NZ COLLEGE OF SEXUAL & REPRODUCTIVE HEALTH

MODULE 2

Early Medical Abortion

CONTENTS

S&RH NZ COLLEGE OF SEXUAL & REPRODUCTIVE HEALTH

MANATŪ HAUORA MINISTRY OF HEALTH

Health New Zealand Te Whatu Ora

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1. LEARNING OBJECTIVES AND MODULE OVERVIEW

What is an Early Medical Abortion (EMA)?

An EMA is the evacuation of the uterus using the medicines mifepristone (an anti-progesterone) and misoprostol (a prostaglandin) in early pregnancy. EMA usually occurs in the community, most often in the pregnant person's home.

An EMA can be carried out from 28 days to 70 days after the last menstrual period (LMP).

Some possible reasons for choosing a medical instead of a surgical abortion:

- It usually requires no surgery
- It requires no sedation or anaesthesia
- It has the potential for greater privacy
- Some people feel it gives them greater control over their bodies
- It may feel more "natural" for some people

Module overview and learning objectives

In this module you will learn about supporting patients through the EMA process. The first section describes the medicines used, and is followed by details of the process, including the pre-abortion assessment (also covered in Module 1 but present here with a focus on EMA), doses used and pain management recommendations.

The next sections describe aftercare and management of complications, and the final section summarises information to be communicated to the patient to ensure that they are fully informed about what to expect during the EMA and afterwards.

A review of key learning points and further reading options and resources are included with this module, along with a short quiz to revise your knowledge and understanding of providing EMA in New Zealand.

Learning objectives

1. Support patients through the EMA process
2. Describe the range of what to expect during EMA with the patient
3. Assess for completion of EMA
4. Assess and manage common complications of EMA

2. TIKANGA IN ABORTION CARE

Abortion provider staff should complete a Te Tiriti o Waitangi-focused course that will assist them to reflect upon their own cultural assumptions about Māori and how these influence their capacity to provide culturally safe services to Māori, and indeed to all people.

Cultural competence should be incorporated into abortion providers' continuing education. With respect to cultural competence and Māori, this should include an awareness of Māori understandings and approaches to good health and wellbeing. Te Whare Tapa Whā conceptualises Māori health and wellbeing as incorporating four domains:

- Te taha hinengaro (mental health)
- Te taha tinana (physical health
- Te taha wairua (spiritual health)
- Te taha whānau (family health)

Consideration of each of domain should be used to inform the practices of clinicians, social workers and others involved with Māori undergoing a medical abortion. In keeping with Te Whare Tapa Whā model and in particular the principle of te taha whānau, abortion services should ensure that whānau members who have come along to support a Māori person considering a medical abortion are made to feel welcome and are treated with respect. For some Māori people and whānau, having a karakia led by the patient or a whānau member at any stage of the EMA process may feel appropriate. However, not all Māori people and whānau will deem karakia necessary, and their right to choose the path that best suits their requirements must be respected.

Click here for more information about Te Whare Tapa Whā.

EMA management of the products of conception or kukune

> New Zealand Aotearoa Abortion Clinical Guideline 2021, recommendation 5.2.3 is: "*Disposal of any products of conception must consider the person's individual choice as required by criteria 1.7.8 in Section 1.7 Kua whai mōhio ahau, ā, ka taea e au te mahi whiringa | I am informed and able to make choices*".

Patients have the right to retain the products of conception or kukune following their EMA procedure if they choose. As part of the EMA information process, abortion provider staff might suggest in advance that people undergoing an EMA may wish to bring a container to carry the kukune home. If the EMA procedure happens at home, Māori people may wish to place the kukune (and sanitary pads) into a container to dispense with as they see fit.

3. MEDICINES USED FOR EMA

For a video discussing EMA and the medicines used, click here

New Zealand Aotearoa Abortion Clinical Guideline 2021, recommendation 2.2.2 is: *"For medical abortion up to 10+0 weeks' gestation, recommend combination regime that includes 200 mg oral dose of mifepristone and 800 micrograms dose of misoprostol"*.

Mifepristone

Mifepristone (e.g. Mifegyne®) is a synthetic steroid (Figure 1) with anti-progestational properties as a result of competition with progesterone for progesterone receptors. In people at doses of ≥ 1 mg/kg, mifepristone antagonises the endometrial and myometrial effects of progesterone. During pregnancy it sensitises the myometrium to the contraction-inducing action of prostaglandin. The recommended dose in the datasheet is 200 mg to 600 mg depending on gestation. As peer reviewed research has shown no benefit from the use of the higher 600 mg dose, the dose prescribed in clinical practice is 200 mg.

- Absorption: bioavailability ~69%, time to peak concentration is approximately 90 minutes
- Half-life: 20 – 85 hours
- Storage: No special storage conditions are required.

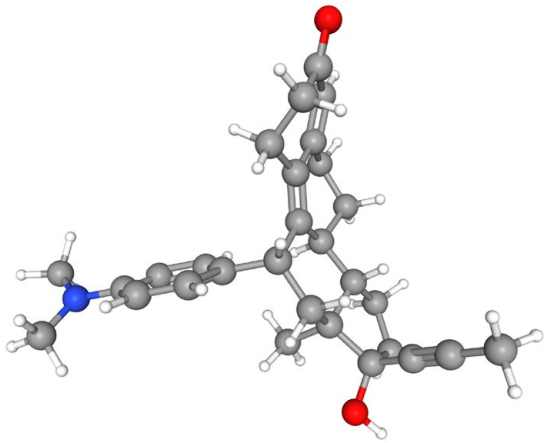

Figure 1. Mifepristone (C29H35NO2, IUPAC name (8S,11R,13S,14S,17S)-11-[4-(dimethylamino) phenyl]-17-hydroxy-13-methyl-17-prop-1-ynyl-1,2,6,7,8,11,12,14,15,16-decahydrocyclopenta[a] phenanthren-3-one). PubChem Identifier: CID 55245.

Misoprostol

Misoprostol (e.g. Cytotec®) is a synthetic prostaglandin E1 analogue (Figure 2), which induces contractions of the smooth muscle fibres in the myometrium and relaxation of the cervix. Oral and sublingual/buccal routes have the advantage of rapid onset of action, while the vaginal application results in prolonged activity and greater bioavailability. Each tablet is 200 micrograms.

- Absorption: 9 – 15 minutes after sublingual, buccal, oral or vaginal application
- Half-life: 20 – 40 minutes
- Storage:
  - Blister packs – Store at or below 25°C and protect from moisture
  - Bottles – Store at or below 30°C and protect from moisture

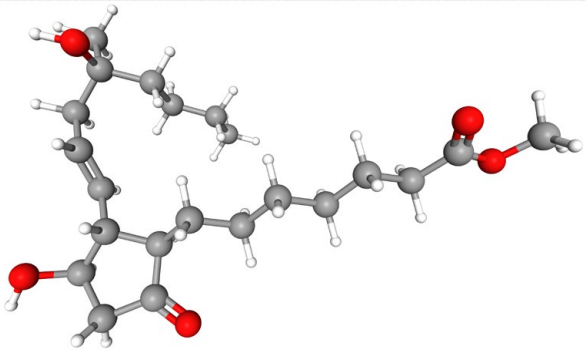

Figure 2. Misoprostol (C22H38O5, IUPAC name methyl 7-[(1R,2R,3R)-3-hydroxy-2-[(E)-4-hydroxy-4-methyloct-1-enyl]-5-oxocyclopentyl]heptanoate). PubChem Identifier: CID 5282381.

Teratogenicity

The Medsafe datasheet for Mifegyne® (mifepristone) states that malformations with sub-abortive test doses have been observed in rabbits, but not in rats, mice or monkeys, and that "the data is too limited to determine whether the drug is a human teratogen". Rare congenital malformations, including limb defects, club foot, central nervous system (CNS) and palate anomalies have been reported with the therapeutic use of misoprostol in clinical practice but no clear causal relationship has been established. The teratogenic mechanism appears to be related to the induction of uterine contractions that deform the embryo, resulting in vascular disruption, haemorrhage and cell death. The Medsafe datasheet for Cytotec® (misoprostol) states "Möbius sequence (i.e. palsies of cranial nerves VI and VII) and terminal transverse limb defects have been associated with first trimester exposure to misoprostol. Other defects including arthrogryposis have been observed. Misoprostol is contraindicated in women who are pregnant."

People seeking an abortion need to be informed of the risk of failure of EMA and the potential teratogenic risk to the fetus. Follow-up pregnancy testing is offered to confirm the abortion is complete. If a viable ongoing pregnancy is diagnosed at follow-up, it is recommended that the patient is advised to complete the abortion. A second EMA process, or an aspiration abortion, should then be performed with the patient's consent. If the patient decides to continue with their pregnancy after a failed EMA, careful ultrasound monitoring of the pregnancy, with a special attention to the limbs, is recommended.

Registered nurse prescribing

The Te Kaunihera Tapuhi o Aotearoa Nursing Council of New Zealand "Guidance for registered nurse prescribing in primary health and specialty teams" (March 2022) contains a medicines list which includes both mifepristone and misoprostol for use in obstetrics and medical abortion.

Use of approved medicines for unapproved indications

When a medicine is registered with Medsafe, it is subject to specific approval parameters, including indications, contraindications, cautions, doses, routes of administration and formulations. If a medicine is prescribed outside of these parameters, this is considered to be an unapproved use of the medicine (also known as "off-label" use). However, under Section 25 of the Medicines Act 1981, authorised prescribers working within the scope of their practice can still procure the supply of any medicine for use in patients under their care, provided requirements under the Code of Health and Disability Services Consumers' Rights 1996 have been applied. People have the right to be fully informed about unapproved medicines and any safety concerns, including in writing (if requested), prior to consenting to their use for EMA. Verbal informed consent from the patient is sufficient and this should be documented in the patient notes. It is not necessary to obtain written consent.

Mifepristone (Mifegyne®) is currently licensed for medical abortion up to 63 days of amenorrhoea. However, the New Zealand Aotearoa Abortion Clinical Guideline recommends that an EMA can be provided for pregnancies up to 10 weeks. The approved mifepristone dose for <50 days of amenorrhoea is 600 mg (3 tablets of 200 mg each) and between 50–63 days of amenorrhoea it is 200 mg. The New Zealand Aotearoa Abortion Clinical Guideline recommends 200 mg at all gestations. Therefore, the 200 mg regimen is off-label use prior to 50 days and between 63 and 70 days.

Misoprostol (Cytotec®) is currently approved for treatment of gastric and duodenal ulcers, and unapproved for all obstetric indications, including abortion.

Anti-D prophylaxis

> New Zealand Aotearoa Abortion Clinical Guideline 2021, recommendation 5.1.1 is: "*Do not routinely offer anti-D prophylaxis to people who are having a medical abortion < 10 weeks' gestation*".

As Anti-D prophylaxis is not recommended for use for EMA, a group and antibody screen is not required prior to an EMA and should not delay care.

4. THE EMA PROCEDURE/PROCESS

Pre-abortion assessment: focused medical history

New Zealand Aotearoa Abortion Clinical Guideline 2021,

- Recommendation 1.3.4 is: "*Obtain relevant medical history*" and
- Recommendation 1.3.5 states: "*Recommend selective testing of haemoglobin as indicated by medical history and/or current symptoms*".

A focused medical history needs to be taken to identify any contraindications for EMA and to aid in subsequent contraceptive choice.

Absolute contraindications for EMA include:

- Allergy to mifepristone or misoprostol
- Adrenal failure
- Poorly controlled severe asthma
- Steroid dependency
- Hereditary porphyria
- IUC *in situ* – it is acceptable to proceed if this is removed prior to commencing the abortion (New Zealand Aotearoa Abortion Clinical Guideline 2021, recommendation 2.2.1 states: "*Remove intrauterine contraception prior to a medical abortion*")
- Known or suspected ectopic pregnancy

Relative contraindications for EMA include:

- Greater than 70 days of pregnancy
- Severe anaemia
- Serious or unstable health conditions such as ischaemic heart disease, uncontrolled epilepsy, renal failure, or hepatic failure
- A known bleeding disorder or taking anticoagulant medicines

A small proportion of patients experience heavy bleeding with an EMA which can be unpredictable in terms of timing. In a large study of EMA complications in Australia, there were 16 cases of haemorrhage (0.1%) from a total of 13,345 EMAs (11 of the 16 reported were haemorrhages with transfusion). It may be safer for a patient with severe anaemia, an unstable health condition or a bleeding disorder to have surgical management in a secondary service, or EMA in a hospital setting.

While the risk of heavy bleeding and cervical shock following an EMA are low, this increases with gestational age. It is essential to ensure people having an EMA in the community are safe and able to access emergency health care facilities if required. Determining whether this is the case needs to form a part of each individual's consultation process. If there are social or practical barriers to emergency care access, then an at home EMA is not appropriate, and other options (e.g. early surgical abortion, or EMA in a different setting) should be offered as part of the shared decision-making process.

Examples of potential barriers to emergency care access:

- No reliable telephone access, or a limited ability to communicate with an emergency health service (e.g. language barriers)
- No transport or no adult companion at home
- Physical distance – e.g. being further than one hour from the nearest emergency health service.

Future fertility
No associations between induced abortion and ectopic pregnancy, infertility, placenta previa, or miscarriage have been found.

Pre-abortion assessment: Estimation of gestational age

New Zealand Aotearoa Abortion Clinical Guideline 2021:

- Recommendation 1.3.3: "*Offer inpatient setting to people having a medical abortion before 10 weeks' gestation if social or medical circumstances dictate*"
- Recommendation 1.3.7: "*Recommend selective ultrasound prior to first-trimester abortion if there is uncertainty about gestational age by clinical means, or if there are symptoms or signs suspicious for ectopic pregnancy*"
- Recommendation 1.3.9: "*Where there is clinical suspicion of ectopic pregnancy, refer the person to an early pregnancy unit/service*"
- Recommendation 1.3.10: "*Perform relevant physical examination as indicated*"

Providers need to take a standard menstrual history focusing on the first day of the patient's last menstrual period (LMP), including:

- How sure they are of the date
- If it was a normal menses for them, including any recent use of hormonal contraception
- If their menstrual cycles are regular, and if so, the average length of the cycle.

In studies of people seeking first trimester abortion who were reasonably certain of their LMP, self-reported gestational age correlated closely to ultrasound gestational age. A bimanual examination helps to estimate the gestational age – studies of pelvic examination to assess gestation agreed with ultrasound for 92% of experienced providers. The estimation of gestational age can be less accurate in the presence of obesity and fibroids.

If the gestational age based on the menstrual history and pelvic examination are consistent, and the person has no symptoms of pain or bleeding, then proceed with the EMA. Ultrasound should not be a barrier to abortion services and often has a cost. An ultrasound decision tool is available to download here.

The provision of point of care ultrasound in an abortion clinic by a trained provider is appropriate but not required for all people. A systematic review found no evidence that routine ultrasound before an EMA improved safety or efficacy compared with other diagnostic methods. If there are any concerns (e.g. about the pregnancy location or gestation), however, arrange for an ultrasound scan.

A transvaginal ultrasound can be performed if an intrauterine pregnancy (IUP) is not identified on a transabdominal scan. The roles of ultrasound in early pregnancy are to determine the pregnancy location (to confirm an IUP), confirm the number (single or multiple), document gestational age, and if appropriate, to detect a fetal heartbeat.

If providing an abortion via telehealth, see Impact of telehealth; advantages and disadvantages in module 1

EMA procedure, up to 10 weeks (70 days)

For an example consultation demonstrating how to explain the EMA process, click here.

The process of an EMA involves the patient taking mifepristone orally, followed by misoprostol administered vaginally, sublingually or buccally. These two drugs in combination cause the pregnancy to end as the uterus contracts to expel the pregnancy in a process similar to that of a miscarriage.

Both mifepristone and misoprostol should be given to the patient by the health practitioner providing abortion care. The health practitioner will be able to access mifepristone and misoprostol on a practitioner supply order (PSO). Mifepristone and misoprostol can also be prescribed if preferred.

Dosing regimen

New Zealand Aotearoa Abortion Clinical Guideline 2021:

- Recommendation 2.2.2: "*For medical abortion up to 10+0 weeks' gestation, recommend combination regime that includes 200 mg oral dose of mifepristone and 800 micrograms dose of misoprostol*"
- Recommendation 2.2.3: "*For medical abortion up to 10+0 weeks' gestation, offer buccal, sublingual or vaginal route of administration of misoprostol to reduce risk of ongoing pregnancy*"
- Recommendation 2.2.4: "*For medical abortion up to 10+0 weeks' gestation, offer interval dosing (24–48 hours) of mifepristone and misoprostol*"

Mifepristone: 200 mg as a single oral dose → **Misoprostol: 800 micrograms as a single buccal, sublingual or vaginal dose, 24 to 48 hours after mifepristone.** → **If the abortion has not occurred within 6 hours of the misoprostol dose, a second dose of misoprostol 400 micrograms may be given.**

Notes:

1. The buccal and sublingual routes have a higher likelihood of side effects than the vaginal route. With the buccal and sublingual routes it takes about 20 minutes for the tablets to dissolve and the residue can be swallowed after 30 minutes.
2. Patients should be advised that an EMA is more effective when the interval between mifepristone and misoprostol is 36 to 48 hours. If the interval is shorter, success rates are reduced. If the interval is longer, the likelihood of heavy bleeding occurring before the misoprostol dose is increased.

Side effects of misoprostol are usually self-limiting and include:

- Nausea (30%) and vomiting (20%)
- Diarrhoea (50%)
- Feeling warm or flushed, fever and chills (45%)

If the patient feels nauseated or has experienced hyperemesis prior to the abortion, offer an anti-emetic prior to taking the mifepristone. If the patient vomits within an hour of taking mifepristone recommend that another dose is taken.

Health practitioners should advise the patient that bleeding and cramping can sometimes start very quickly after misoprostol administration and should have started within 2–6 hours of taking the misoprostol. Bleeding will be heavier than a usual period. It will usually reach a peak over 4–6 hours, with cramps and bleeding heavier than their normal period with large clots; they may see some pregnancy tissue.

Patients need to know that 'too much bleeding' is soaking two maxipads per hour for more than two consecutive hours, or one pad an hour for 10 or more hours, or if they feel faint or dizzy.

Advise the patient to expect cramping and pain before and at the time of the expulsion of pregnancy tissue. More advanced gestation may be associated with more pain. Inform them about the different types of analgesics and when and how to take them.

Pain management and patient comfort

Non-pharmacological management of symptoms in EMA:

- Almost all patients will experience pain and cramping with abortion. The amount of pain varies greatly.
- A person having an abortion may feel anxiety, fear, or apprehension, which can increase sensitivity to pain
- A thorough explanation of what to expect is imperative to improve the person's comfort with the procedure. Communicating this information in a respectful, non-judgemental way with attention to cultural sensitivity, cognitive ability, and social environment is essential.

- The 24-hour availability of a health professional by phone can reduce the anxiety felt experiencing EMA at home
- The presence of a support person, e.g. partner, friend or family member who can remain with the person during the process (if they desire it) can reduce anxiety
- A calm, soothing environment, use of music, or other distraction can be useful
- The use of a hot water bottle or heating pad can assist in comfort and pain relief
- For further information, see: Clinical Practice Handbook for Safe Abortion (WHO).

Pharmacological management of symptoms in EMA:

- Ibuprofen, celecoxib, and other NSAIDs are superior to paracetamol for the management of pain in EMA. Despite their anti-prostaglandin effects, they do not interfere with the action of misoprostol. A NSAID should be taken before or at the onset of cramping and continued regularly until the pain settles.
- RANZCOG recommend a single dose of 1600 mg ibuprofen initially, followed by 400–600 mg eight-hourly, up to a maximum dose of 2400 mg in 24 hours while symptoms of pain persist
- Paracetamol may be useful when there is a history of intolerance to NSAIDs
- There is less evidence over the value of opioids in the management of pain in EMA, although the consensus is that codeine or tramadol should be available as a back-up or add-on medicine to NSAID
- Nausea and vomiting can be present, either as a symptom of pregnancy or as a side effect of medicines. Offer an anti-emetic such as metoclopramide or ondansetron before the ingestion of mifepristone if the person is at risk of vomiting the medicine.
- Recommend another dose of mifepristone if the person vomits within one hour of taking the mifepristone
- Continued use of anti-emetics throughout the medical abortion for "as required" use is an option
- Loperamide may be useful for people with a predisposition to diarrhoea

Prophylactic antibiotics

New Zealand Aotearoa Abortion Clinical Guideline 2021, recommendation 2.1.2 states: "*Do not routinely offer antibiotic prophylaxis to people who are having a medical abortion*".

Routine use of prophylactic antibiotics prior to EMA is not recommended. Prospective studies of first trimester EMA using mifepristone and a prostaglandin found the overall risk of infection was approximately 0.01% to 0.5%. Serious infection requiring hospitalisation is rare. There are no randomised controlled trials examining the effect of prophylactic antibiotics on medical abortion outcomes. In people who have not been screened for STIs, or results are unknown, consider offering prophylactic antibiotics.

Contraception after EMA

New Zealand Aotearoa Abortion Clinical Guideline 2021,

- Recommendation 1.1.4 states: "*Offer contraception counselling in accordance with New Zealand Aotearoa's Guidance on Contraception*".
- Recommendation 5.3.1 is "*Offer contraception counselling in accordance with New Zealand Aotearoa's Guidance on Contraception and criteria 1.7.1 in Section 1.7 Kua whai mōhio ahau, ā, ka taea e au te mahi whiringa | I am informed and able to make choices*".

Contraception should be offered at the time of the abortion consultation or appropriate referral made to obtain the method chosen by the patient. Contraceptive implants (Jadelle®) and injectables (Depo Provera®) can be administered on the day mifepristone is taken. Depo Provera injection at the same time as mifepristone may slightly increase the risk of ongoing pregnancy, although overall the risk is low.

Intrauterine contraception (IUC), including levonorgestrel containing intrauterine systems or copper intrauterine devices, should be inserted as soon as possible after the EMA when it is reasonably certain the person is

no longer pregnant. Expulsion rates of IUCs inserted immediately post-abortion are higher. However, at six months more people are likely to have an IUC in situ compared to those who have delayed insertion.

Further information and guidance is available from Sexual Wellbeing Aotearoa (formerly Family Planning), Protected and Proud, and in New Zealand Aotearoa's guidance on contraception (December 2020), section 2.4 Contraception after abortion. Medical eligibility criteria for contraception are provided by FSRH UK MEC and WHO MEC.

For a short presentation on contraception after EMA, click here.

5. AFTERCARE AND MANAGEMENT OF COMPLICATIONS

Verification of completion of abortion

New Zealand Aotearoa Abortion Clinical Guideline 2021, recommendation 2.2.5 states: "*For medical abortion up to 10+0 weeks' gestation, offer follow-up assessment either in person or by telehealth. Confirm the abortion is complete and exclude ongoing pregnancy by:*

- *serum β-hCG testing: Completion may be confirmed by a drop in serum β-hCG level of 80% or more from day of mifepristone to 7–14 days after mifepristone. If less than 80% drop, investigate further and manage as appropriate*
- *urine β-hCG testing: A negative low-sensitivity urine pregnancy test at 3 or 4 weeks after treatment will exclude an ongoing pregnancy. If positive, investigate further and manage as appropriate*
- *ultrasound scan*."

***It is especially important to confirm abortion is complete if ultrasound has not been performed before early medical abortion, to exclude ectopic pregnancy**".*

Continuing pregnancy after EMA is uncommon (1–3%) but important not to miss. Clinical signs of continuing pregnancy include: 1) having only scant bleeding after taking the medicines; 2) patients who despite significant bleeding are still experiencing ongoing pregnancy related symptoms such as nausea, tiredness, frequent urination and breast tenderness; and 3) people who do not have a return of menses at 4–6 weeks (taking into account any possible changes due to the method of contraception used post abortion).

It is important to verify completion of abortion by one of the following methods:

- Serum βhCG drop of >80% 7 to 14 days after administration of mifepristone (check baseline serum βhCG on day of mifepristone)
- Negative low sensitivity urine pregnancy test 2 to 4 weeks after abortion
- Absence of gestational sac on ultrasound scan which was present before
- Clinical history and examination, e.g. self-reported: the gestational sac was seen to pass, bleeding is settling, pregnancy symptoms have gone, and the uterus is involuted on vaginal examination
- It is the expectation of the Midwifery Council that midwives offer in person follow up post abortion

From 1 December, 2024, β-hCG low sensitivity urine tests (checkToP®) are funded for use both in the community and in Health New Zealand Te Whatu Ora hospitals. The checkToP® test kits are designed for home use after EMA, as an alternative to a blood test, and are not suitable for use for other applications such as miscarriage management. The tests detect β-hCG levels below 1000 mIU/mL and give a result within 5 to 10 minutes. They provide a simple alternative to a blood test, particularly for those who may have limited access to blood test facilities or other barriers to accessing healthcare for EMA follow-up.

The β-hCG low sensitivity urine tests (checkToP®) are listed in Section B on the Pharmaceutical Schedule, and available via prescription and Practitioner's Supply Order (PSO, up to 15 tests). Health practitioners, including midwives, GPs and nurse practitioners can prescribe and order the tests for use in primary care.

If the pregnancy is found to be ongoing following an EMA the patient must be advised of their options; these include to repeat the EMA procedure if they are under 10 weeks, to undergo a surgical abortion or if they choose to continue the pregnancy, they must be referred for ongoing pregnancy care and advised of the risks to the pregnancy including miscarriage and the need for a detailed early scan for limb malformations.

Additional follow-up

New Zealand Aotearoa Abortion Clinical Guideline 2021, recommendation 5.4.1 states: "*Consider selective follow-up with their health practitioner for people who:*

- *Are at risk of (or develop) complications*
- *Still need contraception*
- *May need ongoing mental health support*
- *Are living with complexities*
- *Are young, or*
- *Request follow-up"*

Reporting

To comply with the Contraception, Sterilisation, and Abortion Act 1977 abortion service providers must submit a notification to the Ministry of Health within one month of an abortion. The Ministry of Health collates the national data on abortions and uses this to report on issues such as timely and equitable access to abortion services.

There is a guide provided on the Ministry of Health Abortion Reporting webpage to completing and submitting the notification report, via an online form. A PDF version of the form is also available on request.

For further information, see module 1 section on legal reporting requirements: "Abortion in Aotearoa New Zealand: NZ law, patient rights and professional standards and guidelines"

Signs and management of complications

All abortion providers should have a plan in place for referring a pregnant person to a hospital for emergency assessment and admission if required. Patients should be provided with sufficient information about the EMA procedure to allow another health practitioner elsewhere to manage complications in an emergency situation.

Retained products of conception (RPOC) is the most common complication after EMA. Problematic cramping, pain and/or bleeding in the first week is common (2–9%) but may continue to occur for 2–5 weeks after the medicines. This extended duration of bleeding may result from retained pregnancy tissue (i.e. RPOC). A slow to drop serum βhCG may also suggest RPOC.

- Check how much bleeding is occurring (how long has it been going on, how often are they changing pads, are the pads completely soaked through? Are they faint and dizzy when they stand up?)
- Check pulse and blood pressure
- Do a vaginal speculum examination to look for RPOC at the cervical os and assess amount of bleeding

If the patient **feels unwell or is haemodynamically unstable** provide immediate emergency care as appropriate and refer urgently to secondary care.

If the patient **feels well and is haemodynamically stable** offer a choice of treatments:

- Explain, reassure and manage conservatively (wait to pass spontaneously)
- Give another dose of misoprostol (400 micrograms buccally or sublingually, not vaginally)
- Refer to secondary care for further assessment and management

A previously undiagnosed **ectopic pregnancy** is a rare but important not to miss life-threatening condition. Be alert to this possibility when a person without a confirmed intrauterine pregnancy has an EMA. Ectopic pregnancy may be asymptomatic, and an ectopic pregnancy may only be detected when the follow-up βhCG is not falling as expected. Patients may present with symptoms of pelvic pain, vaginal spotting/bleeding or with tachycardia, hypotension and shock. **Refer all patients with these findings urgently to the nearest hospital**.

Endometritis/ pelvic inflammatory disease after EMA is uncommon but important not to miss. Patients may present with fever, abdominal pain and/or a malodourous vaginal discharge and have uterine or adnexal tenderness on bimanual examination. In cases of suspected **endometritis/pelvic inflammatory disease urgent treatment as per guidelines is recommended**.

6. PATIENT COMMUNICATION AND SUPPORT

General patient safety and support

This 16 minute video is an example of a conversation about EMA between a health practitioner and a person requesting an abortion. Questions asked and discussed include: What does an EMA involve, what side effects can I expect and how will I know if the bleeding is too heavy?

> New Zealand Aotearoa Abortion Clinical Guideline 2021, recommendation 5.2.1 states: *"Following abortion, give verbal and written information on what to expect. See* Table 1: Information for people considering an abortion in Appendix B".

Health practitioners need to ensure that people having a medical abortion in the community are aware of what to expect from the process and have adequate support available to them.

It is very important that practitioners ensure that:

- a safe reliable method of communication chosen by the person for ongoing communication is noted
- the patient has access to 24-hour support during the EMA process
- the patient has access to transport / telephone / emergency health services
- the patient has an adult at home with them who is aware of the EMA

Patient centred information provision

Patients having an EMA at home (outside of a clinic or hospital ward) need to be given clear information about how and when to take the medicines during the EMA process, and what to expect in terms of pain and side effects during and after the abortion. An example of a patient booklet containing information and advice which abortion providers can modify to their needs is available within this EMA module. The DECIDE website is also recommended as a good source of information for patients.

When and how to seek emergency medical attention

Discuss with the person how and when to reach an abortion provider after-hours for telephone advice. Encourage them to call if:

- there is no or scant or little bleeding within 12 to 24 hours of taking misoprostol
- bleeding soaks two or more maxi pads for two or more consecutive hours, or one maxi pad an hour for more than 10 hours
- they feel dizzy or faint
- they have unmanageable pain despite taking prescribed analgesics
- they have unmanageable nausea, vomiting or diarrhoea despite taking prescribed medicines
- they have a sustained fever > 38 degrees for > 3 hours or new onset of fever > 24 hours after taking misoprostol
- there are other prolonged or severe side effects

If the clinician or the patient themselves are concerned, they should seek urgent health advice or attention from the closest health facility that provides after-hours care.

Counselling

> New Zealand Aotearoa Abortion Clinical Guideline 2021, recommendation 5.2.2 states: "*Advise people to seek support if they need it, and how to access counselling and/or social supports*".

Practitioners must advise people that abortion counselling is available on request throughout the process of their abortion and afterwards if requested, at no charge to them.

7. REVIEW OF KEY LEARNING POINTS

1. **Support patients through the EMA process**
   - A focused medical history needs to be taken to identify any contraindications or precautions to EMA
     - Absolute contraindications
       - Allergy to mifepristone or misoprostol
       - Adrenal failure
       - Poorly controlled severe asthma
       - Steroid dependency
       - Hereditary porphyria
       - Greater than 70 days of pregnancy
       - IUC in situ – it is okay to proceed if removed
       - Suspected ectopic pregnancy
     - Relative contradictions: a) severe anaemia, b) serious or unstable health conditions such as ischaemic heart disease or c) taking anticoagulants or having a bleeding disorder
     - Precautions to EMA: a) inability to follow care instructions, b) inability to access emergency help – e.g. no telephone access, no transport or no adult companion at home, c) limited ability to communicate with health professionals in an emergency
   - It is very important that practitioners ensure that:
     - a safe method of communication chosen by the person for ongoing communication is recorded
     - the patient has access to 24-hour support during the EMA process
     - the patient has access to transport/telephone/emergency health services
     - the patient has someone at home with them who is aware of the EMA
   - The process of EMA involves taking a 200 mg dose of mifepristone orally, followed 24 to 48 hours later by 800 micrograms misoprostol vaginally, sublingually or buccally.
     - If the abortion has not occurred after 6 hours, a further dose of misoprostol 400 micrograms can be administered – providers should consider providing a prescription or extra tablets to save them having to return to the clinic
     - If a patient feels nauseated or has experienced hyperemesis prior to the abortion, offer an anti-emetic prior to taking the mifepristone. If a patient vomits within an hour of taking mifepristone, offer them another dose
   - Pain management
     - Non-steroidal anti-inflammatory medicines should be the first-line agents for pain management (for example ibuprofen, naproxen or diclofenac)
     - For more severe pain, consider tramadol or codeine
     - For nausea, offer anti-emetics (for example oral ondansetron)
   - Routine use of prophylactic antibiotics prior to EMA is not recommended
   - Do not routinely offer anti-D prophylaxis to people having an EMA

2. **Address the range of what to expect during the EMA with the patient**
   - A pregnant person should be aware that counselling is freely available, but not required, at all stages of the abortion experience. This should be readily available on request to ensure that there is no unnecessary delay to their abortion
   - Information about the EMA process:
     - Patients should be advised that bleeding and cramping can start very quickly after misoprostol administration, and the abortion will usually be completed within 4 to 6 hours

- It takes about 20 minutes for the tablets to dissolve when taken sublingually and 30 minutes if taken buccally. Any tablet remnants can be swallowed after these times.
- Advise the patient that they will likely experience menstrual-like cramps, pain and bleeding, and that the pain experienced may be more like a miscarriage than menses - the cramping can be severe
- Patients should have clear instructions as to what pain relief is available and this should be provided by the health practitioner (practitioner supply order (PSO) or prescription). Non-pharmacologic pain management such as heat packs, natural remedies, and emotional support from an adult companion should be encouraged

- Patients should be informed of the potential side effects, risks and complications of EMA:
  - Side effects include fever, chills, nausea, vomiting, diarrhoea, weakness, headache, dizziness
  - Risks include ongoing pregnancy, requiring surgical intervention (less than 5%) and blood transfusion (less than 1%)
- Inform the patient how and when to access further support and/or emergency care:
  - If bleeding is excessive, soaking through 2 maxi pads an hour for 2 or more consecutive hours
  - When they may need additional medicine – if they do not bleed within 24 hours of taking misoprostol, or if they fail to take the misoprostol as instructed
  - If their symptoms are suggestive of continuing pregnancy – e.g. less than 4 days bleeding, if they still 'feel' pregnant, if their next period doesn't arrive when expected

3. Assess for completion of EMA

- Completion of abortion may be verified by:
  - Serum βhCG drop of > 80% 7-14 days after administration of mifepristone
  - Negative urine pregnancy test 2-4 weeks after abortion
  - Absence of gestational sac on ultrasound
  - Clinical history and examination (e.g. the person says they saw the gestational sac pass, bleeding is settling, pregnancy symptoms have gone and uterus is involuted on vaginal examination)
- Notify the Ministry of Health of the EMA via the online abortion notification report form.

4. Identify and manage common complications of EMA

- If the abortion has not occurred within 6 hours of the misoprostol dose, a second dose of misoprostol 400 micrograms may be given
- All abortion providers should have a plan in place for referring a pregnant person to a hospital for emergency assessment and admission if required
- Patients should be given sufficient information (electronically or on paper) about the procedure to pass on to another practitioner elsewhere to manage complications

8. FURTHER READING AND RESOURCES

Open access resources are marked with an asterisk (*) at the beginning.

Pharmacology of medicines used for EMA

Frye, L.J., Byrne, M.E., Winikoff, B. (2016). A crossover pharmacokinetic study of misoprostol by the oral, sublingual and buccal routes. The European Journal of Contraception & Reproductive Health Care 21:265-268. Available from: https://doi.org/10.3109/13625187.2016.1168799

Bernard, N., Elefant, E., Carlier, P., *et al*. (2013). Continuation of pregnancy after first-trimester exposure to mifepristone: an observational prospective study. BJOG 120(5):568–74. Available from: https://doi.org/10.1111/1471-0528.12147

Mark, A., Foster, A.M., Grossman, D., *et al*. (2019). Foregoing Rh testing and anti-D immunoglobulin for women presenting for early abortion: a recommendation from the National Abortion Federation's Clinical Policies Committee. Contraception 99(5):265–6. Available from: https://doi.org/10.1016/j.contraception.2019.02.008

* Medsafe. Cytotec Data Sheet. 2019. Available from: https://www.medsafe.govt.nz/profs/Datasheet/c/Cytotectab.pdf

* Medsafe. Mifegyne Data Sheet. 2001. Available from: https://www.medsafe.govt.nz/profs/Datasheet/m/Mifegynetab.pdf

Vauzelle, C., Beghin, D., Cournot, M.P., Elefant, E. (2013). Birth defects after exposure to misoprostol in the first trimester of pregnancy: prospective follow-up study. Reproductive toxicology 36:98–103. Available from https://doi.org/10.1016/j.reprotox.2012.11.009

* Wiebe, E.R., Campbell, M., Aiken, A.R.A., Albert, A. (2019). Can we safely stop testing for Rh status and immunizing Rh-negative women having early abortions? A comparison of Rh alloimmunization in Canada and the Netherlands. Contracept X. 1:100001. Available from https://doi.org/10.1016/j.conx.2018.100001

* A short video explainer (1 min 24 sec) about the action of mifepristone from Advancing New Standards in Reproductive Health (ANSIRH) is available here: https://www.youtube.com/watch?v=GknDInjVPFM. ANSIRH is a programme within the University of California San Francisco (UCSF) Bixby Center for Global Reproductive Health and is a part of UCSF's Department of Obstetrics, Gynecology & Reproductive Sciences.

The EMA procedure

Abbas, D., Chong, E., Raymond, E.G. (2015). Outpatient medical abortion is safe and effective through 70 days gestation. Contraception 92:197–199. Available from https://doi.org/10.1016/j.contraception.2015.06.018

Goldstone, P., Michelson, J., Williamson, E. (2012). Early medical abortion using low-dose mifepristone followed by buccal misoprostol: a large Australian observational study. Med J Aust. 197 (5): 282–286. Available from: https://doi.org/10.5694/mja12.10297

Kaneshiro, B., Edelman, A., Sneeringer, R.K., Ponce De Leon, R.G. (2011). Expanding medical abortion: can medical abortion be effectively provided without the routine use of ultrasound? Contraception 83:194–201. Available from: https://dx.doi.org/10.1016/j.contraception.2010.07.023

Gambir, K., Kim, C., Necastro, K.A., et al. (2020). Self administered versus provider administered medical abortion. Cochrane Database of Systematic Reviews 3:CD013181. https://doi.org/10.1002/14651858.CD013181.pub2

Raymond, E.G., Shannon, C., Weaver, M.A., Winikoff, B. (2012). First-trimester medical abortion with mifepristone 200 mg and misoprostol: a systematic review. Contraception 87:26–37. Available from: https://doi.org/10.1016/j.contraception.2012.06.011

Suhonen, S., Tikka, M., Kivinen, S., Kauppila, T. (2011). Pain during medical abortion: predicting factors from gynecologic history and medical staff evaluation of severity. Contraception 83:357–61. Available from: https://dx.doi.org/10.1016/j.contraception.2010.08.006

* von Hertzen, H., Huong, N.T., Piaggio, G., *et al*. (2010). Misoprostol dose and route after mifepristone for early medical abortion: a randomised controlled noninferiority trial. BJOG 117:1186–1196. Available from: https://dx.doi.org/10.1111/j.1471-0528.2010.02636.x

Zhang, J., Zhou, K., Shan, D., Luo, X. (2022). Medical methods for first trimester abortion. Cochrane Database of Systematic Reviews 5:CD002855. https://doi.org/10.1002/14651858.CD002855.pub5

Follow up care and management of complications

Baiju, N., Acharya, G., D'Antonio, F., Berg, R.C. (2019). Effectiveness, safety and acceptability of self-assessment of the outcome of first-trimester medical abortion: A systematic review and meta-analysis. BJOG 126(13):1536–1544. Available from: https://doi.org/10.1111/1471-0528.15922

Grossman, D., & Grindlay, K. (2011). Alternatives to ultrasound for follow-up after medication abortion: A systematic review. Contraception 83(6):504–510. Available from: https://doi.org/10.1016/j.contraception.2010.08.023

Kerns , J.L., Brown, K., Nippita, S., Steinauer, J. (2023). Society of Family Planning Clinical Recommendation: Management of hemorrhage at the time of abortion. Contraception. Available online 20 September 2023, 110292. Available from https://doi.org/10.1016/j.contraception.2023.110292

Pocius KD, Maurer R, Fortin J, Goldberg AB, Bartz D. (2015). Early serum human chorionic gonadotropin (hCG) trends after medication abortion. Contraception 91:503–506. Available from: https://dx.doi.org/10.1016/j.contraception.2015.03.004

Raymond, E. G., Shochet, T., Bracken, H. (2018). Low-sensitivity urine pregnancy testing to assess medical abortion outcome: A systematic review. Contraception 98(1):30–35. Available from: https://doi.org/10.1016/j.contraception.2018.03.013

Schmidt-Hansen, M., Cameron, S., Lohr, P.A., Hasler, E. (2020). Follow-up strategies to confirm the success of medical abortion of pregnancies up to 10 weeks' gestation: A systematic review with meta-analyses. AJOG 222:551–563.e13. Available from: https://doi.org/10.1016/j.ajog.2019.11.1244

Patient support

Aamlid, I.B., Dahl, B., Sommerseth, E. (2021). Women's experiences with information before medication abortion at home, support during the process and follow-up procedures—A qualitative study. Sexual & Reproductive Healthcare 27:100582. Available from https://doi.org/10.1016/j.srhc.2020.100582

Mahanaimy, M., Gerdts, C., Moseson, H. (2022). What constitutes a good healthcare experience for unintended pregnancy? A qualitative study among young people in California. Culture, Health & Sexuality 24:330–343. Available from https://doi.org/10.1080/13691058.2020.1840631

* Purcell, C., Cameron, S., Lawton, J., et al (2017). Self- management of first trimester medical termination of pregnancy: A qualitative study of women's experiences. BJOG 124:2001–2008. Available from: https://doi.org/10.1111/1471-0528.14690

9. QUIZ ON EMA

Click here to access a quiz and test your understanding of the concepts discussed in the module.

N.B. The module 1 quiz must be completed before attempting the module 2 quiz.

10. FEEDBACK: NEW ZEALAND COLLEGE OF SEXUAL & REPRODUCTIVE HEALTH ABORTION TRAINING

Your feedback is invaluable to us to assist in improving the course. We would appreciate your assistance by completing the short form on the Abortion Training website feedback page.