Guideline

Abortion Medical Management to 9 weeks of Pregnancy

1. Purpose

The Abortion Law Reform Act 2008 allows for the provision of abortion on request for a woman less than 24 weeks of pregnancy. Since 2012, medications for a medical abortion have been available on authority of the Therapeutic Goods Administration (TGA) and listed on the Pharmaceutical Benefits Scheme (PBS) in 2015. This clinical guideline or procedure outlines the requirement for clinicians to plan, prescribe and manage the care of women undergoing medical abortion.

2. Definitions

Women:

This document refers to women to describe those with pelvic anatomy that includes a vagina, a uterus, ovaries, and/or fallopian tubes. It is recognised that not all people with such anatomy identify as women. We encourage the reader to consider the specific needs of non-binary individuals and transgender men and adopt trans-inclusive practice.

MS2Step:

The combined medication regime for medical abortion comprises mifepristone and misoprostol, marketed as MS-2 Step® under licence from MS Health. MS-2 Step®.is a composite pack and consists of mifepristone 200 mg tablet and misoprostol 4 x 200 microgram tablets. The pack is indicated for use in eligible women (see 4.3) for the purpose of a medical abortion of a developing intrauterine pregnancy, up to 63 days of gestation. Mifepristone and misoprostol have been used in overseas jurisdictions for medical abortion in the first trimester pregnancy since the 1980s. The combination of these two medicines is a well-established method for medical abortion and is known to be safe, effective and acceptable to women.
MS-2 Step® is prescribed by a certified Medical Practitioner and dispensed by a certified Pharmacist.

Mifepristone:

Mifepristone is a synthetic steroid with an anti-progestational action as a result of competition with progesterone at the progesterone receptors. This action results in disrupting the attachment of a developing pregnancy.

Misoprostol:

Misoprostol is a synthetic analogue of prostaglandin E1. Misoprostol induces contractions of the smooth muscle fibres in the myometrium and relaxation of the uterine cervix. The uterotonic properties of misoprostol should facilitate cervical opening and evacuation of intrauterine contents.
The combination of misoprostol used in a sequential regimen after mifepristone leads to an increase in the success rate and accelerates the expulsion of the conceptus.

3. Responsibilities

Care of the woman undergoing medical abortion may be provided by a team of health care workers.

- Medical Practitioners oversee and supervise clinical management, obtain informed consent and prescribe MS2Step.
- Nurses and Nurse Practitioners have a recognised role to assess, plan and manage the care of the woman undergoing medical abortion in a task sharing arrangement with the Medical Practitioner.
- Pharmacists dispense the medication.

Medical Practitioners gain prescribing rights and Pharmacists gain dispensing rights based on successful completion of an online training module, see: https://www.ms2step.com.au/

4. Guideline/Procedure

4.1 Choice of method

The request for an abortion and choice of method must be fully considered in a non-judgmental and supportive manner. Obtain psycho-social history to establish suitability for a medical abortion procedure.

4.2 Medical abortion consultation

The medical abortion consultation should establish that the woman:

- has made an informed voluntary choice for medical abortion
- has an intrauterine pregnancy no more than 9 weeks of pregnancy calculated from the first day of last menstrual period or ultrasound
- has no contraindications (see below)
- has a suitable support person available,
- is able to be active in follow-up care
- is able to access an emergency healthcare facility within approximately two hours of road travel.

4.3 Medical abortion can be safely offered to women up to 63days gestation with an intrauterine pregnancy

- who have had a caesarean section,
- have a multi-fetal pregnancy,
- are obese,
- have uterine abnormalities, including fibroids,
- have positive STI pathology and have commenced treatment,
- wish to avoid surgical intervention
- are currently breastfeeding
- are able to commence MS2Step at or before day 63 gestation

4.4 Contraindications: Medical abortion is not suitable in the following circumstances

- Lack of access to emergency medical care within 14 days following administration of mifepristone,
- Suspected or confirmed ectopic pregnancy,
- Intrauterine device (IUD) in place. If an intrauterine contraceptive device is present, it should be removed,
- Uncertainty about gestational age,
- Chronic adrenal failure,
- Concurrent long-term corticosteroid therapy,
- Suspected or known haemorrhagic disorders or treatment with anticoagulants, and
- Hypersensitivity to mifepristone, misoprostol (or any prostaglandin), or any of the excipients used in MS-2 Step.

4.5 Precautions for use

Not recommended in patients with cardiovascular disease, hypertensive disease, hepatic disease, respiratory disease, renal disease, diabetes, severe anaemia, malnutrition, heavy smokers.
It is important that the woman is aware of the risk of teratogenicity associated with misoprostol. Consequently, once MS-2 Step is commenced the woman is followed to completion of the procedure and offered surgical abortion in the case of ongoing pregnancy.

4.6 Risks and complications

Retained products of conception (RPOC)/incomplete abortion	Is uncommon, occurs in approximately 1-4:100 of cases.
Haemorrhage and heavy bleeding	Severe haemorrhage requiring medical or surgical intervention occurs in less than 1:100 of cases. Haemorrhage is defined as blood loss greater than 500ml or severe bleeding requiring transfusion. Heavy bleeding is considered to be 2 (or more) saturated sanitary pads per hour for 2 consecutive hours or passing fist-size clots.
Infection	Less than 1:100 cases
Ongoing pregnancy/failed abortion	Less than 1:100 cases.

4.7 Informed consent

The Medical Practitioner must ensure the patient has understood the following:

- MS2Step process and expected outcome,
- Risks,
- side effects,
- possible complications,
- need for a support person on the day of misoprostol administration,
- access to emergency care, and
- need for follow up care.

Documentation of consent is recorded in the patient clinical notes.

4.8 Baseline investigations

- Pelvic Ultrasound: accurate assessment of gestational age and presence of intrauterine pregnancy, i.e. through visualisation of a yolk sac. Exclude ectopic pregnancy.
- Blood investigations:
  - Quantitative βhCG
  - Full blood count (FBC)
  - Iron studies if indicated
- STI screen: according to risk, minimum requirement bacterial vaginosis, chlamydia, gonorrhoea mycoplasma genitalium and syphilis. For further information see Melbourne Sexual Health Service, STI Tool pdf. https://mshc.org.au/HealthProfessional/MSHCTreatmentGuidelines/STISCREENING

4.9 Dosage and administration of MS2Step

Administer 2 hours before or 2 hours after a meal.
Step 1: Mifepristone: 200 mg (1 tablet) mifepristone oral, followed 36 to 48 hours later by the administration of misoprostol. If vomiting occurs within 1 hour of administration repeat script.
Step 2: Misoprostol: 800 microgram (4 tablets) misoprostol buccal, i.e. kept between the cheek and the gum for 30 minutes, any remaining fragments may be swallowed with water.
If vomiting occurs within 30minutes of Misoprostol administration and tablets are sighted repeat script is required.
It is recommended the woman have an adult support person present during misoprostol administration and for the following 24 hours.

4.10 Rhesus (Rh) Isoimmunisation

Revised guideline for Rhesus Antibody Testing: The National Blood Authority guidance states there is insufficient evidence for the routine use of Rh immunoglobulin before 10 weeks gestation. EMA is no longer listed as a sensitising event requiring immunoprophylaxis (National Blood Authority, 2021).

4.11 Pain and bleeding

It is important to provide clear information to create reasonable expectations about the range of normal physical symptoms women experience with a medical abortion and symptoms that require further advice. Discussion about the complications and risks in a way that she can understand is an essential component of consent with an emphasis on the overall safety of the procedure.
The most common symptoms associated with misoprostol are pain, bleeding and gastrointestinal side effects (nausea, vomiting and diarrhoea). Pre-load medications (30 minutes prior) to misoprostol dose and in the first 24 hours.
Bleeding and cramping usually exceeds the expected individual level of menstrual bleeding and cramping.
Bleeding with clots and cramping usually occur within 1-6 hours of taking misoprostol. Pain and cramping will intensify and reduce as the products of pregnancy are passed.
Expect heavy bleeding with clots in the first 24 hours. Over 7 days, bleeding will gradually become lighter.
Bleeding usually stops by day 14 and may last up to the next expected menstrual period.
Cramping pain may be experienced for several days.
Bleeding may occur following mifepristone, continue with the misoprostol dose at the recommended time.
If no or limited bleeding has occurred within 24 hours of the misoprostol dose, repeat misoprostol dose or arrange a surgical abortion

4.12 Pain management

Establish accurate expectations. Ensure adequate pain relief is taken with an antiemetic 30 minutes prior to misoprostol dose.
Advise on the use of therapeutic techniques such as rest, heat packs and lower back massage.
Non-steroidal anti-inflammatory drugs are effective especially when taken prior to misoprostol dose.
Combinations of codeine may be effective. Paracetamol alone is not sufficient.
Consider:

- Ibuprofen 400mg 8 hourly PRN , with
- Paracetamol 1g 4 to 6 hourly PRN, and
- Paracetamol-codeine 1g-60mg 6 hourly PRN (maximum of 4g paracetamol per 24hours)

4.13 Anti-emetics

Gastrointestinal disorders are a common side effect of misoprostol.
Consider: metoclopramide 10mg 8 hourly PRN, maximum 30mg/day or ondansetron 4mg 8 to 12 hourly PRN.

4.14 Health information

Provide written and verbal information on:

- When to take the medications
- Expected symptoms
- Self-care in the first week
- Symptoms that require urgent review with an action plan
- Follow up plan

4.15 Follow up

Planned follow up is essential even if no adverse events have occurred. Telephone follow up at day 3 and telephone or direct contact at day 14 to 21 post misoprostol are useful methods to assess progress and to ensure the procedure is complete.
The purpose of follow up is to:

- provide support and reassurance,
- assess wellbeing,
- ensure completeness of the abortion procedure, and
- confirm a plan for ongoing contraception (if desired).

Telephone follow up 3 to 5 days. Assess for:

- Bleeding and cramping the first 24hours after taking misoprostol,
- Persistent heavy bleeding,
- Signs of infection,
- Retained products of conception/incomplete abortion,
- Ongoing pregnancy “If you had pregnancy symptoms before the abortion, are they gone now?”

Telephone or direct contact follow up day 14 to 21. Follow the clinical signs and symptoms and use an objective measure i.e. serum beta or urine hCG to confirm the abortion procedure.

- Serum beta hCG pathology taken between day 14 to 21. An 80 percent decline in serum beta hCG levels from day of misoprostol to 14 days later is considered appropriate.
- Low sensitivity urine hCG self-administered from day 14 detects a hCG level of 1000 mIU/mL and above. A negative result confirms the procedure.

Assess the clinical signs and symptoms to monitor completeness of the procedure. Resolution of symptoms or signs of pregnancy, absence of persistent heavy bleeding and serum beta and urine hCG as an objective measure provide reassurance of completeness. USS investigation earlier than 2 to 3 weeks post misoprostol is unlikely to assist management when the patient is clinically well and βhCG is dropping. Blood clots or thick endometrium are common findings post medical abortion.

4.16 *Complications and risks: complications may include*

- Retained products of conception (RPOC)/incomplete abortion: occur in 1-4 percent of cases. Ongoing clinical management is based on symptoms. Common symptoms are heavy or prolonged vaginal bleeding and/or abdominal pain Routine ultrasound scan is NOT recommended as blood clot, debris, or thickened endometrium are common findings and are not usually clinically relevant.
- Problem bleeding: Excessive bleeding is considered to be 2 (or more) saturated sanitary pads per hour for 2 consecutive hours or passing fist-size clots or reports symptoms of dizziness, light-headedness, or racing heart rate.
- Infection: Infection occurs in less than 1 percent of cases. The most common infections are endometritis and undefined genital tract infection.
- Continuing pregnancy: an ongoing pregnancy is considered a failed medical abortion and occurs in less than 1 percent of cases. The woman may continue to experience symptoms of pregnancy or have clinical signs such as rising serum beta hCG or confirmed on ultrasound scan.

See: Abortion or miscarriage: Management of Presentation Following Medication or Surgical Abortion or Miscarriage.

4.17 *Contraception*

The medical abortion consultation is an ideal time to discuss ongoing contraception as the woman/pregnant person has proven fertility, is likely to be motivated to explore options and is currently accessing health care. Ovulation occurs within 1 month of first trimester abortions in 90% of cases. All women seeking contraception need accurate, evidence-based information about the safety, efficacy, advantages and disadvantages of all methods and be supported to make a choice based on their personal needs, preferences and medical suitability. Long acting reversible contraception (LARC) methods are highly effective and safe for women across the reproductive life course.

Timing of Administration	**Method**
Day of mifepristone administration	Etonogestrel (Implanon NXT ®) and levonorgestrel (Microlut ®) Depot medroxyprogesterone acetate (DMPA)
Day following misoprostol administration	Combined Oral Contraceptives (OCP)
At follow up visit once it has been determined the abortion is complete i.e. with βhCG assessment.	Levonorgestrel-Intrauterine Device (IUD) Mirena® - 52mg) or (Kyleena® -19.5mg) and copper IUD

5. Evaluation, monitoring and reporting of compliance to this guideline or procedure

Compliance to this guideline or procedure will be monitored, evaluated and reported through VHIMS and consumer feedback.

6. References

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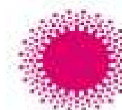
7. Legislation/Regulations related to this guideline or procedure

- Women's Sexual and Reproductive Health: Key Priorities 2017-2020
- https://www2.health.vic.gov.au/about/publications/policiesandguidelines/womens-sexual-health-key-priorities
- Abortion Law Reform Act 2008 http://www.legislation.vic.gov.au/

8. Appendices

Appendix 1: The Women's Position Statement on Abortion

https://www.thewomens.org.au/about/advocacy



The Women's Position Statement: Abortion

About the Women's

The Women's is a leader in women's sexual and reproductive health services and is a public provider of abortion services in Victoria. We are part of a broader health system that includes public and private providers of abortion services.

Our publicly funded abortion service is an important component of our commitment to ensure women's access to safe, high-quality healthcare. We provide priority of access to people with highly complex psychosocial needs, including those who experience violence and reproductive coercion.

The Women's is committed to increasing access to abortion services by building the clinical capacity and expertise of other hospitals, health services and the primary care sector to also provide abortion and contraception services. This is critical to ensure that women can access abortion services that are safe, timely and close to their home and social support networks.

The Women's Position

The Women's is a pro-choice organisation that provides access to abortion services to support women's choice and ability to exercise their reproductive rights.

Access to abortion is fundamental to women's sexual and reproductive healthcare, is a human right and an important public health issue.

The Women's is committed to providing public abortion services, as we believe that every individual – regardless of their age, gender identity, sexuality, ethnicity, religion, social class, and ability – should have access to reproductive healthcare.

The Women's provides abortion services consistent with the *Abortion Law Reform Act 2008* and supports a person's right to access healthcare within this legal framework.

Abortion services must be provided by registered health practitioners and regulated in the same way as all other health procedures and services. We provide support and counselling services, which is an integral part of abortion healthcare.

The Women's strongly supports a person's right to accurate, unbiased sexual and reproductive health information – including options counselling – to support their informed decision-making and health and wellbeing.

The Women's is committed to preventing violence against women. We acknowledge that many women who experience reproductive coercion require timely access to abortion services.

Statement endorsed by

Department of Rural Health