	
Dissemination of misinformation, withholding of information and censorship should be prohibited.	
Information should be acceptable to the person receiving it and of high quality; it should be presented in a way that can be understood.	
Throughout the process there should be an ongoing assessment of the woman's understanding of the information provided, openness to answer any questions and to confirm whether her decision is being taken voluntarily.	

Risks and compications

Risks and complications of uterine evacuation procedures are rare. High quality information provided to the patient will result in timely management of any problems when they occur.

TABLE 1: Risks and complications of abortion (from RCOG 2022)

COMPLICATION / RISK	MEDICAL EVACUATION	SURGICAL ABORTION
Continuing pregnancy	1 - 2 in 100	1 in 1000 Higher in pregnancies <7 weeks
Need for further intervention to complete the procedure	<14 weeks: 70 in 1000	<14 weeks: 35 in 1000
Infection*	Less than 1 in 100	Less than 1 in 100
Severe bleeding requiring transfusion	<20 weeks: less than 1 in 1000	<20 weeks: less than 1 in 1000
Cervical injury from dilation and manipulation	-	1 in 100
Uterine perforation	-	1 - 4 in 1000

*Upper genital tract infection is most commonly associated with pre existing lower genital tract infection at time of procedure

Drugs doses and routes of administration

A combination of mifepristone and misoprostol should be used if available as it is more effective than misoprostol alone for women with missed miscarriage. Combination also reduces side effects, decreases the likelihood of failure of the procedure and shortens the time taken to complete the abortion.

There is no lower gestational age limit for medical abortion.

Recommendations for dosages for early pregnancy loss (from Clinical practice handbook for quality abortion care WHO 2023)

RECOMMENDATIONS	COMBINATION REGIMEN		MISOPROSTOL ALONE
	Mifepristone	Misoprostol (always a minimum of 24 hours after mifepristone)	
Missed abortion <14 weeks	200 mg PO once	800 µg vaginally, sublingually or buccal	800 µg vaginally, sublingually or buccal
Incomplete abortion (<14 weeks uterine size)	Not applicable	Not applicable	600 µg oral or 400 µg sublingual

*Repeat doses of misoprostol can be considered (or repeated at the noted interval) when needed to achieve success of the abortion process. WHO guidance does not indicate a maximum number of doses of misoprostol.

It is important to understand the differences between different routes of administration of medications (Table 2). Not adhering to the instructions may lead to a procedure which is less effective.

TABLE 2 : Routes of administration for mifepristone and misoprostol

ROUTE	INSTRUCTIONS FOR USE
ORAL	Pills are swallowed
BUCCAL	Pills are placed between the cheek and gums and swallowed after 20 - 30 minutes
SUBLINGUAL	Pills are placed under the tongue and swallowed after 30 minutes
VAGINAL	Pills are placed in the vaginal fornices (deepest portions of the vaginal), and the woman is instructed to lie down for 30 minutes

- Pain relief should be offered routinely, either non-steroidal anti-inflammatory drugs (or paracetamol (acetaminophen) where these are not an option).
- Stronger analgesics such as codeine may also be offered depending on the clinical picture.
- Conservative measures such as hot water bottles, heat pads may also provide some relief.

Post procedure care

All women should be given written and verbal information after the procedure or when medications are dispensed. It should be remembered that women may require emotional support as well as physical.

Administrative information

- How and where to access follow up services and their opening times and emergency contact numbers. There should be an open door policy for any follow up questions.
- How to access other services that have been discussed such as STI/HIV counselling, gender based violence support services.

Self care guidance

- Thick sanitary pads are recommended when the bleeding is heavy rather than tampons.
- No douching should be performed.
- Regular pain relief in the form of NSAIDs +/- paracetamol, heat pads, hot water bottles and maintain hydration, +/- antiemetic may be required to manage the side effect of misoprostol.
- She can resume sexual intercourse when she feels ready. There is no evidence that sex when bleeding post abortion leads to a risk of infection.
- The next period may take 4-8 weeks to return.

Follow up instructions

- The woman should seek advice if she experiences the following:
  - Excessive bleeding (e.g. soaking more than two pads in one hour for more than two hours).
  - Pain that is not controlled with medication.
  - Any fever greater than 38°C.
  - Offensive vaginal discharge, severe pain or abdominal distention.

There is no need for routine follow up

Management of complications

Be prepared with clear well developed referral pathways to surgical abortion or higher-level facilities

COMPLICATION	SYMPTOMS	TREATMENT AFTER CLINICAL ASSESSMENT
Incomplete abortion	• Bleeding • Abdominal pain	• Expectant management ('wait and see') if patient is stable • Repeat pills • MVA
Infection	• Fever or chills • Foul smelling vaginal discharge • Abdominal pain • Vaginal bleeding	• Admit to hospital • Under antibiotic coverage check for retained products, re- evacuate uterus • **Severe infections may need hospitalisation**

Post procedure contraception

It is important to discuss this during counselling and ascertain if the woman would like to start a particular method immediately.

The following contraceptive methods may be started immediately if there are no restrictions to medical eligibility after surgical or medical procedures:

Combined hormonal contraceptives

- Given the option of starting hormonal contraception immediately after the first pill of the medical abortion regimen.

Progesterone-only contraceptives (POCs) including implants, injections.

Diaphragm, cap.

Intrauterine devices (IUDs) may be started at the time that success of the abortion procedure is determined but not started immediately after septic abortion

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