Early Medical Abortion (EMA) Prescribing Tool in Primary Care

For Health Professionals

SHINE SA

1 Patient presents requesting termination of pregnancy

- Non-directive pregnancy counselling
- Screen for family violence and reproductive coercion: "Is your decision being influenced by anyone else in your life?"
- Provide information about differences between medical and surgical abortion (see **Appendix A**), considering patient needs and preferences
- Use non-judgmental and non-stigmatising language

2 Initial assessment

- Urine pregnancy test
- Determine gestational age
  - » Clinical history such as LNMP and/or certainty of date of conception +/- abdominal examination if gestation uncertain (palpable uterus suggests gestation >12 wks)
  - » Pelvic ultrasound (TV) confirms gestation, and visualisation of yolk sac or foetal pole ensures pregnancy is **intrauterine**. (Note: Indicate on radiology request form whether or not the patient wishes to view their scan results.)
  - » Note: Quantitative serum beta hCG cannot confirm location of pregnancy or gestation
- Review past medical history, medications, allergies, gynaecological, obstetric, contraceptive, sexual

Pelvic Ultrasound Result

- Intrauterine pregnancy **>64 days** confirmed → Refer to surgical abortion provider → Patient requests surgical abortion
- Intrauterine pregnancy **≤63 days** confirmed → Counsel patient on options → Patient requests medical abortion → Proceed to Step 3
- Pregnancy of uncertain viability and/or location → See **Appendix B**

3 Conduct EMA consultation

- In SA, practitioners are required to provide information on access to counselling services
- Confirm patient eligibility and exclude contraindications to EMA

Contraindications:
- Chronic adrenal failure
- Diseases requiring long-term oral steroids
- Hypocoagulation diseases
- Anticoagulation therapy
- Allergy to mifepristone, misoprostol or other prostaglandin
- Intrauterine device in situ (safe to remove in clinic rooms prior to EMA)
- Known or suspected ectopic pregnancy

Not recommended for patients with:
- Severe anaemia
- Renal failure
- Hepatic impairment
- Malnutrition
- Cardiovascular disease
- >2 hours travel time to emergency care

- Obtain informed voluntary consent
- Pathology
  - Baseline serum quantitative beta hCG, ideally on day of mifepristone
  - Plan repeat serum quantitative beta hCG on day ≥7 post mifepristone (provide form)
  - Consider STI testing (including syphilis) and/or cervical screening
  - Consider haemoglobin +/- iron studies if history of anaemia
  - No need for routine testing of blood group for Rh D status **(Appendix C)**
- Advise how to take EMA medication (see page 2)
- Provide script for MS-2 Step® (mifepristone/misoprostol)
  - PBS listed: Authority required (Streamlined) 14202
    - » Indicated for termination of an intra-uterine pregnancy of up to 63 days gestation
  - Note: A private script can be given to patients w/o Medicare card
- Discuss and provide scripts for analgesia/anti-emetic
  - » Ondansetron 4-8mg 8-12 hrly or Metoclopramide 10mg 8-hrly PRN
  - » Ibuprofen 1600mg single dose (off label), then ibuprofen 400-600mg 8-hrly (max 2400mg per 24 hrs)
  - » Paracetamol 1000mg 4-6 hrly PRN (maximum 4000mg per 24 hrs) **OR**
  - » Consider selective use of opioid analgesia (e.g. paracetamol 1000mg/ codeine 60mg, 4-6 hourly PRN (maximum 4000mg/240mg per 24 hours))
- Discuss contraception → see **Appendix D**
- Identify available support person on day of misoprostol
- Discuss and plan for access to emergency care
- Establish follow-up plan, discuss importance of follow-up

Informed Consent

Written information and consent recommended
(Available at www.ms2step.com.au)

Risks/side effects include:
- Heavy or prolonged bleeding
- Severe cramping not relieved by analgesia
- Nausea, vomiting, diarrhoea, dizziness, headache, fever, chills
- 1% (1 in 100) chance treatment will fail to end the pregnancy (surgical abortion or repeat EMA strongly recommended)
- 4% (4 in 100) chance of incomplete abortion (retained pregnancy tissue or clot) which may require surgery or more medication
- 1-2% (1-2 in 100) chance of heavy bleeding requiring surgical treatment
- 0.1-0.2% (1-2 in 1,000) risk of requiring blood transfusion
- <1% (1 in 100) chance of infection.

4 Follow up

- Day 3-5 following misoprostol, phone call to assess experience of bleeding/cramping, persistent heavy bleeding, signs of infection
- Day 14-21 consult to assess heavy/persistent bleeding signs of infection, signs/symptoms of pregnancy (i.e. failed EMA)
- Confirm pregnancy has ended with:
  - » Repeat serum beta hCG 7-14 days after taking mifepristone (demonstrating decline of at least 80% from baseline)
- Follow-up may be face-to-face, via telehealth or telephone
- See **Appendix E** for management of complications

Instructions for taking EMA medication (MS-2 Step®)

- Provide patient with information booklet from MS-2 Step® website
- Note: Support person recommended for Step 2

Step 1 Mifepristone

- **Take prescribed anti-emetic (e.g. Ondansetron or Metoclopramide) 30 minutes prior to mifepristone.**
- Take 1x tablet (200mg) mifepristone orally and swallow with water. You can go about your usual activities after this.

Step 2 Misoprostol - after 36-48 hours

- **Take anti-emetic AND pain medication 30 minutes prior to misoprostol.**
- Moisten your mouth with some water and place 4x tablets (800mcg) misoprostol between your cheek and gum (2 on each side of mouth).
- Leave in place for 30 minutes, then swallow any residue with water.
- Plan to stay at home for the next 6-10 hours and have a responsible adult stay with you so they can drive you to a clinic/hospital if you need extra care.

What to expect

- **Most people experience bleeding within 4 hours** of misoprostol (Step 2) and possibly clots to pass the pregnancy tissue.
- **Bleeding lasts on average for 10-16 days** and may be heavy, but should become lighter once the pregnancy tissue has been expelled.
- Light bleeding can continue for 30 days or more.
- Some people can experience bleeding between Step 1 and Step 2.
- **Anticipate initial pain to be stronger than your usual menstrual period.**
- **Pre-load analgesic medications prior to misoprostol** (Step 2) and use therapeutic techniques such as rest, heat packs, massage.
- **Do not insert anything into the vagina** (including tampons), avoid swimming/baths and abstain from intercourse until **at least 7 days after taking the medication**, to reduce risk of infection.

When to seek help

- Bleeding through >2 pads per hour for >2 consecutive hours, or feel dizzy or lightheaded, or have a racing heartbeat.
- Severe pain not managed by analgesics.
- Fever >38°C lasting >6 hours and/or flu-like symptoms, weakness/faintness, nausea, vomiting or diarrhoea in the days after treatment.
- If no bleeding has occurred within 24 hours after taking misoprostol.
- **If a client experiences any of the above or has any other concerns, they should contact their healthcare practitioner or other health service or attend the emergency department of their local hospital.**

Appendix A - Comparison of medical and surgical abortion

Medical abortion	Surgical abortion
Avoids surgery - Involves taking medications mifepristone and misoprostol to terminate a pregnancy	Surgical procedure
Can occur in the comfort, privacy and familiarity of the patient's home	Day hospital admission
Can take days to complete, length of procedure cannot be predicted	**Completed in 10-15 minutes** followed by 30-60 minutes of observation time
Anaesthesia is not needed. Pain relief medication will be provided	Pain medication and anaesthesia are required for the procedure
Cramping and bleeding can be more severe and last for longer than with a surgical abortion	**Usually less pain than a medical abortion**
Generally much heavier bleeding than a period	Light bleeding
≥95% success rate within 1-3 weeks	99% success rate
Typically 2-3 office visits plus ultrasonography and blood tests	Typically 1-2 office visits
Support person recommended for Step 2	**Requires a support person after an anaesthetic**
Severe complications are rare Risks: Continuing pregnancy = 0.2 – 2.7% Retained tissue = 1.1 – 4.2% Haemorrhage & transfusion = 0.1% Infection = 0.18-1.56%	**Severe complications are rare** Risks: Continuing pregnancy = <0.3% Retained tissue = 0.3 – 2.0% Haemorrhage & transfusion = 0.02 – 0.3% Infection = 0.1 – 2.0% Perforation of uterus/surgical complication = 0.1%

Appendix B - Pregnancy of uncertain viability and/or location

- Aim for USS to take place at 5-6 weeks of pregnancy, if LMP is known – this gives the best chance of visualizing a yolk sac and confirming an intrauterine pregnancy (IUP)
- If very early pregnancy, repeating serum quantitative beta hCG every 48 hours can guide management: expected to double every 48 hours
- It would be unexpected to be able to confirm IUP before the quantitative beta hCG is above 1500-2000
- Only intrauterine location needs to be confirmed before EMA – viability does not need to be confirmed

Serial quantitative hCG test + USS for uncertain location → Ectopic pregnancy - **REFER**

↓

Nonviable pregnancy → Consider oral misoprostol (not TGA approved for this purpose) OR watchful waiting if haemodynamically stable

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Refer for surgical intervention if clinically indicated OR requested by patient

If not a viable/ intrauterine pregnancy, what could it be?

Consider:

- Ectopic pregnancy
- Blighted ovum
- Molar pregnancy
- Miscarriage

Please contact local abortion provision service, gynaecology department or women's assessment service for advice on interpreting unusual scan results if required.

Appendix C – Revised guidance for Rh immunoglobulin (Anti-D)

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.

View guideline at:
www.blood.gov.au/guidelineprophylactic-use-rh-dimmunoglobulin-pregnancy-care

Appendix D - Contraception

- On average ovulation occurs on day 20 after mifepristone, but can occur as soon as 8 days after mifepristone
- If at risk and repeat pregnancy is not desired, immediate use of an effective contraceptive method after medical abortion is recommended

Form of contraception	Timing to commence after EMA
Combined hormonal contraception (combined oral contraceptive pill, contraceptive ring)	• Day 1-5 after taking misoprostol: immediately effective • >5 days after misoprostol: barrier protection for 7 days
Progestogen-only oral contraception	Levonorgestrel or norethisterone POP: • Day 1-5 after taking misoprostol: immediately effective • >5 days after misoprostol: barrier protection for 2 days Drosperinone POP: • Day 1-5 after taking misoprostol: immediately effective • >5 days after misoprostol: barrier protection for 7 days
Depot medroxyprogesterone acetate (DMPA)	• Can be given on day of mifepristone ie prior to pregnancy expulsion (very small chance of interaction with mifepristone, leading to ongoing pregnancy/ failed EMA) If given after mifepristone/misoprostol: • Day 1-5 after taking misoprostol: immediately effective • >5 days after misoprostol: barrier protection for 7 days
Contraceptive Implant (Implanon)	• Can be given on day of mifepristone ie prior to pregnancy expulsion • Day 1-5 after taking misoprostol: immediately effective • >5 days after misoprostol: barrier protection for 7 days
Levonorgestrel Intrauterine Device (Mirena/Kyleena) or Copper Intrauterine Device	• As soon as possible after expulsion of pregnancy • This can be confirmed clinically (i.e. ↓by 80% quantitative beta hcg and cessation of bleeding) and/ or via pelvic USS

Appendix E – Management of complications

Note: Patients should remain within a 2-hour drive from hospital emergency services with blood transfusion services in the 14 days following the administration of mifepristone.

Haemorrhage	• Severe haemorrhage is a complication occurring in about 0.1 %. It needs ready access to dilatation and curettage facilities. • Less heavy but persistent bleeding is better managed with further home medication with buccal misoprostol and avoidance of surgery where possible.
Ongoing Pregnancy	• If abortion does not occur and the patient remains pregnant, it is recommended that they do not continue the pregnancy. In some cases, the medication may cause malformation of the developing foetus. • Continuing symptoms of pregnancy or a rising beta hCG suggest a continuing pregnancy. This should be confirmed with ultrasound (to exclude molar pregnancy) before commencing any further procedures to terminate the pregnancy. • Surgical management with suction curette if > 9 weeks gestation. • If < 9 weeks (63 days) gestation repeat doses of mifepristone and misoprostol could be an alternative option to surgical management and the patient should be counselled about both options.
Retained products of conception	Management depends on the amount of bleeding, symptoms/signs of infection and the patient's preference: • Medical management with further misoprostol (800 microgram stat buccally followed by 400 microgram buccally every 3 hours up to a maximum of 1600 microgram i.e., 4 doses) **OR** • Surgical management with dilatation and curettage.
Infection	• Severe infections after medical termination are rare • In the case of sepsis, inpatient management with appropriate IV antibiotics is recommended. • Routine antibiotic prophylaxis is not indicated but could be considered for patients deemed to be at high risk of infection. • Less severe infection remains uncommon with a rate of suspected or proven infection of 0.2 %. • Infection is often related to retained products of conception and assessment and treatment for this is also recommended concurrently • Refer to local and national guidelines for antibiotic choice for postpartum endometritis • Consider STI history: if chlamydia/gonorrhoea status is unknown, consider vaginal NAAT swab to screen for these conditions to guide antibiotic choice.