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Clinical Guideline for Abortion Care

An evidence-based guideline on abortion care in Australia and Aotearoa New Zealand

RANZCOG has developed a clinical guideline on abortion care for Australia and Aotearoa New Zealand. An expert group have led the development of the guideline using evidence-based processes.

THE ROYAL AUSTRALIAN
AND NEW ZEALAND
COLLEGE OF OBSTETRICIANS
AND GYNAECOLOGISTS

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This guideline and the accompanying decision aid can be downloaded from the RANZCOG website: https://ranzcog.edu.au/. If alternative file formats are required, please email: guideline@ranzcog.edu.au

Foreword

It is a privilege to introduce the first binational evidence- based clinical practice guideline on abortion care for Australia and Aotearoa New Zealand. We anticipate the guideline will be an important step towards universal access to timely, safe and high-quality abortion care.

Abortion is one of the commonest gynaecological procedures, with estimates that one in four women will access an abortion in their lifetime. We acknowledge women have abortions for many possible reasons, including health concerns for maternal medical conditions, fetal anomalies or to end an unintended pregnancy, and will experience a range of emotions related to their decision.

Recent legislative changes in Australia and Aotearoa New Zealand permit abortion to be performed in all jurisdictions, under certain circumstances, by registered health professionals who are working within their approved scope of practice. Abortion law reform has the potential to enable better access and the modernisation of abortion care, consistent with RANZCOG's vision and mission, although challenges remain for abortion provision particularly in regional, remote and some urban public health services.

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) has facilitated the development of this guideline. RANZCOG supports equitable access to sexual and reproductive health services, including abortion. The college believes women in Australia and Aotearoa New Zealand should be able to choose the method of abortion most acceptable to them, without coercion, informed by their values and preferences.

Both medical and surgical methods are presented in this guideline as safe, effective and acceptable options. Choices about abortion must be based on informed decision-making, where the physical, social, and psychological information needs of women who are considering abortion is supported. To support informed decision-making, RANZCOG has developed a short decision aid as a companion document to this guideline.

Techniques, recommended pain relief and follow up arrangements of either method are presented. Where overlaps with existing national guidelines were identified, steps have been taken to align the recommendations. Within the context of increasing rates of medical abortion, the guideline presents evidence that services by telehealth have been reported to be safe and effective.

This comprehensive guideline was developed by a dedicated team, following RANZCOG's robust processes. We are grateful to the patients, clinicians, researchers and policymakers for their expertise, enthusiasm and genuine engagement in this project.

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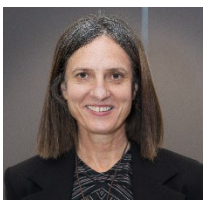

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Table of Contents

1 Introduction

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) supports equitable access to sexual and reproductive health services, including abortion. Recent legislative changes in Australia and Aotearoa New Zealand permit abortion to be performed in all jurisdictions, under certain circumstances, by registered health professionals who are working within their approved scope of practice. These changes are a strong impetus for an evidence-based guideline to guide quality care across Australia and Aotearoa New Zealand. Access to abortion should not be limited by age, ethnicity, language barriers, migration or detention status, geographic isolation, socioeconomic disadvantage, disability, sexual orientation or gender identity.

The most recent estimate of abortion rates for Australia and Aotearoa New Zealand is approximately 15 abortions per 1000 women[i] (wāhine) of reproductive age. Since 2012, the proportion of abortions performed surgically has declined while the proportion of medical abortions has increased and medical abortion now accounts for approximately 25% of abortions in Australia[1] and 44% in Aotearoa New Zealand[2]. There is a range of medical, social, or financial reasons why a woman may request an abortion. Fetal anomaly, either suspected or confirmed, was identified as the reason for abortion in approximately 3% of abortions[3]. Abortion rates among Indigenous Australian women are approximately 10 abortions per 1000 women[3]. Abortion rates among Māori women are not reported, however 21% of women having an abortion in Aotearoa New Zealand in 2020 identified as Māori[2]. These differences in abortion rates between Indigenous and non-Indigenous populations in Australia and Aotearoa New Zealand may stem from a variety of factors, including those resulting from the impacts of colonisation. RANZCOG places a high priority on cultural competency, and is committed to addressing inequity in access to abortion for Indigenous women.

This guideline is the first RANZCOG guideline on abortion for use by registered health professionals working within their scope of practice. Development of this guideline is central to RANZCOG's commitment to achieving excellence in women's health and will allow the delivery of safer, effective and more equitable abortion care. The scope of the guideline aims to support abortion provision and address reported gaps in clinical practice. This guideline is aligned with current jurisdictional legislation, and with Aotearoa New Zealand national standards[4]. It draws upon national guidelines developed by the New Zealand Ministry of Health, and National Institute for Health Care and Excellence (NICE) and international guidelines on abortion developed by the World Health Organization (WHO).

The RANZCOG Research and Policy team has co-ordinated all administrative and governance activities during the development of this guideline, working with an expert guideline development group (Appendix A) to review available evidence that inform the guideline recommendations. The RANZCOG Women's Health Committee, a sub-Committee of the RANZCOG Board has had oversight of the process. The development of this guideline was fully resourced by RANZCOG.

2 Purpose and Scope

The purpose of this guideline is to provide evidence-based recommendations to health care practitioners who provide advice and abortion care in Australia and Aotearoa New Zealand. The document has been prepared having regard to general circumstances (Appendix F). The scope includes all abortion care for the first and second trimester, including:

- Physical, social, and psychological support for women considering abortion, including routine testing;
- Medical abortion, including treatment regimens for early medical abortion, follow up and pain relief; also includes telehealth;
- Surgical abortion, including optimal regimens for cervical priming, techniques (manual versus electric vacuum aspiration), analgesia and approved indications for infection management;
- Management of complications, including abortion following uterine surgery, incomplete abortion or ongoing pregnancy;
- Post abortion care, covering post-abortion contraception and routine follow up

[i] RANZCOG currently uses the term 'woman' in its documents to include all individuals needing obstetric and gynaecological healthcare, regardless of their gender identity. The College is firmly committed to inclusion of all individuals needing O&G care, as well as all its members providing care, regardless of their gender identity.

The following topics were out of the scope of this guideline:

- Funding frameworks such as Medicare Benefits Scheme item numbers for telehealth
- The cost of an abortion service - varies according to location, method of termination and gestation
- Fetal reduction of multiple pregnancies
- Screening for family violence, mental illness, and the discussion of informed consent, as these are part of routine clinical care
- Provision of misleading clinical history by women, for example gestational age
- Abortion performed by non-registered health professionals.

3 Definitions

Term	Interpretation/Definition
Abortion	Abortion is the removal of pregnancy tissue or the fetus and placenta from the uterus
Abdominal palpation	A standard technique used to determine the stage of pregnancy after the first trimester
Antibiotic prophylaxis	The administration of antibiotics before infection has occurred
Anti-D (Rh D immunoglobulin)	A medication to prevent Rh D sensitisation in women who are Rh D negative
Antiemetic	A drug that is effective against vomiting and nausea
Buccal (medication administration route)	Medication is placed between the gum and the inner cheek. This allows the medication to enter the blood stream from the mucous membrane in the mouth
Cervical insufficiency	The inability of the cervix to retain the fetus in the uterus, in the absence of uterine contractions or labour (painless cervical dilatation), owing to a functional or structural defect
Culturally and Linguistically Diverse (CALD) communities	Individuals who have cultural backgrounds different from the majority Australian/ Aotearoa New Zealand culture
Dilatation & curettage (D&C)	Dilatation of the cervix using surgical dilators and removal of pregnancy tissue using a surgical curette. D&C is usually used before 14 weeks
Dilatation and evacuation (D&E)	D&E is used after 12–14 weeks pregnant. D&E requires preparation of the cervix using osmotic dilators and/or pharmacological agents, and evacuating the uterus primarily with forceps and/or vacuum aspiration (refer to entry in this list) to remove any remaining blood or tissue
Early Medical Abortion (EMA)	Australia: up to 9 weeks (63 days) in accordance with TGA authorisation of MS-2 Step Aotearoa New Zealand: up to 10 weeks (70 days) based on jurisdictional protocols.

EVA	Electric vacuum aspiration (refer to entry in this list on vacuum aspiration)
Feticide	A procedure performed by specialists who have appropriate skills, guided by ultrasound, to access the fetal circulation (intracardiac or intraamniotic) to instil an agent resulting in cessation of fetal cardiac activity prior to the commencement of the termination procedure
GDG	Guideline Development Group
Human chorionic gonadotropin (β-hCG)	Serum β-hCG and urine β-hCG testing (at 14-21 days post-procedure) are standard tests for completion of an early medical abortion to exclude an ongoing pregnancy
Incomplete abortion	Clinical presence of an open cervical os and bleeding, whereby all pregnancy tissue has not been expelled from the uterus, or the expelled tissue is not consistent with the estimated duration of pregnancy. Common symptoms include vaginal bleeding and abdominal pain
Informed consent	A person's decision, given voluntarily, to agree to a healthcare treatment, procedure or other intervention that is made, following the provision of accurate and relevant information about the healthcare intervention, the risks involved, and alternative treatments available
IUC	Intrauterine contraception. May include hormonal and non-hormonal devices. A form of long-acting reversible contraception
LARC	Long-acting reversible contraception, such as implants and intrauterine contraceptives
Last Menstrual Period (LMP)	By convention, pregnancies are dated in weeks starting from the first day of a woman's last menstrual period (LMP). If her menstrual periods are regular and ovulation occurs on day 14 of her cycle, conception takes place about 2 weeks after her LMP
Low sensitivity urine pregnancy test (LSUPT)	LSUPT detects β-hCG levels above 1000 IU/L. The threshold for a positive test with an LSUPT is much higher than a standard pregnancy diagnostic test
Medical methods of abortion (medical abortion)	Use of pharmacological agents to terminate a pregnancy
MVA	Manual vacuum aspiration (refer to entry in this list on vacuum aspiration)
NICE	The National Institute for Health and Care Excellence (United Kingdom)
NSAID	Nonsteroidal anti-inflammatory drugs

Ongoing viable pregnancy	A pregnancy that continues to develop after an abortion. This may be suspected if there are ongoing symptoms of pregnancy, a rising β-hCG, or signs of progression of the pregnancy on ultrasound
Osmotic dilators	Short, thin rods made of seaweed (laminaria) or synthetic material. After placement in the cervical os, the dilators absorb moisture and expand, gradually dilating the cervix
PCA	Patient-controlled analgesia
Pregnancy tissue	Tissue produced by the union of an egg and a sperm
PCEA	Patient-controlled epidural anaesthesia
Procedural sedation	The use of a combination of medicines – a sedative to relax and an anaesthetic to block pain – to induce a depressed level of consciousness during a medical procedure
PRN	Pro re nata: refers to the administration of prescribed medication as the situation calls for it
RCT	Randomised controlled trial
Rh D status	Whether someone is Rh D positive or Rh D negative, determined by the presence of the rhesus D (Rh D) antigen in their blood cells
Sublingual (medication administration route)	Medication is placed under the tongue to dissolve and absorb into the blood through the tissue
Surgical methods of abortion (surgical abortion)	Use of transcervical procedures for abortion, including vacuum aspiration, and dilatation and evacuation (D&E)
Systematic review	A study design that attempts to collate all empirical evidence that fits pre-specified eligibility criteria in order to answer a specific research question. It uses explicit, systematic methods that are selected with a view to minimizing bias, thus providing more reliable findings from which conclusions can be drawn and decisions made
Telehealth (or telemedicine)	A mode of health service delivery where providers and clients, or providers and consultants, are separated by distance. That interaction may take place in real time (synchronously), for example, by telephone or video link. Telehealth may also take place asynchronously (store-and-forward), when a query is submitted and an answer provided later, for example, by email or text/voice/audio message. Hotlines, digital apps or other one-way modes of communication (for example reminder text messages) that simply provide information do not meet the WHO definition of telehealth

TGA	Therapeutic Goods Administration. The Australian government authority responsible for evaluating, assessing, and monitoring medicines and medical devices
Trimester	The 3-month periods of time in pregnancy. They are referred to as first, second, or third. For the purpose of this guideline the first trimester was up to 14 weeks pregnant and second trimester was from 14 weeks pregnant
Vacuum aspiration	Vacuum aspiration involves evacuation of the contents of the uterus through a plastic or metal cannula, attached to a vacuum source. Electric vacuum aspiration (EVA) employs an electric vacuum pump. With manual vacuum aspiration (MVA), the vacuum is created using a hand-held, hand-activated, aspirator (also called a syringe)
WHO	World Health Organization

4 Guideline development process

The RANZCOG Women's Health Committee established an Abortion guideline development group (2022-2023) (GDG) (Appendix A) following an expression of interest.

RANZCOG guidelines are developed according to the RANZCOG approved processes (see RANZCOG Handbook). The clinical questions (Appendix E) were developed by the Abortion guideline development group and evidence summaries prepared by the RANZCOG Research and Policy team with external research support provided.

Where the clinical question for the RANZCOG Clinical Guideline for Abortion Care and published guidelines were similar, the evidence in the published guideline was reviewed. Where a Cochrane review or other peer-reviewed published systematic review was the evidence source, this was used as the primary source of evidence for the clinical question. Where the guideline development organization (WHO/NICE) had undertaken its own systematic review and meta-analysis, which was not otherwise published, this was used as the primary evidence source for the clinical question. Further evidence searches were undertaken, using the previous search string if published, to identify any additional evidence published since the date of the search for the existing review.

Where no international guidelines addressed a clinical question, new searches were undertaken in the Cochrane Library. Where Cochrane reviews were available they were used as evidence and updates undertaken for further publications since the search date of the Cochrane review. Where no Cochrane review addressed the clinical question, new literature searches were undertaken in MEDLINE and CENTRAL databases, using general search terms to identify all relevant articles. After a preliminary screen of titles and abstracts, full text articles were reviewed in duplicate for inclusion and a quality assessment completed.

RANZCOG Research and Policy team do not undertake new systematic reviews or meta-analyses. Any new studies identified by the updated searches that were not already in systematic reviews are reported as individual studies.

Formal searches were not undertaken for each domain of the Evidence to Decision (EtD) framework (Appendix E) but where studies were identified in the process of searches for the clinical question these were cited in the appropriate domains of the EtD. Certainty of evidence was determined using GRADE methodology. See RANZCOG Handbook.

The RANZCOG Research and Policy team has co-ordinated all administrative and governance activities of the Abortion guideline development group. The RANZCOG Women's Health Committee, a sub-Committee of the RANZCOG Board, and Statements and Guideline Group had oversight of the process.

Users will note that the gestational thresholds vary according to the available evidence, and existing regulations in place in Australia and Aotearoa New Zealand (which differ by method, and by drugs used). For the purpose of this guideline the first trimester was up to 14 weeks pregnant and second trimester was from 14 weeks pregnant.

5 List of recommendations

5.1 Information provision about abortion

Recommendation 1	Evidence-based recommendation	Conditional

The guideline development group recommend that women who are seeking an abortion are provided with information on the following topics:

- Which tests may be required prior to abortion
- The different types of abortion procedure available depending on the gestation of the pregnancy, medical history and local service availability and choice
- The benefits and disadvantages of each option
- The steps involved in the procedure and what to expect
- What to expect if they choose to view pregnancy tissue following a medical or surgical abortion
- The options for pregnancy tissue management after the abortion procedure (acknowledging the cultural significance of this for many groups)
- What to expect in terms of pain and bleeding, and options to manage this
- The lack of association of abortion with increased risk of infertility, cancer, or mental health issues
- The options for psychological support, social services, and local cultural support services and resources available after the abortion procedure, as required
- Follow-up after abortion if indicated and signs of ongoing pregnancy
- Possible short- and long-term complications associated with abortion procedures, including an explanation of expected increase in these risks based on the specific woman's medical history (for example previous uterine surgery):
    - Anaesthetic complications
    - Severe bleeding. Refer to "Principles of post early medical abortion care" from the Royal Women's Hospital Melbourne for information on abnormal or pathological bleeding patterns following an abortion
    - Side effects of the medication
    - Damage to the uterus
    - Incomplete abortion
    - Ongoing pregnancy
    - Pelvic infection
- Contraceptive options available and timing of initiation following abortion.

GRADE of evidence: Low

Good Practice Point 1

The guideline development group recommends the use of a decision aid about abortion options.

5.2 Early medical abortion by telehealth

Recommendation 2	Evidence-based recommendation	Conditional

For women seeking early medical abortion, all abortion services or components of abortion services could be accessed by telehealth or in person.

GRADE of evidence: Low

Good Practice Point 2

For medical abortions up to 10^{+0} weeks[ii], offer expulsion of pregnancy at home based on patient preference, clinical need and access to timely urgent care.

5.3 Testing prior to an abortion

5.3.1 Abortion without prior testing of haemoglobin, Rh D status

Recommendation 3	Consensus-based recommendation

Routine testing of haemoglobin is not required prior to abortion.

[ii] Note: Australia: up to 9 weeks (63 days) in accordance with TGA authorisation of MS-2 Step. Aotearoa New Zealand: up to 10 weeks (70 days) based on jurisdictional protocols.

Recommendation 4	Consensus-based recommendation

Routine testing of blood group for Rh D status, up to 10 weeks pregnant for either medical or surgical abortion, is not required prior to abortion.

Good Practice Point 3

Clinical judgement should be used to evaluate selective testing of haemoglobin and blood group prior to abortion in women at increased risk of haemorrhage, including but not limited to anaemia or advanced gestation.

Good Practice Point 4

Anti-D[iii] administration is recommended for abortion in pregnancies 10 weeks or more for Rh D negative women. Individualised care based on an individual's risk-benefit profile could be considered.

5.3.2 Ultrasound prior to abortion up to 14 weeks pregnant

Recommendation 5	Evidence-based recommendation	Conditional

The gestational age of the pregnancy should be determined prior to an abortion; this could be by clinical means (history including last menstrual period, with or without examination) or by ultrasound scan.
GRADE of evidence: Very low

Good Practice Point 5

An ultrasound is recommended prior to abortion up to 14 weeks pregnant if there is uncertainty about gestational age by clinical means, or if there are symptoms or signs suspicious for ectopic pregnancy or other clinical concerns.

Where gestational age has been established by clinical means, the decision about ultrasound prior to abortion should be made according to patient preferences and access to services.

After 14 weeks pregnant, all women seeking an abortion should have an ultrasound scan to confirm gestational age and position of placenta if previous uterine surgery.

5.4 The optimal treatment regimen for Early Medical Abortion up to 10 weeks[iv] pregnant

Recommendation 6	Evidence-based recommendation	Strong

For early medical abortion up to 10 weeks pregnant the recommended regimen comprises mifepristone 200 mg orally followed 24-48 hours later by misoprostol 800 mcg by buccal, sublingual or vaginal route.
GRADE of evidence: Moderate

Good Practice Point 6

The recommended regimen is guided by local regulatory frameworks.

Good Practice Point 7

Anti-nausea and analgesic medication should be offered.

5.5 Follow-up of Early Medical Abortion up to 10 weeks pregnant

Recommendation 7	Evidence-based recommendation	Conditional

Serum or urine β-hCG following medical abortion up to 10 weeks pregnant can be used to detect an ongoing pregnancy.
GRADE of evidence: Low

Good Practice Point 8

If using urine β-hCG, ongoing pregnancy is excluded by a negative low-sensitivity urine pregnancy test at 14-21 days from mifepristone. If the test is positive or invalid, investigate further and manage as appropriate.

If using serum β-hCG, an ongoing pregnancy is excluded by a decrease in serum β-hCG level of 80% or more from ingestion of mifepristone (if β-hCG taken within 72 hours) to 8-16 days afterwards. If less than 80% decrease, investigate further and manage as appropriate.

[iii] Rh D immunoglobulin
[iv] Note: Australia: up to 9 weeks (63 days) in accordance with TGA authorisation of MS-2 Step. Aotearoa New Zealand: up to 10 weeks (70 days) based on jurisdictional protocols.

Good Practice Point 9
After early medical abortion (up to 10 weeks pregnant), follow-up should be offered to exclude an ongoing pregnancy and assess for complications. Clinical history alone is not reliable in excluding ongoing pregnancy. Options for follow-up include: • face-to-face appointments • telehealth • self-assessment including urine testing

5.6 Medical abortion from 10 weeks pregnant

Recommendation 8	Evidence-based recommendation	Conditional
For medical abortion between 10^{+1} and 20 weeks pregnant, the suggested regimen comprises: • Mifepristone 200 mg orally • Initial dose of misoprostol 800 mcg vaginally or 600 mcg sublingually, 36 to 48 hours after mifepristone • Repeat doses of misoprostol 400 mcg (vaginally, sublingually or buccally), every 3 hours until expulsion of pregnancy A shorter interval between mifepristone and misoprostol may be used if preferred but is associated with a longer duration from taking the initial misoprostol dose to expulsion of pregnancy. GRADE of evidence: Moderate		

Recommendation 9	Consensus-based recommendation
For medical abortion after 20 weeks pregnant the guideline development group recommends use of an adjusted regimen with lower doses of misoprostol and longer intervals between doses, in accordance with local guidelines. Factors that could be taken into consideration include gestation, whether or not the fetus is alive, previous uterine surgery, and parity.	

5.7 The optimal regimen for cervical priming for surgical abortion up to 14 weeks pregnant

Recommendation 10	Evidence-based recommendation	Strong
Cervical priming with misoprostol should be offered for surgical abortion up to 14 weeks in order to reduce the risk of incomplete abortion, ongoing pregnancy, future cervical insufficiency and preterm birth, and reduce the need for additional mechanical dilatation. GRADE of evidence: Moderate		

Good Practice Point 10
The suggested regimen for cervical priming prior to surgical abortion up to 14 weeks pregnant is misoprostol 400 mcg sublingually, vaginally or buccally 1-3 hours prior to the procedure. If misoprostol is unable to be used, then suggest mifepristone 200 mg orally 24–48 hours prior to the procedure.

5.8 The optimal regimen for cervical priming for surgical abortion from 14 weeks pregnant

Recommendation 11	Consensus-based recommendation
For women having a surgical abortion from 14 weeks pregnant cervical priming should be offered.	

Recommendation 12	Evidence-based recommendation	Conditional
For women having surgical abortion from 14-24 weeks pregnant it is reasonable to offer either osmotic dilators alone (or in combination with mifepristone), or misoprostol alone, or a combined regimen of mifepristone and misoprostol. It is noted that the addition of misoprostol to osmotic dilators may lead to increased side effects at later gestations without obvious benefit. GRADE of evidence: Moderate		

5.9 The optimal surgical approach for surgical abortion

Recommendation 13	Evidence-based recommendation	Strong

Manual vacuum aspiration and electric vacuum aspiration are both suitable options for surgical abortion (up to 14 weeks pregnant).

GRADE of evidence: Moderate

5.10 Medical or surgical abortion and pain relief

Good Practice Point 11

The guideline development group recommends that analgesia for surgical or medical abortion should be individualised to patient preferences, clinical need, clinician capabilities, local policies and/or contextual factors.

5.10.1 Pain relief up to 14 weeks pregnant

Recommendation 14	Evidence-based recommendation	Strong

For surgical abortion up to 14 weeks pregnant offer combination of:

- Pre-procedure analgesia with non-steroidal anti-inflammatory (NSAID) medications
- Conscious or deep sedation with the possible addition of paracervical block

GRADE of evidence: Moderate

Good Practice Point 12

For surgical abortion up to 14 weeks pregnant, general anaesthesia could be offered if clinically indicated or patient preference.

Recommendation 15	Evidence-based recommendation	Strong

For medical abortion up to 14 weeks pregnant offer a single dose ibuprofen 1600 mg (off-label use), followed by ibuprofen 400 mg to 600 mg eight-hourly. A maximum dose of ibuprofen 2400 mg can be taken in 24 hours while symptoms of pain persist.

GRADE of evidence: Moderate

Good Practice Point 13

For medical abortion up to 14 weeks pregnant, pain relief can be optimised by:

- Offering paracetamol (1000 mg 4 to 6 hourly as required with a maximum 4000 mg per 24 hours) in addition to ibuprofen with antiemetic 30 minutes prior to administration of misoprostol
- Considering selective use of opiate analgesia

5.10.2 Pain relief from 14 weeks pregnant

Recommendation 16	Consensus-based recommendation

For surgical abortion from 14 weeks pregnant:

- For dilator placement for cervical priming, suggest the use of pain relief (including paracervical block/intravaginal lignocaine gel or conscious or deep sedation or general anaesthesia) according to patient and surgeon choice
- Offer pre- and peri-operative analgesia with non-steroidal anti-inflammatory (NSAID) medications
- The analgesia can be given one to three hours before the commencement of the procedure
- Offer paracervical block in addition to conscious or deep sedation according to clinician or patient preference
- Paracervical block could be offered at the time of general anaesthesia, according to clinician preference.

Recommendation 17	Consensus-based recommendation

For medical abortion from 14 weeks pregnant, offer pain relief comprising a range of options from oral analgesia through to patient-controlled intravenous analgesia and regional anaesthesia in accordance with local protocols.

5.11 Abortion and antibiotic prophylaxis

Good Practice Point 14

Offer routine sexually transmitted infection (STI) screening for all women having medical or surgical abortion. However, STI screening should not cause delay to providing timely abortion care, and same day provision of abortion care should take precedence. Treatment for women who test positive for an STI and partner notification should be performed as per local sexual health guidelines.

Recommendation 18 Evidence-based recommendation Conditional

Use antibiotic prophylaxis for all women having a surgical abortion. The treatment regimen should be according to local policy.

Do not routinely use antibiotic prophylaxis for women having medical abortion up to 14 weeks pregnant as the likelihood of severe infection is very low (<1%) and there are widespread concerns regarding adverse effects of antibiotics and development of antibiotic resistance.

GRADE of evidence: Very low

Recommendation 19 Consensus-based recommendation

The guideline development group recommends against the routine use of antibiotic prophylaxis for medical abortion from 14 weeks pregnant.

5.12 Contraception following abortion

Recommendation 20 Evidence-based recommendation Strong

For women choosing an intrauterine contraceptive (IUC), immediate insertion should be offered at the time of surgical abortion, or for medical abortion as soon as possible after the pregnancy has been expelled.

For women choosing contraceptive implants, immediate insertion should be offered after surgical abortion, or for medical abortion at the same time mifepristone is administered.

GRADE of evidence: Low

Good Practice Point 15

For women having a medical abortion and requesting depot medroxyprogesterone acetate, the injection may be administered at the time of medical abortion (including prior to pregnancy expulsion), after discussing the potential small added risk of ongoing pregnancy with the woman.

5.13 Choice of medical or surgical abortion up to 14 weeks pregnant

Good Practice Point 16

Women should be able to choose the method of abortion most acceptable to them, without coercion, informed by their values and preferences, after appropriate information is provided.

Recommendation 21 Evidence-based recommendation Conditional

Consider offering a choice of medical or surgical abortion up to 14 weeks pregnant, as both methods are safe, effective and acceptable.

GRADE of evidence: Moderate

5.14 Choice of medical or surgical abortion from 14 weeks pregnant

Good Practice Point 16

Women should be able to choose the method of abortion most acceptable to them, without coercion, informed by their values and preferences, after appropriate information is provided.

Recommendation 22 Evidence-based recommendation Conditional

Offer a choice of a medical or surgical abortion from 14-24 weeks pregnant, as both methods are safe although medical abortion is associated with higher risk of incomplete abortion and may require surgical evacuation.

GRADE of evidence: Low

5.15 Abortion following uterine surgery

Recommendation 23	Evidence-based recommendation	Conditional

The method of abortion for women with previous uterine surgery should be a decision made between the woman and their clinician as there are increased risks of complications at the time of procedure.
GRADE of evidence: Low

Good Practice Point 17

The guideline development group recommends that in women over 14 weeks with a uterine scar (including caesarean birth) ultrasound examination should be performed to assess for placenta accreta spectrum to assist in planning the appropriate method and location for the abortion to take place.

5.16 Incomplete abortion and ongoing pregnancy following abortion

5.16.1 Incomplete abortion

Recommendation 24	Evidence-based recommendation	Conditional

Women with incomplete early medical abortion could be offered surgical evacuation, a repeat dose of misoprostol, or expectant management. This decision will depend on the preferences of the woman, signs and symptoms, clinical stability, and access to surgery.
GRADE of evidence: Very low

Recommendation 25	Consensus-based recommendation

Women with incomplete abortion after surgical methods could be offered a repeat surgical evacuation of the uterus, misoprostol, or expectant management. This decision will depend on the preferences of the woman, signs and symptoms, clinical stability, and access to surgery.

Good Practice Point 18

Ultrasound for suspected retained products is not required prior to medical management with misoprostol but is generally recommended prior to surgical evacuation unless heavy bleeding is present. Refer to "Principles of post early medical abortion care" from the Royal Women's Hospital Melbourne for information on abnormal or pathological bleeding patterns following an abortion.

Good Practice Point 19

Misoprostol dose for management of incomplete abortion (regardless of initial method): misoprostol 800 mcg buccally followed by repeat dose of misoprostol 400 mcg 4 hours later if pregnancy tissue has not passed.

5.16.2 Ongoing pregnancy following abortion

Recommendation 26	Evidence-based recommendation	Conditional

If there is an ongoing viable pregnancy, a repeat medical or surgical abortion can be offered according to patient preference and access to abortion services.
GRADE of evidence: Very low

Good Practice Point 20

Clinicians should advise women with ongoing viable pregnancy on the small increased teratogenic risks associated with misoprostol use if the pregnancy continues. Refer to Risk of fetal malformations (Ipas guidance).

5.17 Feticide prior to abortion

5.17.1 The effectiveness of feticide

Recommendation 27	Evidence-based recommendation	Conditional

The decision for feticide prior to surgical or medical abortion should be made on patient preference and service availability. A discussion between the woman and their clinician should include harms and benefits.
GRADE of evidence: Moderate

Good Practice Point 21

The guideline development group recommends that feticide should be considered for abortions at or beyond 22^{+0} weeks pregnant or based on local jurisdictional guidelines.

5.17.2 Method of feticide

Recommendation 28	Evidence-based recommendation	Conditional

Consider using digoxin, potassium chloride (KCl), or lignocaine to perform feticide prior to surgical or medical abortion using the route most appropriate for the agent. See table in Method of feticide. The decision about feticide agent should be made according to patient and clinician preference, and service availability.
GRADE of evidence: Moderate

Good Practice Point 22

In the uncommon event that a method of feticide has failed to achieve fetal asystole, the procedure should be repeated with either the same or an alternate method as is locally appropriate for the service.

6 Narrative summary of the evidence with recommendations

This chapter outlines the available evidence for each clinical question and includes the quality assessment together with recommendations and good practice points. See Appendix E for detailed reports of the evidence summary tables and the Evidence to Decision summaries (based on GRADE methodology).

6.1 Information provision about abortion

Clinical Question 1: What information (written or verbal) would a woman want when considering whether to have an abortion and when choosing the method of abortion?

Source of evidence: NICE Systematic Review (Information needs of women undergoing an abortion) from the NICE Abortion Care Guideline. Additional searches identified 10 qualitative studies for inclusion[5-14].
Certainty of evidence: GRADE-CERQual Low (ranges from high to very low, mostly low).

Women should have access to information before making decisions about abortion. Information provided by a registered health professional to women prior to an abortion should be based on principles of informed consent and shared decision-making.[v]

Qualitative evidence identified women wanted information on the different procedure options available for their specific circumstances; the benefits and disadvantages of each option; the steps involved in the procedure and what to expect from these; what to expect when viewing the pregnancy; the severity of pain expected; expected bleeding patterns; and other bodily experiences of abortion procedure (such as, vaginal expulsion, side effects of medicines). Additionally, women appreciated non-directive contraceptive counselling at time of abortion.

Studies outlined that women wanted sufficiently detailed information on the above aspects of the abortion care, including how to manage side effects, prior to their abortion procedure in order to prepare themselves emotionally and logistically for the abortion experience, and to prevent psychosocial distress from unexpected events arising during and around the time of the abortion. Although there was a strong desire for more information, women also appreciated information that was tailored to their specific needs (including individual psycho-social, cultural and spiritual needs), and geographic location.

The additional information topics included in the recommendation, which were not specifically outlined in the qualitative evidence review (including risks for infertility, cancer, or mental health issues, and support services available) should be covered as part of informed consent.

There is a range of patient information and consumer decision tools accessed by women prior to consultation about abortion, and women highlighted difficulty in identifying reliable and unbiased sources of abortion care information in the community. It is acknowledged that inequities may exist around information for marginalised groups[vi], culturally and linguistically diverse (CALD) communities and those unable to access online information.

v New Zealand Health Care Quality and Safety Commission: shared decision making is a process where a health care professional and consumer work together to make a health care decision. Based on clinical evidence and the consumers informed preference.
vi These include (but are not limited to) those with a disability and the LGBTQIA+ community.

Respectful language will help reduce the barriers and assist with decision making about abortion. A "one size fits all" approach does not usually apply. For some, health literacy may be low and there may be discomfort discussing these issues. Understanding of religious beliefs and cultural taboos and norms, particularly around menstruation and pregnancy are important and translation services should be made available where necessary. The Victorian Government's Health Translations website provides healthcare providers with fact sheets on abortion in some languages. In Aotearoa New Zealand an understanding of the principles of Te Tiriti o Waitangi and knowledge of tikanga or cultural practice (whilst acknowledging that there may be differences in customs between groups) will help with achieving the best health outcomes for Māori women[vii]. People who are Aboriginal and Torres Strait Islander also have unique cultural practices that need to be taken into consideration. For Pacific communities, sex and sexuality are often regarded as sacred and are not openly discussed, even among families. Health services could usefully provide a cultural liaison officer or equivalent to assist.

Recommendation 1	Evidence-based recommendation	Conditional

The guideline development group recommend that women who are seeking an abortion are provided with information on the following topics:

- Which tests may be required prior to abortion
- The different types of abortion procedure available depending on the gestation of the pregnancy, medical history and local service availability and choice
- The benefits and disadvantages of each option
- The steps involved in the procedure and what to expect
- What to expect if they choose to view pregnancy tissue following a medical or surgical abortion
- The options for pregnancy tissue management after the abortion procedure (acknowledging the cultural significance of this for many groups)
- What to expect in terms of pain and bleeding, and options to manage this
- The lack of association of abortion with increased risk of infertility, cancer, or mental health issues
- The options for psychological support, social services, and local cultural support services and resources available after the abortion procedure, as required
- Follow-up after abortion if indicated and signs of ongoing pregnancy
- Possible short- and long-term complications associated with abortion procedures, including an explanation of expected increase in these risks based on the specific woman's medical history (for example previous uterine surgery):
    - Anaesthetic complications
    - Severe bleeding. Refer to "Principles of post early medical abortion care" from the Royal Women's Hospital Melbourne for information on abnormal or pathological bleeding patterns following an abortion
    - Side effects of the medication
    - Damage to the uterus
    - Incomplete abortion
    - Ongoing pregnancy
    - Pelvic infection
- Contraceptive options available and timing of initiation following abortion.

GRADE of evidence: Low

Good Practice Point 1

The guideline development group recommends the use of a decision aid about abortion options.

6.2 Early Medical Abortion by telehealth

Clinical Question 2: *For a woman seeking early medical abortion (up to 10 weeks[viii] pregnant), are abortion services delivered by telehealth with a trained health practitioner as safe, effective, and acceptable as in-person abortion services?*

vii See page 40 of the New Zealand Aotearoa Abortion Clinical Guideline for information on Cultural Safety in New Zealand.

viii Note: In Australia, the medication used for early medical abortion is currently TGA-licensed (MS-2 Step) up to 9 weeks (63 days) pregnant, including via telehealth. Aotearoa New Zealand permits early medical abortion up to 10 weeks (70 days) pregnant. A national abortion telehealth service provides support.

Source of evidence: Two Cochrane reviews[15, 16, 17] and a Cochrane Response review[18] have informed the recommendation. An additional single cohort study[19] and a randomised controlled trial (RCT)[19] were identified from literature searches undertaken.
Certainty of evidence: Low (range from low to very low)

Abortion via telehealth, compared with in-person abortion care, showed little or no difference in complete abortion, ongoing pregnancy, the need for blood transfusion due to haemorrhage, or uptake of contraception following abortion, level of patient satisfaction with the care received, willingness to use the same service again in the future, or whether women would recommend the method to a friend. Provision of abortion care by telehealth may result in a small reduction in referral for surgical abortion[16, 17].

Medical abortion services by telehealth have been reported to be safe and effective in many countries, including Australia [19-21]. Benefits include being able to consult with a health professional from outside their local community for the sake of anonymity. Telehealth is widely regarded as having increased access to EMA (acknowledging that remote areas of Australia and New Zealand may have limited access to timely medical care)[22]. Improving access to EMA is likely to have substantial benefit for Māori and Aboriginal and Torres Strait Islander women, who are more likely to live in rural and remote regions, as well as enabling them to have greater choice in where their abortion takes place to ensure their care preserves their dignity, supports their *tikanga* or cultural practice, and is culturally safe.

Significant barriers to access may remain for those without the minimum requirements to facilitate telehealth consultations, including inadequate private and safe space in which to participate in a telehealth consultation (including women experiencing domestic violence), limited English and digital literacy skills, and limited access to required technologies[23]. Concerns about privacy and safety are also relevant to women who have attended an in-person appointment, but then receive the EMA medications at home, take the medications at home, and/or pass the pregnancy at home. It is important to check that all stages of an EMA can be performed at home in privacy and safety, without coercion.

Combined care models where elements of abortion care are delivered by telehealth have also been studied. Endler et al 2022 found a combined care model where participants completed an online abortion consultation but went on to receive an in-person examination and ultrasound if indicated was as safe and effective as in-person care, and was preferred by women over in-person care[19]. There is also evidence to support the safety and efficacy of misoprostol being self-administered at home by women up to 9 weeks pregnant[15].[viii]

Information needs are similar for those who receive EMA by telehealth or by in-person care. Particular emphasis for telehealth should include specific and clear information on how to take their medications, expected timeframes, effects and side effects of the medications (including how to manage these), signs and symptoms of concern, how and when to obtain healthcare provider support (including in an emergency), how to assess the effectiveness of treatment, and how failure of the abortion may be managed. Women having EMA by telehealth (or at home after in-person care) are advised to have a support person present (who can assist in contacting and accessing support and/or emergency care, if needed) at least until the pregnancy has passed.

Recommendation 2	Evidence-based recommendation	Conditional

For women seeking early medical abortion, all abortion services or components of abortion services could be accessed by telehealth or in person.
GRADE of evidence: Low

Good Practice Point 2

For medical abortions up to 10^{+0} weeks[viii], offer expulsion of pregnancy at home based on patient preference, clinical need and access to timely urgent care.

6.3 Testing prior to an abortion

6.3.1 Abortion without prior testing of haemoglobin, Rh D status

Clinical Question 3a: For a woman seeking a medical or surgical abortion in the first trimester, is selective or no testing of haemoglobin, Rh D status, prior to abortion as safe, acceptable and accessible as routine testing of haemoglobin, Rh D status?

Source of evidence: Systematic review[24]. Additional supporting evidence from two studies[25, 26], and annual reports from the UK's national haemovigilance system the Serious Hazards of Transfusion (SHOT) database[27].
Certainty of evidence: No direct evidence

The benefits and risks of pre-procedure haemoglobin or Rh D testing are unclear.

Rh D negative women who are exposed to the Rh D antigen may become sensitised by fetal blood cells during pregnancy and as a result develop antibodies to Rh-positive red blood cells (RBCs) and may cause fetal anaemia in a subsequent pregnancy. Anti-D (Rh D immunoglobulin) is administered to prevent such Rh D sensitisation.

A systematic review[24] of Anti-D[ix] prophylaxis for the NICE Abortion Care Guideline did not identify any studies comparing Anti-D prophylaxis with no Anti-D prophylaxis among women having an abortion prior to 13 completed weeks.

National guidelines in Australia and Aotearoa New Zealand report that administration of Anti-D for women seeking a medical abortion less than 10 weeks pregnant is no longer indicated.[x] WHO 2022 and RCOG 2022 guidelines for abortion care have reached a consensus that Anti-D prophylaxis is not required for surgical abortion less than 12 weeks pregnant based on recent studies indicating fetal red blood cell exposure during surgical abortion under 12 weeks is below the calculated threshold to cause maternal Rh D sensitisation[25].

The UK's national haemovigilance system, the SHOT database (2015-2022), has recorded 132 cases of Rh D sensitisation following pregnancy, and in only three cases of potential events reported abortion as the sensitising event. In only one abortion was the gestation known and it was 11 weeks[27]. In the same time period there were at least 1.6 million abortions in the UK and the majority of these were likely to be in the 1st trimester. Since 2019, under 10 weeks Anti-D prophylaxis was not recommended in the NICE Abortion Care Guideline. Furthermore, it is reported that fewer fetal cells than are needed for sensitisation are present in the maternal blood in surgical abortion up to 12 weeks[25]. These data suggest that it is unlikely that abortion before 10 weeks' gestation is a risk factor for Rh D sensitisation.

Whilst the benefits of Anti-D for medical and surgical abortions under 10 weeks pregnant have not been clearly demonstrated in existing literature, and any risks in not giving it are unlikely to be significant, the benefits of not testing and administering Anti-D are significant to women and providers. There is a small risk of anaphylaxis associated with the administration of Anti-D. Requirement for Anti-D administration for surgical abortion may raise access issues, particularly for those who need to travel long distances, or who receive same-day abortion care.

Individualised care based on an individual's risk-benefit profile may be considered. Anti-D is more likely to be beneficial in later gestations, in young women who are likely to desire pregnancies in the future and where there would be no delay to their care by testing. In contrast, for same-day procedures where administration of Anti-D would necessitate a repeat visit, especially for rural women and those at earlier gestations, and where the woman considers her family (whānau) complete, an assessment may conclude that Anti-D is not warranted.

For recommendations on STI testing, see *6.11*.

[ix] Rh D immunoglobulin

[x] Note: Australia: In the setting of medical abortion <10 weeks of pregnancy there is insufficient evidence to suggest the routine use of Rh D immunoglobulin (National Blood Authority Australia, Guideline for the prophylactic use of Rh D immunoglobulin in pregnancy care.
New Zealand: There is insufficient evidence to recommend the use of Anti-D for medical abortion <10 weeks of pregnancy (New Zealand Blood Service, Use of Rh D Immunoglobulin (Anti-D Immunoglobulin) During Pregnancy and the Post Partum Period (111G130)).

Recommendation 3	Consensus-based recommendation

Routine testing of haemoglobin is not required prior to abortion.

Recommendation 4	Consensus-based recommendation

Routine testing of blood group for Rh D status, up to 10 weeks pregnant for either medical or surgical abortion, is not required prior to abortion.

Good Practice Point 3

Clinical judgement should be used to evaluate selective testing of haemoglobin and blood group prior to abortion in women at increased risk of haemorrhage, including but not limited to anaemia or advanced gestation.

Good Practice Point 4

Anti-D[xi] administration is recommended for abortion in pregnancies 10 weeks or more for Rh D negative women. Individualised care based on an individual's risk-benefit profile could be considered.

6.3.2 Ultrasound prior to abortion

Clinical question 3b: For a woman seeking a medical or surgical abortion in the first trimester, is an ultrasound prior to abortion as safe, acceptable and accessible as no ultrasound prior to abortion?

Source of evidence: A single large retrospective cohort study conducted in England of a no-test (including no ultrasound) abortions provides direct evidence for EMA only[28]. No direct evidence for ultrasound and no ultrasound prior to surgical abortion was identified. The NICE Abortion Care Guideline systematic review (2019) of two non-randomised studies with and without ultrasound evidence of an intra-uterine abortion provides indirect evidence although all women had an ultrasound[29].
Certainty of evidence: Very low (range low to very low)

An ultrasound has been standard practice prior to abortion to confirm gestation and exclude ectopic pregnancy. The large retrospective cohort study comparing two months before and after service changes due to COVID-19, used a flowchart, based on risk factors for ectopic pregnancy, and found that no-test (no-ultrasound) abortion was deemed appropriate for 61% of women having EMA. Compared to the group that had in-clinic assessment and ultrasound, the no-test group had a statistically significantly higher rate of successful abortions with no differences in serious adverse events[28]. Indirect non randomised studies reported little or no difference in ectopic pregnancy, complete abortion without repeat surgical intervention, or ongoing pregnancy[29].

Knowledge of gestational age may influence decisions about choice of method of abortion. Alternatives to the ultrasound considered reliable to establish gestational age include the date of the last menstrual period (LMP), and certainty of date of conception.

Access to ultrasound services may vary across Australia and Aotearoa New Zealand and may be particularly challenging for those living in rural and remote areas. If ultrasound is only used where there is no knowledge of the gestational age, or if there are risk factors or ectopic pregnancy is suspected, then access to abortion may be improved. For a decision aid for Early Medical Abortion without ultrasound, see Figure 2 of Aiken et al. (2021)[28].

Recommendation 5	Evidence-based recommendation	Conditional

The gestational age of the pregnancy should be determined prior to an abortion; this could be by clinical means (history including last menstrual period, with or without examination) or by ultrasound scan.
GRADE of evidence: Very low

[xi] Rh D immunoglobulin

Good Practice Point 5
An ultrasound is recommended prior to abortion up to 14 weeks pregnant if there is uncertainty about gestational age by clinical means, or if there are symptoms or signs suspicious for ectopic pregnancy or other clinical concerns. Where gestational age has been established by clinical means, the decision about ultrasound prior to abortion should be made according to patient preferences and access to services. After 14 weeks pregnant, all women seeking an abortion should have an ultrasound scan to confirm gestational age and position of placenta if previous uterine surgery.

6.4 The optimal regimen for Early Medical Abortion up to 10 weeks[xii] pregnant

Clinical Question 4: For a woman seeking early medical abortion (EMA) (up to 10 weeks or 70 days from LMP), what medication regimen (including type of medication, dosage, and dose interval) is the safest, and most effective, accessible, and acceptable?

Source of evidence: One Cochrane review was identified[15]. A subsequent search did not identify any additional studies.
Certainty of evidence: Moderate (high to very low)

Early Medical Abortion is practiced up to 9 weeks pregnant (63 days) in Australia and 10 weeks (70 days) in Aotearoa New Zealand. A composite pack containing mifepristone (Linepharma mifespristone 1 × 200 mg tablet and GyMiso misoprostol 4 × 200 mcg tablets) (MS-2 Step®) is the medication regimen approved for EMA up to 9 weeks in Australia. The only approved route for misoprostol administration in Australia is buccally. Mifepristone use for abortion is approved in Aotearoa New Zealand for abortion up to 9 weeks pregnant (63 days), after this gestation its use is off label. Misoprostol use for abortion is off label in Aotearoa New Zealand at any gestation, and consequently there are no restrictions on the route of misoprostol administration or a strict upper gestational limit for its use.

Overall, a combined regimen of mifepristone and misoprostol resulted in lower rates of failure to complete the abortion compared to misoprostol alone. In a combined regimen, an 800 mcg dose of misoprostol is likely to be most effective[15]. Administration of misoprostol 24-48 hours following mifepristone is the most effective dosing interval for completion of abortion. There was little or no difference in the occurrence of side effects (vomiting, diarrhoea, abdominal pain), rates of ongoing pregnancy, and women's dissatisfaction with the procedure, among the different time interval groups of misoprostol.

Misoprostol may be administered by buccal, sublingual, vaginal or oral routes. Buccal or vaginal routes resulted in lower rates of ongoing pregnancy compared to the oral route, and had similar rates of successful abortion, safety, and satisfaction.

Medical abortions should be performed where there is the ability to receive timely medical care. A clear referral pathway for retrieval in the event of complications is recommended, such as aero-medical retrieval. In-patient care may be more appropriate in remote locations.

For information on analgesic options, see *6.10*.

Recommendation 6	Evidence-based recommendation	Strong
For early medical abortion up to 10 weeks pregnant the recommended regimen comprises mifepristone 200 mg orally followed 24-48 hours later by misoprostol 800 mcg by buccal, sublingual or vaginal route. GRADE of evidence: Moderate		

Good Practice Point 6
The recommended regimen is guided by local regulatory frameworks.

[xii] Note: Australia: up to 9 weeks (63 days) in accordance with TGA authorisation of MS-2 Step. Aotearoa New Zealand: up to 10 weeks (70 days) based on jurisdictional protocols.

Good Practice Point 7
Anti-nausea and analgesic medication should be offered.

6.5 Follow-up of Early Medical Abortion up to 10 weeks pregnant

Clinical Question 5: For a woman who has undergone an early medical abortion up to 10 weeks pregnant is assessment of completion of the abortion by urine ß-hCG test as safe, effective, accessible, and acceptable as blood ß-hCG testing?

Source of evidence: One systematic review was identified comprising 4 RCTs[30]. This review provides indirect evidence as the in-person follow-up included serum β-hCG testing in only one of the included studies. Other in-person follow-up assessments included interview ± examination ± ultrasound ± in-person urine β-hCG testing.
Certainty of evidence: Low (downgraded for indirectness)

There was no direct evidence comparing serum β-hCG and urine β-hCG testing following EMA. The SR reported little or no difference in ongoing pregnancy between the at-home urine β-hCG and in-clinic follow-up[30]. The rate of missed ongoing pregnancies was not reported. The loss to follow-up in the at-home group was lower than in-clinic group (3.75% versus 6.49%). Although there was no direct evidence to indicate patient preference almost 82% of the at-home test group would prefer that method again[xiii].

A systematic review of diagnostic accuracy of low sensitivity urine pregnancy testing compared to serum β-hCG or ultrasound two weeks following abortion reported that the sensitivity of the Low Sensitivity Urine Pregnancy Test (LSUPT) for detecting an ongoing pregnancy ranged from 67% to 100%[31]. A prospective study of women undergoing EMA reported that the mean serum β-hCG decline among women with a complete abortion was 91% by day 5[32]. The results were not influenced by the initial β-hCG level or gestation at the time of the EMA. In another prospective study a drop in serum β-hCG of 80% from pretreatment levels by day 8 to 16 accurately predicted successful expulsion in 98.5% of cases.

Suggested protocols when using serum β-hCG testing to exclude an ongoing pregnancy require a baseline β-hCG on the day of mifepristone administration. This would be impractical in some situations such as rural communities, and in this case serum β-hCG within 72 hours of mifepristone, or follow-up using urine β-hCG could be used.

Recommendation 7	Evidence-based recommendation	Conditional
Serum or urine β-hCG following medical abortion up to 10 weeks pregnant can be used to detect an ongoing pregnancy. **GRADE of evidence: Low**		

Good Practice Point 8
If using urine β-hCG, ongoing pregnancy is excluded by a negative low-sensitivity urine pregnancy test at 14-21 days from mifepristone. If the test is positive or invalid, investigate further and manage as appropriate. If using serum β-hCG, an ongoing pregnancy is excluded by a decrease in serum β-hCG level of 80% or more from ingestion of mifepristone (if β-hCG taken within 72 hours) to 8-16 days afterwards. If less than 80% decrease, investigate further and manage as appropriate.

Good Practice Point 9
After early medical abortion (up to 10 weeks pregnant), follow-up should be offered to exclude an ongoing pregnancy and assess for complications. Clinical history alone is not reliable in excluding ongoing pregnancy. Options for follow-up include: • face-to-face appointments • telehealth • self-assessment including urine testing

[xiii] Note: No semi-quantitative pregnancy tests are currently licensed in Australia. High sensitivity urine pregnancy (HSUP) tests can detect β-hCG at a level of ≥25 IU/L β-hCG (some as low as 10IU/L) but are not useful for early confirmation of a successful abortion.

6.6 Medical abortion from 10 weeks pregnant

Clinical Question 6: For a woman seeking medical abortion from 10 weeks pregnant what medication regimen (including dosage, and dose interval) is the safest, and most effective, accessible, and acceptable?

Source of evidence: NICE Abortion Care Guideline (literature search to 2018) with no additional studies identified in subsequent search of the literature. The evidence is from the NICE Abortion Care Guideline, which applied a gestational limit of 24^{+0} weeks. A new search did not identify additional evidence beyond this gestational age.

Note: agents that are not commonly available, less stable, or not as cost-effective are not supported by the World Health Organization (WHO). For this reason, these rarely used prostaglandins (including gemeprost, dinoprostone, carboprost, and sulprostone) were excluded from the evidence summary in this guideline.

Certainty of evidence: Moderate (range moderate to very low)

Misoprostol is widely used for second trimester abortion. It is inexpensive, stable at room temperature, and rapidly absorbed by vaginal, sublingual, buccal, and oral routes. Misoprostol use is associated with minor side effects such as nausea, vomiting, diarrhoea, and abdominal pain. Serious complications such as uterine rupture are rare. Mifepristone sensitises the myometrium of the uterus to prostaglandin and is used as pretreatment prior to misoprostol administration.

Misoprostol and mifepristone are the first line options offered for second trimester medical abortion, but among mifepristone and misoprostol regimens, there are different doses, timings, routes, and frequencies reported.

Route of administration: There is some evidence that vaginal and sublingual routes of administration are associated with a shorter time to expulsion and vaginal route was associated with fewer gastrointestinal side effects, when compared to oral route of administration of misoprostol.

Timing and place of administration: Among women receiving buccal misoprostol either simultaneously with mifepristone or 24 hours later, little or no difference was reported in the proportion of complete abortion, incomplete abortion requiring surgical procedure, haemorrhage, or patient satisfaction. Time to expulsion was longer in the simultaneous administration group (13 hours versus 8 hours). Among women receiving vaginal misoprostol 24 hours versus 48 hours after mifepristone little or no difference was reported in the proportion of complete abortion, incomplete abortion, or haemorrhage. The interval of 36 to 48 hours was the most common dosing interval in the included trials, reported in 4 out of 11 included trials. There is no evidence on the location – in some settings, pregnancy expulsion at home is offered with medical abortions up to 12 weeks. However, it is more common practice for pregnancy expulsion to occur in a health facility with medical abortion after 10 weeks.

Loading dose: misoprostol 800 mcg vaginally or misoprostol 600 mcg sublingually. No evidence was identified for buccal misoprostol loading doses.

No evidence was identified of the efficacy, safety, and acceptability of different doses, timings, routes, and frequencies for medical abortion beyond 24 weeks, with most studies limiting gestation to 20 weeks. Dosages and frequencies can be informed by local guidelines, or inferred from indirect evidence of induction of labour and management of intrauterine fetal demise at these gestations for which other abortion specific evidence is not available.

Recommendation 8	Evidence-based recommendation	Conditional

For medical abortion between 10^{+1} and 20 weeks pregnant, the suggested regimen comprises:

- Mifepristone 200 mg orally
- Initial dose of misoprostol 800 mcg vaginally or misoprostol 600 mcg sublingually, 36 to 48 hours after mifepristone
- Repeat doses of misoprostol 400 mcg (vaginally, sublingually or buccally), every 3 hours until expulsion of pregnancy

A shorter interval between mifepristone and misoprostol may be used if preferred but is associated with a longer duration from taking the initial misoprostol dose to expulsion of pregnancy.
GRADE of evidence: Moderate

Recommendation 9	Consensus-based recommendation

For medical abortion after 20 weeks pregnant the guideline development group recommends use of an adjusted regimen with lower doses of misoprostol and longer intervals between doses, in accordance with local guidelines. Factors that could be taken into consideration include gestation, whether or not the fetus is alive, previous uterine surgery, and parity.

6.7 The optimal regimen for cervical priming for surgical abortion up to 14 weeks pregnant

Clinical Question 7: For a woman undergoing a surgical abortion up to 14 weeks pregnant, what method of cervical priming is the safest, and most effective, accessible, and acceptable?

Source of evidence: Cochrane Review[33]. The guideline development group accessed an updated version of this review, which is currently in press.
Certainty of evidence: Moderate (ranged from high to very low)

Cervical priming with misoprostol is associated with a reduced need for additional dilatation and reduced need for re-aspiration/incomplete abortion when compared to placebo. Cervical injury and uterine perforation are rare in either group with little or no difference found. Misoprostol is associated with nausea, and more abdominal pain/cramping compared to the women in the placebo group. Mifepristone alone (given day before procedure) compared to placebo has similar findings as misoprostol (single study, Cochrane Review).

For long-term outcomes, previous abortion has been shown to be associated with an increased risk of preterm birth (OR 1.12 95% CI 1.09 to 1.16). This association is less strong when analyses are limited to abortions performed after 2004 when the proportion of surgical abortions performed without cervical priming was less than 1% (OR 1.02, 95% CI 0.95 to 1.09)[34].

Recommendation 10	Evidence-based recommendation	Strong

Cervical priming with misoprostol should be offered for surgical abortion up to 14 weeks in order to reduce the risk of incomplete abortion, ongoing pregnancy, future cervical insufficiency and preterm birth, and reduce the need for additional mechanical dilatation.
GRADE of evidence: Moderate

Good Practice Point 10

The suggested regimen for cervical priming prior to surgical abortion up to 14 weeks pregnant is misoprostol 400 mcg sublingually, vaginally or buccally 1-3 hours prior to the procedure.

If misoprostol is unable to be used, then suggest mifepristone 200 mg orally 24–48 hours prior to the procedure.

6.8 The optimal regimen for cervical priming for surgical abortion from 14 weeks

Clinical Question 8: For a woman undergoing a surgical abortion from 14 weeks pregnant, what method of cervical priming is the safest, and most effective, accessible, and acceptable?

Source of evidence: Cochrane Review[35]. The guideline development group accessed an updated version of this review, which is currently in press.
Certainty of evidence: Moderate (range from moderate to very low)

For induced abortions, the difficulty with dilatation is an important consideration among health professionals to avoid risk of cervical trauma. For dilatation and evacuation procedures, the cervix must be dilated sufficiently to allow passage of operative instruments and pregnancy tissue without injury to the uterus or cervical canal. Adequate preoperative preparation to soften the cervix using osmotic dilators or prostaglandin analogues aims to reduce the risk of injury.

Misoprostol versus osmotic dilators: There is little or no difference in ability to complete the procedure, and the extent of dilatation achieved, the procedure time and the need for additional dilatation.

Combination of mifepristone and misoprostol versus osmotic dilators: There is little or no difference in ability to complete the procedure, and the procedure time. There was less dilatation achieved and a greater need for additional dilatation in the combined mifepristone and misoprostol group compared to osmotic dilators.

Osmotic dilators combined with misoprostol versus medical method alone: the combination of osmotic dilators with misoprostol was associated with greater dilatation achieved, and reduced need for additional dilatation.

Osmotic dilators combined with misoprostol versus osmotic dilators alone/placebo: there was little or no difference in the ability to perform the procedure, reduced need for additional dilatation and shorter procedure times. However, early expulsion of the fetus may be increased in the combined group.

The number of cervical lacerations requiring suturing, haemorrhage requiring transfusion, emergency hospitalisations, and uterine perforations was too low to determine if misoprostol plus dilators plus misoprostol made any difference.

Osmotic dilators combined with mifepristone versus osmotic dilators alone or plus placebo: compared to dilators plus placebo, mifepristone plus dilators has little or no effect on ability to perform procedure but is associated with increased dilatation. There was no effect on need for additional dilatation. No instances of pre-procedure expulsion were reported.

Osmotic dilators combined with misoprostol and mifepristone versus misoprostol and osmotic dilators. It is uncertain if mifepristone plus misoprostol plus dilators has any effect on dilatation achieved or need for additional dilatation compared to misoprostol plus dilators.

Note: The NICE Abortion Care Guideline does not recommend the use of misoprostol on the day of the abortion in addition to osmotic dilators inserted the day before the procedure. An increased risk of adverse events requiring emergency hospital admission (cervical laceration, haemorrhage) is associated when misoprostol is used as an adjunct to osmotic dilators. Further, there are limited data to demonstrate the safety of misoprostol prior to surgical abortion in women with a uterine scar. The NICE Abortion Care Guideline recommends after 19 weeks that osmotic dilators and mifepristone be used in combination.

Prior surgical abortion by D&E was found to be associated with an increased risk of preterm birth compared to those without a previous history of abortion[36] (OR 1.39; 95% CI 1.08 - 1.80 (5.5% versus 4.3%)). Adequate cervical priming prior to a surgical abortion at 14 weeks or more, reducing the amount of mechanical dilatation required, may lessen the risk of cervical insufficiency and preterm birth in future pregnancies.

Recommendation 11	Consensus-based recommendation

For women having a surgical abortion from 14 weeks pregnant cervical priming should be offered.

Recommendation 12	Evidence-based recommendation	Conditional

For women having surgical abortion from 14-24 weeks pregnant it is reasonable to offer either osmotic dilators alone (or in combination with mifepristone), or misoprostol alone, or a combined regimen of mifepristone and misoprostol. It is noted that the addition of misoprostol to osmotic dilators may lead to increased side effects at later gestations without obvious benefit.
GRADE of evidence: Moderate

6.9 The optimal surgical approach for surgical abortion

Clinical Question 9: For a woman undergoing surgical abortion up to 14 weeks pregnant, is the use of manual vacuum aspiration (MVA) more acceptable than electric vacuum aspiration (EVA)?

Source of evidence: Cochrane review[37], with three additional RCTs identified through an updated search[38-40].
Certainty of evidence: Moderate (range high to low).

Overall, the benefits between the two techniques (MVA and EVA) are comparable for women seeking abortion up to 14 weeks pregnant.

Little or no difference in rates of completion, initial cervical dilatation (up to 10 weeks pregnant), uterine perforation, febrile morbidity, need for repeat uterine evacuation, and patient preference/satisfaction was found between the two approaches. EVA was associated with a slightly longer procedure (< 1 minute)[38], and slightly more blood loss (< 7 mL), however the clinical significance of these findings is likely to be negligible[38]. No instances of cervical injury in either MVA or EVA were reported in included studies. MVA is perceived as a more difficult technique but is associated with less procedural pain and can be performed in smaller regional centres. The guideline development group noted that in general, later gestations are associated with an increase in provider difficulty and longer procedure times with MVA compared to EVA.

Finally, the environmental impact of resources used was considered. MVA is associated with single use plastic devices/syringes and EVA uses disposable tubing/curettes. Sterilisation of reusable devices up to 20-30 times is practiced by some centres while others use single use plastics. The guideline development group recommended future research on the environmental considerations of both techniques.

Recommendation 13	Evidence-based recommendation	Strong
Manual vacuum aspiration and electric vacuum aspiration are both suitable options for surgical abortion (up to 14 weeks pregnant). GRADE of evidence: Moderate		

6.10 Medical or surgical abortion and pain relief

There was a paucity of direct evidence on pain relief, and it was noted that most current pain relief practice for abortion is not informed by evidence.

Good Practice Point 11
The guideline development group recommends that analgesia for surgical or medical abortion should be individualised to patient preferences, clinical need, clinician capabilities, local policies and/or contextual factors.

6.10.1 Pain relief up to 14 weeks pregnant

Clinical Question 10a: For a woman undergoing a medical or surgical abortion up to 14 weeks what pain relief regimen is the safest, most effective, and acceptable?

Source of evidence: Cochrane systematic review on analgesia for medical abortion[41], and the WHO Abortion Care Guideline evidence summaries[42]. An additional literature search undertaken to identify studies articles published after the search dates of the systematic review did not identify any additional studies.
Certainty of evidence: Moderate (range high to low)

All women should be offered pain relief when undergoing a medical or surgical abortion, as both procedures are likely to be painful[41, 42]. Provision of adequate information about pain was valued by women having an abortion, and not receiving information may result in them being unprepared[6].

For surgical abortions: pain scores were lower if ibuprofen 600 mg was taken pre-procedure in addition to paracervical block (PCB), compared to placebo plus PCB. During procedure, there was a lower mean pain score within 24 hours when PCB was used compared to placebo. However, little or no difference was found in use of additional narcotics when comparing PCB with placebo. PCB combined with sedation had lower pain scores and greater satisfaction reported compared to PCB alone.

However, PCB alone probably has little or no difference on satisfaction with pain relief compared to placebo. Additional research into the evidence on PCB in combination with sedation was performed at the request of the guideline development group and found no studies that compared sedation in combination with PCB, or with sedation alone, so the recommendation was aligned with the evidence presented in the WHO Abortion Care Guideline.

For medical abortions: there was little or no difference in pain score or reported side effects found when comparing ibuprofen 800 mg with placebo, nor when comparing therapeutic versus prophylactic administration of ibuprofen 800 mg. One study reported increased vomiting with ibuprofen compared to placebo. No safety outcomes were reported. Worst pain score reported within 24 hours of abortion was higher in women receiving ibuprofen 1600 mg compared to paracetamol 2000 mg. No studies were identified that compared use of opiates for first trimester medical abortion to other analgesia options. The guideline development group noted that Australian and Aotearoa New Zealand maternity services advise against the use of codeine for medical abortion in women who are breastfeeding. This may need to be taken into consideration for some women having an abortion.

The dosages used in existing evidence exceed the guidance from Australian & New Zealand College of Anaesthetists (ANZCA) and approved dosages in Australia and Aotearoa New Zealand. However, optimising pain relief using off label doses of paracetamol 2000 mg, and ibuprofen 1600 mg as a single dose is supported by evidence. Analgesia for abortion is only required for a short duration helping to lessen the occurrence of adverse events associated with these higher dosages, however total daily dose limits of paracetamol 4000 mg and of ibuprofen 2400 mg should not be exceeded.

Recommendation 14	Evidence-based recommendation	Strong

For surgical abortion up to 14 weeks pregnant offer combination of:

- Pre-procedure analgesia with non-steroidal anti-inflammatory (NSAID) medications
- Conscious or deep sedation with the possible addition of paracervical block

GRADE of evidence: Moderate

Good Practice Point 12

For surgical abortion up to 14 weeks pregnant, general anaesthesia could be offered if clinically indicated or patient preference.

Recommendation 15	Evidence-based recommendation	Strong

For medical abortion up to 14 weeks pregnant offer a single dose ibuprofen 1600 mg (off-label use), followed by ibuprofen 400 mg to 600 mg eight-hourly. A maximum dose of ibuprofen 2400 mg can be taken in 24 hours while symptoms of pain persist.

GRADE of evidence: Moderate

Good Practice Point 13

For medical abortion up to 14 weeks pregnant, pain relief can be optimised by:

- Offering paracetamol (1000 mg 4 to 6 hourly as required with a maximum 4000 mg per 24 hours) in addition to ibuprofen with antiemetic 30 minutes prior to administration of misoprostol
- Considering selective use of opiate analgesia

6.10.2 Pain relief from 14 weeks pregnant

Clinical Question 10b: For a woman undergoing a medical or surgical abortion from 14 weeks pregnant what pain relief regimen is the safest, most effective, and acceptable?

Source of evidence: A systematic review on pain management for medical and surgical termination of pregnancy between 13 and 24 weeks[43], and the WHO Abortion Care Guideline evidence summaries[42]. A literature search was undertaken to identify articles published after the above systematic reviews which identified additional studies[44, 45].
Certainty of evidence: Low (range high to low)

Abortions at later gestations are associated with an increase in the intensity and length of time that women experience pain[43], and therefore separate recommendations for pregnancies after 14 weeks were felt to be required.

For medical abortions: there was little or no difference between the pain ratings and satisfaction scores for patient-controlled epidural analgesia (PCEA) compared to patient-controlled analgesia (PCA). The addition of pregabalin to a PCEA probably decreases pain slightly. There was little or no difference in the need for additional narcotic pain relief between pain relief using NSAIDs and other non-NSAID analgesia, however the need for additional narcotic relief was high in both groups (~65%). There was little or no difference in the rates of the adverse events of nausea and vomiting, across all the analgesic interventions.

For surgical abortions, in terms of dilator placement, there was little or no difference in worst pain rating when lignocaine spray was compared to placebo; paracervical block (PCB) to placebo; or volume of lignocaine used in PCB. PCB may be associated with worse reported pain when compared to intra-vaginal lignocaine gel, possibly due to its injected route of administration. In terms of procedure pain management, one study showed that PCB in addition to general anaesthesia compared to general anaesthesia without PCB reduces worst pain by only a clinically negligible amount.

As there was little clear evidence on which to base a recommendation, a consensus-based recommendation was proposed by the guideline development group. The guideline development group proposed that deep sedation or general anaesthesia (GA) for dilator placement could be offered instead of local anaesthetic agents if clinically indicated/patient preference.

Note: Information on minimal or moderate procedural sedation can be found in the Australian and New Zealand College of Anaesthetists Guideline on procedural sedation (2022).

Recommendation 16	Consensus-based recommendation

For surgical abortion from 14 weeks pregnant:

- For dilator placement for cervical priming, suggest the use of pain relief (including paracervical block/intravaginal lignocaine gel or conscious or deep sedation or general anaesthesia) according to patient and surgeon choice
- Offer pre- and peri-operative analgesia with non-steroidal anti-inflammatory (NSAID) medications
- The analgesia can be given one to three hours before the commencement of the procedure
- Offer paracervical block in addition to conscious or deep sedation according to clinician or patient preference
- Paracervical block could be offered at the time of general anaesthesia, according to clinician preference.

Recommendation 17	Consensus-based recommendation

For medical abortion from 14 weeks pregnant, offer pain relief comprising a range of options from oral analgesia through to patient-controlled intravenous analgesia and regional anaesthesia in accordance with local protocols.

6.11 Abortion and antibiotic prophylaxis

Clinical Question 11: For a woman undergoing a medical or surgical abortion what antibiotic prophylaxis regimen (including no antibiotic prophylaxis) is the safest, most effective, and acceptable?

Source of evidence: NICE Abortion Care Guideline[46] and a Cochrane systematic review on perioperative antibiotics to prevent infection after first-trimester abortion[47]. A literature search was undertaken to identify articles published after the NICE Abortion Care Guideline and found no additional studies.
Certainty of evidence: Very low (range moderate to very low)

During an abortion procedure, cervical instrumentation can cause bacteria from the vagina and cervix to be introduced into the endometrial cavity, leading to upper genital tract infections[47]. Antibiotics given around the time of abortion can reduce the rate of infections[47].

For medical abortion up to 14 weeks pregnant, lower rates of infection with antibiotic prophylaxis compared to no antibiotic prophylaxis were reported, however rates of severe infection were very low in both arms of the study. Higher rates of severe nausea and vomiting were reported with antibiotic prophylaxis compared to no antibiotic prophylaxis[46]. There was a lack of evidence on antibiotic use for medical abortion over 13 weeks pregnant.

For surgical abortion, a reduction of upper genital tract infections with antibiotic prophylaxis compared to placebo/no antibiotic prophylaxis was reported[47]. A further study compared the incidence of upper genital tract infections between the screen and treat approach as opposed to universal prophylaxis, and suggested a benefit with universal prophylaxis[47].

No specific antibiotics are recommended by RANZCOG as providers' policies vary, and antibiotic resistance, drug shortages, and new drug developments may influence which antibiotics are most appropriate to use now and in the future. Suggested antibiotic prophylaxis regimens for surgical abortion can be found in the Australian Therapeutic Guidelines (eTG), and the New Zealand Aotearoa Abortion Care Clinical Guideline 2021. Consideration should be given to screening for STIs and/or antibiotic prophylaxis for STIs if unscreened (based on risk profile) in accordance with published guidelines and considering local prevalence. See specific guidance in the box below. However, STI screening should not cause delay to providing timely abortion care and same day provision of abortion care should take precedence. Treatment for women who test positive for an STI and partner notification should be performed as per local sexual health guidelines while maintaining confidentiality of the abortion advice and services.

Good Practice Point 14
Offer routine sexually transmitted infection (STI) screening for all women having medical or surgical abortion. However, STI screening should not cause delay to providing timely abortion care, and same day provision of abortion care should take precedence. Treatment for women who test positive for an STI and partner notification should be performed as per local sexual health guidelines.

Recommendation 18	Evidence-based recommendation	Conditional
Use antibiotic prophylaxis for all women having a surgical abortion. The treatment regimen should be according to local policy. Do not routinely use antibiotic prophylaxis for women having medical abortion up to 14 weeks pregnant as the likelihood of severe infection is very low (<1%) and there are widespread concerns regarding adverse effects of antibiotics and development of antibiotic resistance. **GRADE of evidence: Very low**		

Recommendation 19	Consensus-based recommendation
The guideline development group recommends against the routine use of antibiotic prophylaxis for medical abortion from 14 weeks pregnant.	

6.12 Contraception following abortion

Clinical Question 12: For a woman receiving abortion and requesting either contraceptive implant or IUC is provision of this contraception at the same visit for surgical abortion or in-person medical abortion as safe, effective, and acceptable as provision of contraception at a post-abortion follow-up visit?

Source of evidence: NICE Abortion Care Guideline[46] and a Cochrane systematic review on post-abortion insertion of contraceptive implants[48]. A literature search was undertaken to identify articles published after the NICE Abortion Care Guideline. Three additional studies were found[49-51].
Certainty of evidence: Low (range moderate to very low)

Ensuring people are enabled to exercise their reproductive rights across a lifespan is paramount in the provision of contraceptive information and services. Reducing the number of unplanned pregnancies through improved understanding and use of contraception continues to be important (while noting that some unplanned pregnancies result from failure of contraception beyond the control of its users). Offers of contraception at the time of abortion should be tailored to the indication for the abortion and the woman's plans for future pregnancies. Ovulation occurs within 1 month following first trimester abortions in 90% of cases[52]. Evidence suggests that insertion of long-acting reversible contraception (LARCs; such as implants and intrauterine contraceptives) at the time of abortion is convenient and highly acceptable to users. Early insertion is more convenient than delayed, and this is more likely to improve accessibility and uptake of long-acting contraception. Immediate insertion of LARCs may be impractical in the event of a medical abortion where the medications are taken at home.

For intrauterine contraceptives (IUC) (hormonal and copper), immediate insertion at the time of the abortion was associated with higher uptake and continuation rates. For insertion at less than nine weeks pregnant, there was little or no difference in expulsion with immediate or delayed (by more than one week) insertion of any IUC. At later gestations there may be an increased risk of expulsion with immediate insertion but the evidence is uncertain.

For implants, there were higher satisfaction and lower rates of unintended pregnancy when an etonogestrel implant was inserted at the same time as medical abortion and surgical abortion compared to a delayed implant insertion (at 6 weeks)[48]. Insertion should be at the time of mifepristone.

For this guideline, the clinical question focused on LARCs, and so recommendations on other forms of contraception were out of scope. However, evidence on depot medroxyprogesterone acetate was reviewed by the NICE Abortion Care Guideline[46]. For information on other forms of contraception after an abortion, see The Faculty of Sexual and Reproductive Healthcare's Contraception After Pregnancy Guideline.

Recommendation 20	Evidence-based recommendation	Strong

For women choosing an intrauterine contraceptive (IUC), immediate insertion should be offered at the time of surgical abortion, or for medical abortion as soon as possible after the pregnancy has been expelled.

For women choosing contraceptive implants, immediate insertion should be offered after surgical abortion, or for medical abortion at the same time mifepristone is administered.
GRADE of evidence: Low

Good Practice Point 15

For women having a medical abortion and requesting depot medroxyprogesterone acetate, the injection may be administered at the time of medical abortion (including prior to pregnancy expulsion), after discussing the potential small added risk of ongoing pregnancy with the woman.

6.13 Choice of medical or surgical abortion up to 14 weeks pregnant

Clinical Question 13: For a woman having an abortion less than 14 weeks pregnant are medical methods safer, more effective, and more acceptable than surgical methods?

Source of evidence: Cochrane systematic review on medical versus surgical methods for first trimester abortions[53]. A literature search for articles published after the systematic review identified one additional study[54]. A further observational study of surgical abortion only, reported on Asherman's syndrome[55].
Certainty of evidence: Moderate (moderate to very low)

Decision-making about which abortion method to choose depends on a number of factors that include evidence about each method, local availability, and personal choice. A woman's preference of abortion method may be informed by their previous history of abortion, pregnancy loss or birth. This question provides the evidence where there has been a direct comparison of medical and surgical methods of abortion. Identified studies were limited by poor recruitment as there were strong preferences for one method over the other.

Both surgical and medical abortion methods are highly effective; little or no difference was found in the proportion of abortions completed by the assigned method. Medical abortion was associated with longer duration of bleeding (3 days more), an increase in vomiting and diarrhoea, and higher pain scores than surgical abortions. Overall, the experience of any pain was high in both groups (91% with surgical and 98% with medical abortions)[53]. Higher satisfaction ratings were reported with the surgical abortion (vacuum aspiration) method at 2 weeks compared to medical abortion (mifepristone and misoprostol)[54]. Women who had surgical abortion were more likely to opt for surgical abortion again in the future compared to those who had medical abortion. Little or no difference was found in the time taken to return to work. Overall, both methods were found to be safe, effective and acceptable to women.

There may be increased risks of complications such as uterine perforation, or intrauterine adhesions, associated with surgical abortion or evacuation after a medical abortion, although there was no evidence identified that compared both methods. Uterine perforation has been noted to be a rare event (approximately 0.1% of surgical abortions)[33]. In a study of women with symptoms suggesting Asherman's syndrome following surgical abortion, the incidence at hysteroscopy was 1.6%[55].

There is a range of reasons that can be discussed in choosing one method over the other.

A medical abortion may be preferred for the following reasons:

- Desire to be awake/avoid a general anaesthetic
- Shorter time to access the abortion
- Improved access, for example via telehealth
- Reported by participants as being "easier" or "less traumatic" and "more natural"
- Can be in a private place (for example, at home) with support people present.

A surgical abortion was preferred for the following reasons:

- Desire to be unaware
- Desire not to see the pregnancy tissue
- Prior experience
- Shorter time to complete the abortion.

Good Practice Point 16
Women should be able to choose the method of abortion most acceptable to them, without coercion, informed by their values and preferences, after appropriate information is provided.

Recommendation 21	Evidence-based recommendation	Conditional
Consider offering a choice of medical or surgical abortion up to 14 weeks pregnant, as both methods are safe, effective and acceptable. GRADE of evidence: Moderate		

6.14 Choice of medical or surgical abortion from 14 weeks pregnant

Clinical Question 14: For a woman having an abortion from 14 weeks pregnant are medical methods safer, more effective, and more acceptable than surgical methods?

Source of evidence: NICE Abortion Care Guideline[46]. A literature search was undertaken to identify articles published after the NICE systematic review. This search did not identify any additional studies.
Certainty of evidence: Low (moderate to very low)

Abortions from 14 weeks pregnant constitute approximately 10% of all abortions worldwide but are responsible for two-thirds of major abortion-related complications such as haemorrhage, infection, uterine rupture, and hospitalisation[56]. Therefore, it is important to determine safety, effectiveness and acceptability of medical and surgical abortions from 14 weeks pregnant.

There was a lower rate of abortions completed by the intended method in the medical group compared to the surgical group[46]. This related to a higher rate of incomplete abortions requiring surgical intervention for retained placenta in the medical abortion group (13%) compared to the surgical abortion group (3%). There was little or no difference reported in the rates of haemorrhage, infection, and patient satisfaction between the two methods. Neither group reported any cases of uterine rupture or cervical injury.

Overall, both medical and surgical abortion are safe, effective, and acceptable. Decision making about which abortion method to choose depends on a number of factors that include evidence about each method, local availability, and personal choice. A woman's preference on abortion method may be informed by their previous history of abortion, pregnancy loss or birth. When women seeking a second-trimester abortion because of fetal anomalies were given the opportunity to choose their method of second-trimester abortion, they had a more positive experience overall[57].

Good Practice Point 16
Women should be able to choose the method of abortion most acceptable to them, without coercion, informed by their values and preferences, after appropriate information is provided.

Recommendation 22	Evidence-based recommendation	Conditional
Offer a choice of a medical or surgical abortion from 14-24 weeks pregnant, as both methods are safe although medical abortion is associated with higher risk of incomplete abortion and may require surgical evacuation. GRADE of evidence: Low		

6.15 Abortion following uterine surgery

Clinical Question 15: For a woman seeking an abortion who has had previous uterine surgery (including caesarean section, hysterotomy, myomectomy, or perforation) what additional investigations and management is required to ensure safety and efficacy of the abortion procedure?

Source of evidence: No systematic review was identified that directly answered this question. Indirect evidence for the second trimester was obtained from a systematic review of comparative observational studies that reported on the associated adverse events and not on management[58]. A further two studies were identified[59, 60].
Certainty of evidence: Low (range low to very low).

Uterine rupture is a rare but well-described serious complication of abortion in women with existing uterine scars[58]. Although case reports were identified of uterine rupture following abortion in the first trimester among women having had previous uterine surgery, research has been focused on abortion in the second trimester, when risks of uterine rupture may be higher due to greater uterine distention.

The body of evidence from observational studies indicates that there is a small increased risk of perforation or rupture regardless of the method among women having a second trimester abortion with a uterine scar compared to those without a scar. The proportion of uterine rupture in women with at least one previous caesarean birth who have medical abortion was

1.4% and for surgical abortion using mechanical methods of cervical priming followed by D&E was 1.3%. It is uncertain if a history of one previous caesarean birth increases the risk of major complications of medical or surgical abortion in the second trimester, due to conflicting results between studies. A history of two or more caesarean births appears to increase substantially the risk of uterine perforation/rupture and other major complications among women having both medical abortion, and surgical abortion. The magnitude of these effects differs between studies.

Although the limited evidence suggests an increased risk of complications associated with previous uterine surgery there is a lack of evidence about management of these.

Recommendation 23	Evidence-based recommendation	Conditional
The method of abortion for women with previous uterine surgery should be a decision made between the woman and their clinician as there are increased risks of complications at the time of procedure. GRADE of evidence: Low		

Good Practice Point 17
The guideline development group recommends that in women over 14 weeks with a uterine scar (including caesarean birth) ultrasound examination should be performed to assess for placenta accreta spectrum to assist in planning the appropriate method and location for the abortion to take place.

6.16 Incomplete abortion and ongoing pregnancy following abortion

6.16.1 Incomplete abortion

Clinical Question 16a: For a woman who has undergone an abortion who has an incomplete or partially completed abortion what additional management is required?

Source of evidence: No systematic review directly answered this question. A single RCT of medical management after EMA was identified[61]. As no studies comparing medical and surgical management in women with incomplete abortion following medical or surgical abortion were identified, indirect evidence from a network meta-analysis of management of miscarriage using the sub-population of incomplete miscarriage was used to inform this recommendation[62].
Certainty of evidence: Very low (range moderate to very low)

Incomplete abortion is a well-known complication after an abortion. It refers to any pregnancy tissue that remains in the uterus after incomplete expulsion of pregnancy[61] (also commonly referred to as retained products of conception, RPOC).

One RCT compared repeat medical management with expectant management in women who had EMA and had an incomplete abortion (defined as retained products measuring 12 mm or greater on transvaginal (TV) ultrasound performed 21 days after mifepristone administration)[61]. Little or no difference was found in the rate of treatment success (avoidance of surgical management) between women treated with misoprostol (61.8%) and those having expectant management (57.1%). No participants received a blood transfusion or experienced endometritis. Little or no difference was reported in need for emergency surgical intervention, or unscheduled emergency department visits, number of adverse events, pain score, or analgesia use between the medical and expectant management groups. Regardless of the treatment allocation, for each 1 mm increase in retained pregnancy tissue size the likelihood of treatment failure (requirement for surgical management at eight (8) weeks from start of treatment) increased by 12%.

Evidence from a network meta-analysis using the sub-population of incomplete miscarriage supports the following options for achieving complete miscarriage (ranked in order of effectiveness), suction aspiration, D&C, misoprostol alone, combination of mifepristone and misoprostol, and expectant management.

No studies specifically looking at surgical abortion were found.

Recommendation 24	Evidence-based recommendation	Conditional

Women with incomplete early medical abortion could be offered surgical evacuation, a repeat dose of misoprostol, or expectant management. This decision will depend on the preferences of the woman, signs and symptoms, clinical stability, and access to surgery.
GRADE of evidence: Very low

Recommendation 25	Consensus-based recommendation

Women with incomplete abortion after surgical methods could be offered a repeat surgical evacuation of the uterus, misoprostol, or expectant management. This decision will depend on the preferences of the woman, signs and symptoms, clinical stability, and access to surgery.

Good Practice Point 18

Ultrasound for suspected retained products is not required prior to medical management with misoprostol but is generally recommended prior to surgical evacuation unless heavy bleeding is present. Refer to "Principles of post early medical abortion care" from the Royal Women's Hospital, Melbourne for information on abnormal or pathological bleeding patterns following an abortion.

Good Practice Point 19

Misoprostol dose for management of incomplete abortion (regardless of initial method): misoprostol 800 mcg buccally followed by repeat dose of misoprostol 400 mcg 4 hours later if pregnancy tissue has not passed.

6.16.2 Ongoing pregnancy following abortion

Clinical Question 16b: For a woman who has undergone an abortion who has an ongoing pregnancy *what investigations and management is required?*

Source of evidence: A systematic review of observational data from RCTs[63, 64].
Certainty of evidence: Very low

For the purposes of this guideline ongoing pregnancy was defined as presence of a gestational sac with or without fetal cardiac activity at follow-up after medical or surgical abortion.

Management of ongoing pregnancies following EMA (up to 63 days) with misoprostol have been reported in two different publications. In a systematic review of four RCTs, a sub-group of women with ongoing pregnancies received a second dose of misoprostol and abortion was then completed in 91-100%. If a complete abortion was not achieved after the second misoprostol dose, then surgical management was performed[63]. In a further study of two different RCTs of EMA, only 62% who received a repeat misoprostol dose had a complete abortion[64].

No studies of medical management of ongoing pregnancies following surgical abortion were identified.

No studies of surgical management of ongoing pregnancies after medical or surgical abortion were identified.

If the pregnancy is continued, the use of misoprostol (but not mifepristone alone) in the first trimester has been associated with a small increased risk of malformations (see Ipas guidance).

Recommendation 26	Evidence-based recommendation	Conditional

If there is an ongoing viable pregnancy, a repeat medical or surgical abortion can be offered according to patient preference and access to abortion services.
GRADE of evidence: Very low

Good Practice Point 20

Clinicians should advise women with ongoing viable pregnancy on the small increased teratogenic risks associated with misoprostol use if the pregnancy continues. Refer to Risk of fetal malformations (Ipas guidance).

6.17 Feticide prior to abortion

The guideline development group recognise the special circumstances where late termination of pregnancy may be regarded by the managing registered health professionals and the woman as the most suitable option in a particular circumstance. The procedure is associated with required expertise and specific ethical and legal considerations. Selective fetal reduction (feticide in multiple pregnancies) is out of the scope for this guideline.

6.17.1 The effectiveness of feticide

Clinical Question 17a: For a woman undergoing an abortion is pretreatment induced fetal death (feticide) safer, more effective, and more acceptable than usual abortion care?

Source of evidence: One RCT[65] and one cohort study[66] were identified.
Certainty of evidence: Moderate

From 22^{+0} weeks pregnant, a live birth becomes increasingly common when performing an abortion[67]. When a decision has been made to have an abortion after 22^{+0} weeks, feticide is usual practice. However, it may be appropriate to perform an abortion without feticide if the fetus has a condition incompatible with life, and on the request of the parents.

The RCT reported that intraamniotic digoxin was effective in inducing fetal death in 92% of cases where it was used[65]. Little or no difference was reported in the proportion of women with complications between women receiving digoxin versus those with placebo. Participants in the study reported that if they were faced with the same situation in the future, they would prefer feticide.

A prospective cohort study surveyed 291 women about the acceptability of having feticide with intracardiac potassium chloride or not, prior to D&E from 18-24 weeks pregnant[66]. Most women in both groups found their procedure (feticide plus Dilapan insertion versus Dilapan insertion alone) very acceptable or acceptable with no significant difference between the groups.

Observational studies reported conflicting results with feticide versus no feticide and are likely to have selection bias. Therefore, they have not been included.

Recommendation 27	Evidence-based recommendation	Conditional
The decision for feticide prior to surgical or medical abortion should be made on patient preference and service availability. A discussion between the woman and their clinician should include harms and benefits. **GRADE of evidence: Moderate**		

Good Practice Point 21
The guideline development group recommends that feticide should be considered for abortions at or beyond 22^{+0} weeks pregnant or based on local jurisdictional guidelines.

6.17.2 Method of feticide

Clinical Question 17b: For a woman undergoing an abortion what method of feticide is the *safest, most effective, and most acceptable?*

Source of evidence: A systematic review[68] was identified. An additional search was undertaken on potassium chloride (KCl) and identified one study[69].
Certainty of evidence: Moderate

Different agents have been used to induce feticide, the most commonly used being digoxin, potassium chloride, and lignocaine[68]. No studies reported on patient satisfaction or acceptability.

A systematic review reported that intraamniotic digoxin resulted in lowered effectiveness (measured as fetal asystole at 24 hours after administration) compared to intracardiac digoxin (RR 0.88 95%CI 0.81 - 0.96). Overall, both methods demonstrated high efficacy (94% intracardiac; 83% intraamniotic). Little or no difference was reported between routes in pre-procedure expulsion and any adverse event[70]. Adverse event rates were low overall (2-5%). There were no reported instances of adverse reactions to digoxin, chorioamnionitis, haemorrhage requiring transfusion, or need for additional surgery.

One RCT compared intracardiac potassium chloride to intracardiac administration of lignocaine prior to medical abortion and reported little or no difference in efficacy (measured as fetal asystole at 3 mins after feticide administration). No instances of adverse reactions to medications were reported in either group. A secondary procedure (saline 10 mL to 20 mL into the fetal pericardium) was performed in cases where fetal asystole was not achieved with the primary medication. This procedure was effective in 100% of cases[69].

While no RCT evidence directly comparing the two most common techniques (intraamniotic digoxin, intracardiac KCl) was identified, a prospective cohort study compared intraamniotic digoxin, intracardiac KCl, and funic KCl (into the umbilical vein) for abortion of pregnancies with fetal anomaly between 22 and 31 weeks pregnant[71]. All feticide methods had high rates of achieving fetal asystole by 36 hours (93.0%, 95.1%, and 97.5% for intraamniotic digoxin, intracardiac KCl, and funic KCl respectively). Intraamniotic digoxin was associated with shorter procedure times, lower procedural difficulty scores, and lower patient pain scores. However, in this study it was unclear how the method of feticide was chosen, and selection bias is possible.

In summary, digoxin, potassium chloride, and lignocaine have similar safety and effectiveness.

Recommendation 28	Evidence-based recommendation	Conditional
Consider using digoxin, potassium chloride (KCl), or lignocaine to perform feticide prior to surgical or medical abortion using the route most appropriate for the agent. See table below. The decision about feticide agent should be made according to patient and clinician preference, and service availability. GRADE of evidence: Moderate		

Good Practice Point 22
In the uncommon event that a method of feticide has failed to achieve fetal asystole, the procedure should be repeated with either the same or an alternate method as is locally appropriate for the service.

Agent	Dosage	Route of administration (under ultrasound guidance)	Comment
Digoxin	0.5 - 2 mg 1 mg dosage is most commonly used with the broadest evidence base for safety	• Intraamniotic (most common) • Intracardiac • Intrafetal – into the fetal abdomen	• Intraamniotic administration may require >24 hrs to achieve fetal asystole. Repeat ultrasound should be performed prior to inducing abortion to ensure fetal asystole • The failure rate of the procedure appears independent of dosage above 1 mg. • Higher failure rates of intraamniotic administration may be expected in cases of fetal anomaly where swallowing or intestinal amniotic fluid passage are restricted, such as duodenal atresia, or where polyhydramnios is present
Potassium Chloride (KCl)	2-5 mL of 10 mmols/10 mL (7.5%) KCl solution Additional aliquots of 2–3 mL of KCl are administered until asystole is observed for 2–5 min, up to a maximum of 20 mL	• Intracardiac (most common) • Intrafunic – into the umbilical vein	Intracardiac and intrafunic routes require ultrasound guidance and administration by an experienced clinician The amount of KCl required to achieve fetal asystole increases with increasing gestational age. • First trimester 1 – 2 mL KCl • Second trimester 5 mL KCL • Third trimester 10 mL KCL Repeat ultrasound 30-60 mins following procedure to ensure fetal asystole prior to inducing abortion
Lignocaine	Lignocaine of 1% 20 mL or lignocaine of 2% 10 mL	• Intracardiac	• Less studied and less commonly used
Saline	Saline 10 to 20 mL	• Intracardiac • Into the pericardium to achieve cardiac tamponade	• Often reserved for use if other methods have failed

7 Follow-up

When a woman is discharged from the treatment facility, whether before or after completion of the abortion, she should be given clear written instructions as to how to access advice on a 24-hour basis and help in an emergency, as well as information about what to expect and follow-up arrangements. The RANZCOG patient decision aid has information on expected blood loss, pain, and other symptoms. This could be used to discuss information on when to self-refer for medical attention after abortion. The decision aid also contains information on returning to work and other activities after an abortion.

Local service providers such as primary care providers are responsible for the follow-up of women after an abortion for whom they have prescribed EMA medications. See Good Practice Point 9.

8 Regulatory and legal requirements

Registered health professionals should be aware of the abortion legislation that applies in the jurisdiction in which they practice.

Jurisdiction	Status	Details	Safe access/exclusion zone
Australian Capital Territory[1]	Legal. Accessible (no gestational limit)	Must be provided by medical doctor	Exclusion zone >50 metres (during opening hours)
New South Wales[2]	Legal. Accessible up to 22 weeks	Beyond 22 weeks legal with two doctors' approval	Safe access zones: 150 metres
Aotearoa New Zealand[3]	Legal. Accessible up to 20 weeks	Beyond 20 weeks legal with two doctors' approval	Safe access zones: 150 metres (by application)
Northern Territory[4]	Legal. Accessible up to 24 weeks	Beyond 24 weeks legal with two doctors' approval	Safe access zones: 150 metres (during opening hours)
Queensland [5]	Legal. Accessible up to 22 weeks	Beyond 22 weeks legal with two doctors' approval	Safe access zones: 150 metres (unless prescribed by Minister)
South Australia[6]	Legal. Accessible up to 22 weeks and 6 days	Beyond 22 weeks and 6 days legal with two doctors' approval	Safe access zones: 150 metres
Tasmania[7]	Legal. Accessible up to 16 weeks	Beyond 16 weeks legal with two doctors' approval	Safe access zones: 150 metres
Victoria[8]	Legal. Accessible up to 24 weeks	Beyond 24 weeks legal with two doctors' approval	Safe access zones: 150 metres
Western Australia[9]	Legal. Accessible up to 23 weeks	Beyond 23 weeks legal with two doctors' approval. Jurisdictional requirements regarding parental involvement for minors may apply	Safe access zones: 150 metres

[1] Health Act 1993 (ACT) Part 6 Div 6.2 ss 85-87
[2] Abortion Law Reform Act 2019 and Public Health Amendment (Safe Access to Reproductive Health Clinics) Act 2018 No 26
[3] New Zealand Abortion Legislation Act 2020
[4] Termination of Pregnancy Law Reform Act 2017; Termination of Pregnancy Law Reform Legislation Amendment Act 2021
[5] Termination of Pregnancy Act 2018 (Qld) Part 4
[6] Termination of Pregnancy Act 2021
[7] Reproductive Health (Access to Terminations) Act 2013 (Tas) s 9
[8] Public Health and Wellbeing Act 2008 (Vic) Part 9A ss 185A185H, Public Health and Wellbeing Amendment (Safe Access Zones) Act 2015 (Vic) Part 9A
[9] Western Australia. Acts Amendment (Abortion). Act 1998. No. 15 of 1998. Amended 20th September 2023.

Registered health professionals who have a conscientious objection to abortion are legally entitled to decline to provide advice and assistance in Australia and Aotearoa New Zealand. If a registered health professional has a conscientious objection to abortion they must tell the woman of their objection and inform the woman how to access the closest provider of abortion services within a clinically reasonable time. Conscientious objection must not impose delay, distress or health consequences on a woman seeking an abortion[xiv].

The RANZCOG Clinical Guideline for Abortion Care aligns with current regulatory guidelines for prescription medicines for Australia and Aotearoa New Zealand. In Australia, the medication used for EMA (MS-2 Step) is currently TGA-licensed up to 9 weeks pregnant (63 days), including via telehealth. In Aotearoa New Zealand EMA up to 10 weeks pregnant (70 days), including via telehealth, is possible but misoprostol is prescribed "off-label". If a medicine is prescribed outside of the parameters of its registration with the regulatory body for medicines (TGA in Australia, Medsafe in Aotearoa New Zealand), this is considered to be an unapproved use of the approved medicine (also known as "off-label" use). "Off-label" prescribing occurs when a drug is prescribed for an indication, a route of administration, or a patient group that is not included in the approved product information document for that drug. There is no legal impediment to prescribing off-label, however the onus is on the prescriber to defend their prescription for an indication that is not listed in the product information. If, in the opinion of the prescriber, the off-label prescription can be supported by reasonable quality evidence the prescriber should proceed if this is in the woman's best interests[72]. Use of misoprostol for medical abortion is supported by international high-quality evidence and clinical guidelines from the WHO and NICE and hence New Zealand prescribers should proceed.

9 Recommendations for future research

1. General Questions
   a. Explore information needs for populations such as rural and remote, different ethnic backgrounds, new immigrants, refugees, LGBTQIA+.
   b. Researchers should use the core outcomes for reporting STAR[11] and consider also reporting the time to expulsion for medical abortion, requirement for uterotonics, time to return to menstruation, and clinically meaningful time point for measuring study outcomes following abortion. Other outcomes to be considered include quality of life and sexual functioning after abortion.

2. Comparative studies of medical and surgical method
   a. Reporting specific side effects, bleeding patterns, acceptability and financial impact of different methods.
   b. There is a need for trials to address the efficacy, especially of currently used methods, and women's preferences at later gestations.
   c. The rate of serious adverse events associated with medical and surgical abortions (for example, infection).

3. Studies of EMA should include the following questions
   a. Is self-administration as safe as provider-administration including at less than 6 weeks pregnant.
   b. How best to inform and support women who choose to self-administer, including when to seek clinical care.
   c. Types of healthcare providers who can be involved during the medical abortion process to ensure safety.
   d. Assess the self-administration of a misoprostol-alone regimen to understand its safety and effectiveness, along with operational research to understand how to train healthcare providers to dispense abortion medication and support women during the abortion process.
   e. Acceptability studies to investigate the components of medical abortion regimens.
   f. Comparison of home urine pregnancy test with serum β-hCG for EMA follow-up.
   g. Medical abortion in settings where back-up facilities are not available and women are less likely to attend for follow-up.
   h. Diagnosing and managing incomplete abortion and ongoing pregnancy.
   i. Research on digital health technologies to support self-management for women having an abortion.
   j. The safety and efficacy of very early medical abortions.

[xiv] See the Australian Medical Association's position statement on Conscientious Objection

4. Abortion up to 14 weeks pregnant
    a. Do women having any abortion up to 14 weeks pregnant require blood tests for haemoglobin and Rh D status?
    b. What are the additional benefits in having routine ultrasound prior to abortion?
    c. Is there a subgroup of women at higher risk of complications who should be recommended to have an ultrasound? For example, previous uterine surgery, greater risk of ectopic pregnancy.

5. Medical abortion after 10 weeks pregnant
    a. Effectiveness, safety and acceptability of outpatient medical abortion after 10 weeks pregnant.
    b. What is the optimal interval between mifepristone and misoprostol?
    c. Optimal location for medical abortions after 10 weeks pregnant (at home or in facility).

6. Medical abortion after 14 weeks pregnant
    a. Trials to test the effectiveness, safety, and acceptability of self-administered versus provider-administered medical abortion and among women and girls aged less than 18 years.
    b. Optimal misoprostol dosing for medical abortions after 20 weeks pregnant.

7. Cervical priming up to 14 weeks pregnant
    a. What is the optimal gestational age where cervical preparation decreases adverse events and whether there are groups of women where cervical preparation is particularly important (adolescents or nulliparae).
    b. The use of mifepristone for cervical preparation from 10 weeks pregnant should be investigated.
    c. Women's preferences for cervical preparatory techniques have been inadequately explored and should be included in future research.

8. Cervical preparation for dilatation and evacuation from 14 weeks pregnant
    a. The effectiveness of same-day cervical preparation for procedures from 14 weeks pregnant.
    b. The utility of adding misoprostol to Laminaria for cervical preparation in advanced gestations.
    c. The role of mifepristone in combination with osmotic dilators for cervical preparation for D&E from 14 weeks pregnant.
    d. Comparing Foley catheter with prostaglandins or osmotic dilators.
    e. The effectiveness of medications alone for cervical priming for surgical abortion beyond 16^{+0} weeks pregnant.
    f. The optimal timing of dilator use and number inserted for abortion from 14 weeks pregnant.
    g. Management of cervical priming prior to dilatation and evacuation (D&E) at gestational ages ≥ 18 weeks pregnant in settings where osmotic dilators are not available.

9. Surgical methods for abortions up to 14 weeks pregnant
    a. Some outcomes have not been adequately addressed in the trials included. For example, the need for pain relief, long-term consequences or physicians' preference for the instrument.
    b. What is the environmental impact of different methods of surgical abortion?
    c. Safety, convenience and acceptability of re-using manual vacuum aspiration (MVA) equipment.

10. Surgical methods for abortion from 14 weeks pregnant
    a. Studies of pain management during D&E procedure for surgical abortion after 14 weeks pregnant (only consider pain management during osmotic dilator placement).
    b. WHO: Safety, effectiveness and acceptability of anti-epileptics and anxiolytics for pain management for medical abortion after 14 weeks pregnant.

11. Perioperative antibiotics to prevent infection after abortion up to 14 weeks pregnant
    a. Settings including LMIC where prevalence of lower genital tract infections may be higher.

b. Time period that is long enough to investigate the incidence of re-infection and the outcomes of partner notification, where appropriate, in women who have received antibiotic prophylaxis.
c. Accuracy and reproducibility of diagnostic criteria for upper genital tract infection would help to improve objective diagnosis.
d. Antibiotic prophylaxis for medical and surgical abortion.
e. Different antibiotic agents, dosages, and routes of administration.
f. Optimal antibiotic regimens for post-abortion infection prophylaxis.
g. Screening and antibiotic treatment for pelvic inflammatory disease before surgical abortion versus provision of pre- or perioperative prophylactic antibiotics without screening or risk assessment for pelvic inflammatory infection.

12. Adolescent population
    a. Longer follow-up periods (more than 12 months) to determine rates of utilization and unintended pregnancy are required.
    b. Whether immediate postpartum contraceptive implant insertion increases the risk of adverse effects including on breastfeeding compared to standard insertion is warranted.
    c. Studies in low- and middle-income countries are needed.
    d. Study with longer follow-up periods to evaluate abortion rate, unintended pregnancy, and satisfaction are required.

13. Women with previous uterine surgery
    a. Report on the risk of complications including uterine rupture with medical abortion from 14 weeks pregnant.
    b. No studies reported on outcomes for women having abortion in the first trimester with previous uterine surgery on which to make a recommendation.

10 Recommendations for workforce development

A cornerstone of the provision of good health care is the availability of well-trained health professionals.

The guideline development group considered workforce requirements as outside the scope of the guideline but during the development of the guideline, the following workforce development and succession planning needs were identified:

- A more cohesive approach to reproductive health care, including a focus on contraception, sexual health care and education, and unbiased counselling.
- Recruitment and training of sufficient registered health professionals (including medical students) to provide safe clinical care. The provision of training and succession planning is a priority in the circumstance of a tenuous skilled workforce to deliver the commitments of the legislative reform.

Issues relating to abortion should be included in the education of all registered health professionals (both in primary and secondary care), particularly those who are primarily involved in women's health care. No member of the health team should be expected to perform abortion against his or her personal convictions, but all have a professional responsibility to inform women where and how such services can be accessed and obtained and to be respectful of the women's decision.

11 Implementation

The guideline development group identified the following enablers for the implementation of the RANZCOG Clinical Guideline for Abortion Care:

1. Engagement with policy-makers to make changes to the following

- The National Blood Authority and New Zealand Blood Authority for Rh D testing and Anti-D[xv] administration before 12 weeks pregnant in line with the RCOG and WHO guidelines.
- Therapeutic Guidelines (eTG) and National Health Pathways Aotearoa New Zealand.
- Therapeutic Goods Administration and MedSafe re: off-label use of misoprostol.
- Expand health care providers of abortion to include hospital and community pharmacists and midwives.

2. Engagement with funders for all aspects of abortion care
   - Early medical abortion requires expansion to primary care and devolution from hospital-based services.
   - Funding for low sensitivity urine pregnancy tests to accompany early medical abortion medications at the time of dispensing.
   - For telehealth provisions for women including those in rural and remote areas.
   - Funding for ultrasound services.

3. Service reconfiguration
   - To deliver optimal timing for cervical priming prior to surgical abortion after 14 weeks.
   - Changes to current processes around use of ultrasound.
   - Education and training on provision of both medical and surgical abortion for second trimester.
   - Education and training on provision of feticide.
   - Education about the guideline recommendations; for example, changes in practice around EMA, priming, testing prior to abortion, abortions after 24 weeks.
   - Emergency physicians to be provided with information about service linkages for women seeking pre-or post-abortion care.

4. Partnerships
   - RANZCOG could consider partnership with The Royal Australian College of General Practitioners (RACGP), Australian College of Rural and Remote Medicine (ACRRM), Royal New Zealand College of General Practitioners (RNZCGP), Family Planning Australia and the Australian Chapter of Sexual Health Medicine (AChSHM), Royal Australasian College of Physicians (RACP) for endorsement of the guideline.
   - Other abortion provider societies, for example MSI Australia.

5. Education strategy
   - RANZCOG advanced training module.
   - Update RANZCOG and medical school curricula.
   - Training for surgical abortions in the second trimester.
   - Guideline development group members providing education pieces across the regions.

6. Patient-focused information
   - Engagement with consumers.
   - Decision aid.
   - Other patient information for specific populations, for example Māori and Pacific peoples, Aboriginal and Torres Strait Islander peoples, LGBTQIA+, Culturally and Linguistically Diverse communities.

12 Review of the guideline

This guideline was developed and financed by RANZCOG. In accordance with the College processes this guideline will be regularly reviewed for updates. A routine update of this guideline is due: November 2028.

[xv] Rh D immunoglobulin

13 Links to relevant resources

Links provided in the body of the guideline are collated here. Where guidance from individual hospitals has been cited, this has been done as it was the best available evidence provided to the Guideline Development Group and has been reviewed by the entire group. This list should not be implied as RANZCOG endorsement of the material.

Source	Name of resource and hyperlink
Australian and New Zealand College of Anaesthetists	Guideline on procedural sedation
Faculty of Sexual & Reproductive Healthcare	Contraception After Pregnancy Guideline
Ipas	Risk of fetal malformations
National Blood Authority Australia	Guideline for the prophylactic use of Rh D immunoglobulin in pregnancy care
National Institute for Health and Care Excellence	Abortion Care
Manatū Hauora Ministry of Health	New Zealand Aotearoa Abortion Clinical Guideline
New Zealand Blood Service	Use of Rh D Immunoglobulin (Anti-D Immunoglobulin) During Pregnancy and the Post Partum Period (111G130)
Royal College of Obstetricians and Gynaecologists	Termination of Pregnancy for Fetal Abnormality
Society of Obstetricians and Gynaecologists of Canada	No. 360-Induced Abortion: Surgical Abortion and Second Trimester Medical Methods
The Royal Women's Hospital Melbourne	Abortion Medical Management to 9 weeks of Pregnancy
The Royal Women's Hospital Melbourne	Principles of post early medical abortion care
Victorian Government	Health Translations
World Health Organization	Abortion Care Guideline

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Appendices

Appendix A: Guideline Development Group membership (includes RANZCOG staff)

Name	Position
Dr Gillian Gibson	Chair and Board member (President Elect)
Professor Kirsten Black	A/Chair, SRHSIG Chair
Professor Danielle Mazza	Diplomate Representative
Dr Kate Poland	Diplomate Representative (Rural Health)
Dr Dan Wilson	Diplomate Representative (Rural Health)
Dr Anna Hudspith	Member (Aotearoa New Zealand)
Dr Catriona Melville	Member
Assoc. Professor. Patricia Moore	Member
Dr Alyce Wilson	Member (Public Health Physician)
Ms Kate Chaouki	Midwifery Representative, Australia
Dr Ahmad Syahir Mohd Soffi	Trainee representative (First Nation's services)
Dr Vanessa Gray	Trainee/Community Representative (proud Darug woman)
Ex officio	
Dr Ben Bopp	President, RANZCOG
Ms Vase Jovanoska	CEO, RANZCOG
Technical team	
Professor Cindy Farquhar, University of Auckland	Dean of Research and Policy, RANZCOG
Assoc. Professor. Michelle Wise, University of Auckland	Advisor
Dr Karyn Anderson, University of Auckland	Research Fellow
Mr Sudi Sekhar, RANZCOG	Executive Director, Innovation, Learning and Quality Assurance
Ms Jinty Wilson, RANZCOG	Head of Research and Policy
Dr Jasmine Schipp, RANZCOG	Research & Policy Senior Coordinator

Appendix B: Acknowledgements

RANZCOG wishes to acknowledge the permission of the New Zealand Ministry of Health to access the evidence summaries of the New Zealand Aotearoa Abortion Clinical Guideline (2021). Under Copyright Licence executed on 10th January 2022, the New Zealand Ministry of Health permitted use of the copyright material of which has provided the foundation for the development of the RANZCOG Guideline. RANZCOG also wishes to acknowledge the support of Mrs Helen Nagels (Managing Editor Cochrane) for her copy edit services to this guideline.

Appendix C: Conflict of interest disclosure

Declaring interests is essential in order to prevent any potential conflict between the private interests of members, and their duties as part of RANZCOG Women's Health Committee or working groups.

A declaration of interest form has been developed specific to guideline development (approved by the RANZCOG Board in September 2012). All members of the Guideline Development Group, and Women's Health Committee were required to declare their relevant interests in writing on this form prior to participating in the review of this guideline. The conflict of interest disclosures are presented in the table below.

Members were required to update their information as soon as they become aware of any changes to their interests and there was also a standing agenda item at each meeting where declarations of interest were called for and recorded as part of the meeting minutes.

There were no significant real or perceived conflicts of interest that required management during the process of updating this guideline.

Name	Conflict of Interest
Dr Gillian Gibson, Chair	1. Board Director, Istar Limited, charitable organisation supplying mifepristone in Aotearoa New Zealand
Professor Kirsten Black, Deputy Chair	None
Professor Danielle Mazza	None
Dr Kate Poland	1. MSI Australia contractor delivering private EMA and surgical abortion services (WA). Provided assistance to update MSI Australia's 'Cervical Preparation at time of STOP' guideline
Dr Dan Wilson	1. Non-Executive Director, Sexual Health Victoria 2. Non-Executive Director, Rural Doctors Association Victoria 3. Non-Executive Director, Australian College of Rural and Remote Medicine
Dr Anna Hudspith	None
Dr Catriona Melville	1. Executive Director of Clinical Excellence, MSI Australia. MSI Australia is an NGO provider of sexual and reproductive health care in Australia including medical and surgical abortion care 2. Member of the writing group for the Queensland Health clinical guideline on Termination of pregnancy (2019)
Assoc. Professor. Patricia Moore	None
Dr Alyce Wilson	None
Ms Kate Chaouki	None

Dr Ahmad Syahir Mohd Soffi	1. Clinical lead of the Pregnancy Options Service, Royal Darwin and Palmerston Hospitals (public hospital abortion program) 2. Medical Director, Family Planning Welfare Association Northern Territory, NGO provider of public-funded early medication abortions (up to September 2023) 3. Member, Northern Territory Termination of Pregnancy Steering Committee responsible for the review and update of the Northern Territory Termination of Pregnancy Clinical Guidelines (2022) 4. Member, SPHERE Women's Sexual Reproductive Health Coalition, an advocacy coalition that develops consensus statements advocating for abortion-related issues 5. Chair, Northern Territory Maternal Newborn Network Termination of Pregnancy Working Group, governmental advisory group that provides abortion policy and health system advice to NT Health
Dr Vanessa Gray	None
Ex officio	
Dr Ben Bopp	N/A as an ex-officio member, Dr Bopp has not directly contributed to the development of the guideline recommendations
Ms Vase Jovanoska	N/A as an ex-officio member, Ms Jovanoska has not directly contributed to the development of the guideline recommendations
Technical team	
Professor Cindy Farquhar, University of Auckland	None
Assoc. Professor. Michelle Wise, University of Auckland	1. Developed New Zealand Aotearoa Abortion Clinical Guideline (2021) for the Ministry of Health
Dr Karyn Anderson, University of Auckland	None
Mr Sudi Sekhar, RANZCOG	None
Ms Jinty Wilson, RANZCOG	None
Dr Jasmine Schipp, RANZCOG	1. Independent consultant for a diabetes technology start-up (Balance Health)

Appendix D: Overview of the review process for this guideline

RANZCOG guidelines are developed according to the RANZCOG Handbook on guideline development processes. These processes are informed by the standards of the Australian National Health and Medical Research Council (NHMRC), which includes the use of GRADE methodology. The draft guideline is developed with oversight of the RANZCOG Women's Health Committee.

The RANZCOG Women's Health Committee and Council approved the draft guideline ahead of open public consultation in keeping with NHMRC recommended consultation periods.

The public consultation invited structured feedback from the RANZCOG membership (including affiliated midwives and consumer groups), affiliate medical colleges, societies and organisations in Australia and Aotearoa New Zealand, government departments, peak bodies representing specific ethnic groups, consumer groups and the general public.

Appendix E: Evidence profiles and evidence to decision tables

Clinical Question 1: Information needs prior to abortion

What information (written or verbal) would a woman want when considering whether to have an abortion and when choosing the method of abortion?

P: Woman considering abortion
I: i) information provided by health practitioner in person
ii) Written information sources
iii) Telephone support with health care worker
C: None (studies do not need to specify comparator)
O: Satisfaction with information provided
- acceptability of information
- safety - fulfilment of informed consent

Evidence to decision

Benefits and harms

Research evidence

Outcomes presented from the NICE Abortion Care Guideline: [B] Information needs of women undergoing an abortion. 2019. Searches up to date to April 2018.

This systematic review included studies with a patient perspective.

An updated literature search was performed by the University of Auckland on 18th May 2023 using the search terms used by NICE limiting to studies published from 2018 to current. 1300 articles were identified. Two researchers independently reviewed articles for inclusion. Inclusion criteria were:

- patient perspective
- high income country
- no self-managed abortion
- not psychosocial counselling, rather clinical and procedural information provision
- not specific fetal abnormality

10 studies were included in addition to those included in the NICE review.

Themes are presented as a narrative summary in two evidence tables - one for abortion not for fetal abnormality, and one for abortion with fetal abnormality.

Certainty of the evidence

CERQual quality of evidence tool used for qualitative reviews. The most common reasons for downgrading evidence were methodological limitations in not reporting data saturation, and adequacy of data. CERQual values from NICE applied to outcomes from their review.

For individual qualitative studies the CASP tool was applied. A holistic impression of quality of evidence-based on the 10 questions was applied as CASP does not report an overall impression framework.

Values and preferences

Overall women having an abortion are likely to value more information rather than less.

Resources

Regardless of the method of abortion chosen, all women should have access to information before making decisions about their body.

Equity

All women seeking abortion should receive information on options and harms and benefits and pathways. In order to improve equity and inclusivity for people identifying as TGE (transgender, non-binary, and gender expansive), services providing abortions should adopt gender neutral processes including in written information and staff should use gender neutral language.

Acceptability

No impact

Feasibility

Providing information is an expected part of clinical care

PICO (1.1)
Population: Pregnant women and people seeking an abortion (any gestation) not for fetal anomaly
Intervention: Information provided by health practitioner discussing having an abortion and the method of abortion (written or verbal)
Comparator: None (studies do not need to specify comparator)

Theme [Author]	Study description	Description of theme	Certainty of the evidence (Quality of evidence)	Citations for studies included in theme
Abortion not for fetal anomaly: What to expect from the procedure [SR] NICE 2018	Based on data from 72 participants in 3 studies	Studies conducted in Sweden, Mexico City, and Scotland with women undergoing abortion not for fetal anomaly reported that women valued information on what to expect during and after the procedure. Women particularly valued the opportunity to ask questions when receiving information.	**Moderate** Moderate concerns for methodological limitations as 2 studies did not discuss data saturation, and 1 study had limited information on sampling and limited quotes to support the theme of interest	Included studies: Andersson (2014), Mukkavaara (2012), Purcell (2017)

Abortion not for fetal anomaly: Information format - family and friends [SR] NICE 2018	Based on data from 22 participants in 2 studies	Evidence from 1 study conducted in Sweden with women undergoing abortion not for fetal anomaly reported that women often sought information from friends and family about abortion.	Low Moderate concerns with methodology as data saturation and sampling were limited, very minor concerns with relevance and coherency, moderate concerns with adequacy as data from one study with a small sample size	Included studies: Andersson (2014)
Abortion not for fetal anomaly: What to expect from viewing the pregnancy products [SR] NICE 2018	Based on data from 150 participants in 3 studies	Studies conducted in Sweden, Mexico City, and Scotland with women undergoing abortion not for fetal anomaly, reported that women valued information on what to expect when seeing the pregnancy.	Moderate Minor concerns for methodological limitations as 1 study did not discuss saturation, moderate concerns with the relevance of data outside the setting of home medical abortion as 96% of the population were women undergoing home medical abortion	Included studies: Kero (2009), Mukkavaara (2012), Purcell (2017)
Abortion not for fetal anomaly: Pain and bleeding [SR] NICE 2018	Based on data from 44 participants in 3 studies	Studies conducted in Sweden, Mexico City, and Scotland with women undergoing abortion not for fetal anomaly, reported that women valued information on the pain and bleeding associated with the procedure.	Moderate Moderate concerns for methodological limitations as 2 studies did not discuss data saturation, and 1 study did not discuss triangulation in their data analysis methods	Included studies: Ekstrand (2009), Mukkavaara (2012), Sherman (2017)
Abortion not for fetal anomaly: Information format - language [SR] NICE 2018	Based on data from 6 participants in 1 study	Studies conducted in Mexico City and USA reported that women valued information on the abortion to be delivered in a simplified manner with repetition. Women highlighted that the language used by healthcare professionals were too complex. Among transgender, nonbinary, and gender expansive (TGE) people gender neutral language was preferred.	Very low Moderate concerns with the quality of the study as data saturation was not assessed and triangulation in their data analysis methods was not discussed, moderate concerns with the relevance of the data to the Australia/ Aotearoa New Zealand setting as 1 study was based in the public abortion services of Mexico City 3 years after decriminalisation of abortion, and the other study only included TGE people, moderate concerns with the adequacy of the data as only two studies with a small sample size reported this theme.	Included studies: Mukavaara (2012)

Abortion not for fetal anomaly: Information format - Internet [SR] NICE 2018	Based on data from 68 participants in 2 studies	Studies conducted in Sweden and Scotland with women undergoing abortion not for fetal anomaly, reported that women often looked on the internet for information about abortion	**Moderate** Moderate concerns with the quality of the studies as 2 studies did not discuss data saturation and there were limited quotes to support the theme of interest	Included studies: Andersson (2014), Purcell (2016)
Abortion not for fetal anomaly: Information format - Healthcare professionals [SR] NICE 2018	Based on data from 66 participants in 2 studies	Studies conducted in Sweden and Scotland with women undergoing abortion not for fetal anomaly, reported that women most often received information from healthcare professionals on abortion. Women valued the information received, however did not mention which healthcare professionals specifically they valued information from.	**High** Minor concerns with the quality of the studies as 1 study did not discuss data saturation, limited information on sampling and there were limited quotes to support the theme of interest	Included studies: Andersson (2014), Purcell (2016)
Abortion not for fetal anomaly: Contraception - Timing [SR] NICE 2018	Based on data from 46 participants in 1 study	Study conducted in Scotland with women undergoing a medical abortion at ≤9 weeks' gestational age not for fetal anomaly, reported that women valued information on future contraception at the time of medical abortion. Most women highlighted that it was an appropriate time to discuss contraception.	**Moderate** Minor concerns for methodological limitations as data saturation was not discussed in the methods	Included studies: Purcell (2016)
Abortion not for fetal anomaly: Contraception - Effectiveness [SR] NICE 2018	Based on data from 22 participants in 1 study	Study conducted in the USA with women undergoing abortion not for fetal anomaly, reported that women valued information on the effectiveness of future contraception use.	**Low** Moderate concerns with the quality of the study as the qualitative methods used an open-ended question, which gave no opportunity for further probing, data saturation was not discussed in the methods, and there was unclear justification for thematic analysis in their data analysis methods, moderate concerns with the adequacy of the data as only 1 study with a small sample size reported this theme	Included studies: Becker (2008)

Abortion not for fetal anomaly: Contraception - Choice [SR] NICE 2018	Based on data from 42 participants in 2 studies	Studies conducted in Mexico City and the USA with women undergoing abortion not for fetal anomaly, reported that women valued information on the different choices of future contraceptive method. Women highlighted that they didn't like information to be restricted to specific methods of contraception.	Low Moderate concerns with the quality of the studies as 2 studies did not discuss data saturation, 1 study used an open-ended question as a qualitative method, which gave no opportunity for further probing (Becker 2008), and 1 study had unclear sampling method, moderate concerns with the relevance of the data to the Australia/Aotearoa New Zealand setting as 1 study was based in the public abortion services of Mexico City 3 years after decriminalisation of abortion, where resources may differ significantly.	Included studies: Becker (2008), Olavarrieta (2012)
Abortion not for fetal anomaly: navigating the system [SR] NICE 2018	Based on data from 16 participants in 1 study	Evidence from 1 study conducted in rural and remote northern Canada with women undergoing a surgical abortion reported that women valued information on accessing abortion services at first point of contact.	Very low Very minor concerns with methodology, serious concerns with relevance as study took place in rural and remote northern Canada and options available to women were not similar (mifepristone and misoprostol was not yet available to women in the study), very minor concerns with coherence, moderate concerns with adequacy as data only from one study with a small sample size	Included studies: Cano (2016)
Abortion not for fetal anomaly: Contraception - pressure [SR] NICE 2018	Based on data from 46 participants in 1 study	Studies conducted in Scotland and USA with women undergoing a medical abortion at ≤9 weeks' gestational age not for fetal anomaly, reported that most women valued that the delivery of information on future contraception was gently "forced". Whereas some women did not value the "pushy" delivery of information on future contraception and felt overwhelmed.	Low Minor concerns with the quality of 1 study as data saturation was not discussed in the methods, moderate concerns with the coherence of the data as women in one study found the pressurised delivery of future contraception to be both helpful and unhelpful, moderate concerns with the adequacy of the data as only 1 study with a small sample size reported this theme	Included studies: Purcell (2016)

Access to the health system: information about abortion procedures - adolescents (10-19yrs) from high income countries [SR] Assifi (2020)	Based on data from participants in 35 studies	This systematic review of mixed method studies included four studies covering the domain of "information about the procedure". Adolescents encountered abortion misinformation and inaccuracies in common social belief about abortion. Adolescents were well placed to use technology-based information provision methods such as telemedicine, web chat, and web searching due to their societal exposure to computers. Opportunities to enhance abortion access for adolescents include enhancing the quality of information and harnessing innovative delivery approaches such as telemedicine.	**Moderate** Minor concerns about adequacy due to the small number of participants	Included studies: O'Donnell (2018), Deeb-Soosa (2014), Feilding (2002), and Welsh (2001)
Insufficient information resulting in uncertainties [Survey and Qualitative study] Georgsson (2019)	Based on data from 185 participants in 1 study	A web-based survey consisting of 5 open-ended questions was recruited through Swedish public discussion boards and social media. Participants reported vague or a lack of preparatory information for their abortion, resulting in uncertainties. Insufficient information was reportedly provided on pain and pain relief options, onset and characteristics of vaginal bleeding, vaginal expulsion, administration of medications, possible side effects and complications, seeing fetal remains, having to share a room (for hospital-based abortions), possible psychological distress and where to find support, length of time required for appointments and procedures, and future contraception. Not knowing what to expect from the abortion process resulted in fear.	**Moderate** Methodological limitation as lower than expected response rate given recruitment strategy	

Difficulties finding high-quality information [Survey and Qualitative study] Georgsson (2019)	Based on data from 185 participants in 1 study	A web-based survey consisting of 5 open-ended questions was recruited through Swedish public discussion boards and social media. 99 participants searching the web for information about abortion. Virtual communities and blogs were used to read about abortion related experiences and communicate with peers. Web-based information was prone to misinformation, and biased information. While some participants found that web-based information was more honest than information provided by health professionals. Participants felt that health professionals lacked written information resources and recommendations for suitable websites.	As above
Difficulties finding high-quality information [Survey and Qualitative study] Georgsson (2019)	Based on data from 185 participants in 1 study	99 participants searching the web for information about abortion. Virtual communities and blogs were used to read about abortion related experiences and communicate with peers. Web-based information was prone to misinformation, and biased information. Some participants found that web-based information was more honest than information provided by health professionals. Participants felt that health professionals lacked written information resources and recommendations for suitable websites.	As above
Unexpectedly poor health professional treatment and support [Survey and Qualitative study] Georgsson (2019)	Based on data from 185 participants in 1 study	More than one third of participants reported unexpectedly poor health professional treatment and support. While some health professionals had shown much appreciated compassion and empathy, others were considered to have shown very poor behaviour which made women feel disrespected, blamed, and questioned.	As above

Logistical information: general lack of knowledge and information among women needing to travel long distances for abortion [Qualitative study] Kavanaugh (2019)	Based on data from 29 participants in 1 study	In depth interviews with US women in two states who travelled more than 100km or out of state for an abortion. 15 participants felt they had limited information regarding abortion and where to get one when first confronted with an unwanted pregnancy. Participants described information about abortion as being difficult to find (even using internet searches) and once found, to navigate in terms of accuracy and reliability. The absence of easily accessible information led some to question the safety of abortion and whether facilities providing it were legitimate	**Moderate** Uncertain as no recruitment rate reported
Suggestions to improve abortion experience for transgender, non-binary, and gender expansive (TGE) people [Survey] Moseson (2021)	Based on data from 67 participants in 1 study	67 respondents identifying as a TGE person who had a pregnancy ending in abortion from an online survey offered gender-related recommendations to improved abortion care. Respondents most frequently recommended clinics adopt gender-neutral registration forms that are gender affirming and sexual orientation affirming. It was recommended that staff should use gender-neutral language. Clinicians should consider reasons for preferring 1 method of abortion over the other may differ for TGE patients compared with cisgender patients.	**Moderate** Context specific to TGE people

Fear of the procedure and pain in women considering abortion [Qualitative survey] Nguyen (2023)	Based on data from 1005 participants in 1 study	Participants were recruited to an online baseline and follow-up survey consisting of closed and open questions. 45 participants cited fear of pain or aspects of the procedure as challenging parts of the abortion experience. Some participants noted the inability to receive sedation or general anaesthesia prior to a surgical abortion was a barrier to accessing abortion. While others reported they were more concerned about psychological distress and awareness of what was happening. Abortion related resources, particularly online, should provide accurate and unbiased information about abortion methods and pain to help patients feel more prepared.	Low Adequacy data was limited (only 45 cited pain), relevance as survey included women who decided to continue the pregnancy.	
Information prior to an abortion: rural Australia [Qualitative study] Noonan (2022)	Based on data from 20 participants in 1 study	In-depth interviews with participants living in Central to Far West rural NSW, who had an unwanted pregnancy within the past 5 years. Participants reported relying on their local health professional's knowledge for abortion. For some participants receiving information about all possible options for abortion helped them find the service providers they needed and meant they could explore and discuss their options in a confidential setting. The time-consuming process of finding local health services that had adequate expertise intensified the sense of time passing, the pregnancy progressing, and the potential limiting of options with this (i.e. gestational limits for EMA) for at least half the participants.	Moderate Relevance to women in rural settings in one state	

Being informed and prepared [Qualitative study] Whitehouse (2021)	Based on data from 24 participants in 1 study	In-depth interviews with women having undergone an abortion in the past 6 months at several locations in England and Wales. Participants reported it was useful to receive information via several different modalities, including websites, brochures, photo consultations, and verbally. They expressed a desire to receive detailed information. Desired clinical information included information on pain, identification and management of excessive bleeding, access to postabortion counselling, permitted support people, and the length of the procedure. Participants described feeling anxious or underprepared if the information given did not correlate with their actual experience.	Low Approached by clinical staff to participate, adequacy
Choices in care [Qualitative study] Whitehouse (2021)	Based on data from 24 participants in 1 study	Participants reported it was important to them to be offered choices around postabortion contraception. Most felt they were not under any pressure to start contraception and valued this.	As above

Prior information effects on women's feeling of safety during home abortion [Qualitative study] Aamud (2021)	Based on data from 23 participants in 1 study	In-depth interviews with women from Norway having undergone a medication abortion at home under 12 weeks, recruited via website and social media. Participants described the information they received prior to abortion as inadequate, and that the information should be more detailed and personalized. Information received about pain and bleeding was especially inadequate and understated. They felt uncertain about dosage and intervals for pain relief provided. Information about the procedure and expulsion of the fetus was also described as insufficient. They emphasized the role detailed information played in coping with the abortion process. Information was often inadequate on the acceptable amount of bleeding and participants were unsure whether it was necessary to contact the hospital with concerns about excessive bleeding.	**Moderate** Context is telemedicine followed by EMA at home, adequacy	

PICO (1.2)

Population: Pregnant women seeking an abortion (any gestation) for fetal anomaly

Intervention: Information provided by health practitioner discussing having an abortion and the method of abortion (written or verbal)

Comparator: None (studies do not need to specify comparator)

Theme [Author]	Study description	Description of theme	Certainty of the evidence (Quality of evidence)	Citations for studies included in theme
Abortion for fetal anomaly: diagnosis of fetal anomaly [SR] NICE 2018	Based on data from 22 participants in 1 study	Evidence from 1 study conducted in rural and remote northern Canada with women undergoing a surgical abortion reported that women valued information on accessing abortion services at first point of contact.	**Low** Moderate methodological concerns with data saturation and sampling, moderate concerns with adequacy as only one study with a small sample size.	Included studies: Andersson (2014)

Abortion for fetal anomaly: choice of abortion method [SR] NICE 2018	Based on data from 31 participants in 1 study	Evidence from 1 study conducted in the USA among women undergoing second trimester abortion for fetal anomaly reported that women valued nondirective information on the advantages and disadvantages of both surgical and medical abortion to make an informed decision of which abortion method was best for the woman.	**Moderate** Minor concerns with methodology as justification for framework of grounded theory is unclear, moderate concerns with adequacy as only one study with small sample size	Included studies: Kerns (2012)
Abortion for fetal anomaly: what to expect from the procedure [SR] NICE 2018	Based on data from 31 participants in 1 study	Studies conducted in Sweden and the UK among women undergoing abortion for fetal anomaly reported that women valued detailed information on what to expect during and after the procedure. Women particularly valued the opportunity to ask questions when receiving information.	**Moderate** Moderate concerns with methodology as tow of the three studies had a high risk of recall bias	Included studies: Andersson (2014), Carlsson (2016) Fisher (2015), Lotto (2016)
Abortion for fetal anomaly: what to expect from viewing the pregnancy [SR] NICE 2018	Based on data from 133 participants in 2 studies	Studies conducted in Sweden among women undergoing abortion for fetal anomaly reported that women valued information on what to expect when seeing the pregnancy. Women highlighted that they wanted information on what the pregnancy would look like and if there would be signs of fetal life.	**Low** Moderate concerns with methodology as 1 study had a high risk of re-call bias as it was a retrospective self-report with an unlimited timeframe and the online methodology gave no opportunity for further probing, moderate concerns with adequacy as only 1 study with a small sample size using a semi-structured interview design (Asplin 2014) reported this theme, whereas the other study relied on data from a virtual chat room to construct the theme (Carlsson 2016)	Included studies: Asplin (2014), Carlsson (2014)
Abortion for fetal anomaly: fetal remains [SR] NICE 2018	Based on data from 287 participants in 1 study	Studies conducted in Sweden among women undergoing abortion for fetal anomaly reported that women valued information on what to expect when seeing the pregnancy. Women highlighted that they wanted information on what the pregnancy would look like and if there would be signs of fetal life.	**Low** Moderate concerns with the quality of the study as there is a high risk of re-call bias as it was a retrospective self-report with an unlimited timeframe and the online methodology gave no opportunity for further probing (Fisher 2015), moderate concerns with the adequacy of the data as only 1 study with a small sample size reported this theme	Included studies: Fisher (2015)

Abortion for fetal anomaly: disclosing the end of the pregnancy with other adults [SR] NICE 2018	Based on data from 28 participants in 1 study	Evidence from 1 study conducted in the UK among women undergoing an abortion for fetal anomaly reported that women valued information on how to disclose the end of their pregnancy to other adults.	Low Moderate concerns with the quality of the study as there was a high risk of recall bias as there was an unlimited timeframe for the interviews, and some women were interviewed with their partners, rather than alone, moderate concerns with the adequacy of the data as only 1 study with a small sample size reported this theme	Included studies: France (2013)
Abortion for fetal anomaly: disclosing the end of the pregnancy with children [SR] NICE 2018	Based on data from 28 participants in 1 study	Evidence from 1 study conducted in the UK among women undergoing an abortion for fetal anomaly reported that women valued information on how to disclose the end of their pregnancy to their children and the appropriate language to use when doing so.	Low Moderate concerns with the quality of the study as there was a high risk of recall bias as there was an unlimited timeframe for the interviews, and some women were interviewed with their partners, rather than alone, moderate concerns with the adequacy of the data as only 1 study with a small sample size reported this theme	Included studies: France (2013)
Abortion for fetal anomaly: information format - internet [SR] NICE 2018	Based on data from 22 participants in 1 study	Evidence from 1 study conducted in Sweden among women undergoing an abortion for fetal anomaly and not for fetal anomaly reported that the women often looked on the internet for information.	Low Moderate concerns with the quality of the study as data saturation was not discussed, limited information on sampling, and limited quotes to support the theme of interest (Andersson 2014), moderate concerns with the adequacy of the data as only one study with a small sample size reported this theme	Included studies: Andersson (2014)

Abortion for fetal anomaly: information format - healthcare professionals [SR] NICE 2018	Based on data from 383 participants in 2 studies	Studies conducted in Sweden and the UK among women undergoing abortion for fetal anomaly reported that women valued the information received from healthcare professionals on abortion. However, women did not mention which healthcare professionals specifically they valued information from.	**Moderate** Moderate concerns with the quality of the studies as 1 study had a high risk of re-call bias as they were retrospective self-reports with an unlimited timeframe and the online methodology gave no opportunity for further probing (Fisher 2015). 1 study did not discuss data saturation, provided limited information on sampling, and limited quotes to support the theme of interest (Andersson 2014), moderate concerns with the adequacy of the data as only 1 study with a small sample size used a semi-structured interview design (Andersson 2012) reported on this theme, whereas the other study relied on data from an online survey to construct the theme (Fisher 2015)	Included studies: Andersson (2014), Fisher (2015)
Abortion for fetal anomaly: information format - support organisations [SR] NICE 2018	Based on data from 388 participants in 2 studies	Studies conducted in the UK among women undergoing abortion for fetal anomaly reported that women found support organisations such as Antenatal Results and Choice (ARC) and Stillbirth Neonatal Death Charity (SANDS) pivotal in providing information on the abortion for fetal anomaly. Women highlighted that healthcare professionals should signpost these organisations as early as possible in the process.	**Moderate** Moderate concerns with the quality of the 2 studies as there was a high risk of recall bias due to the unlimited timeframe for the interviews (Fisher 2015; France 2013), the online methodology of 1 study gave no opportunity for further probing (Fisher 2015); and in 1 study some women were interviewed with their partners, rather than alone (France 2013)	Included studies: Fisher (2015), France (2013)
Abortion for fetal anomaly: information format - specific and consistent [SR] NICE 2018	Based on data from 33 participants in 2 studies	Studies conducted in Sweden among women undergoing abortion for fetal anomaly reported that women wanted information that was specific and consistent.	**Moderate** Moderate concerns with the quality of 1 study as data saturation was not discussed and limited information on sampling and quotes to support the theme of interest (Andersson 2014)	Included studies: Andersson (2014), Asplin (2014)

Abortion for fetal anomaly: information format - timing [SR] NICE 2018	Based on data from 383 participants in 2 studies	Studies conducted in Sweden and the UK with women undergoing abortion for fetal anomaly reported that women valued information delivered at the most appropriate time. Women highlighted that for information on future pregnancies they valued the information to be delivered sooner rather than later. Whereas, providing information for decision making during an abortion was not valued.	**Low** Moderate concerns with the adequacy of the data as only 1 study with a small sample size used a semi-structured interview design (Andersson 2012) reported on this theme, whereas the other study relied on data from an online survey to construct the theme (Fisher 2015)	Included studies: Andersson (2014), Fisher (2014)
Abortion for fetal anomaly - healthcare services: information [Qualitative study] Malope (2023)	Based on data from 12 participants in 1 study	Semi-structured interviews with 12 participants in South Africa having had an abortion for a pregnancy with a serious congenital abnormality (no definition). Most participants understood the information provided and were able to recall the diagnosis. Although the information was felt by participants to be necessary, it was often overwhelming in volume and complexity. Some participants found a follow-up information session helpful.	**Moderate** Methodological limitation with a lack of clarity in the research question	
Abortion for fetal anomaly - healthcare services: freedom of choice [Qualitative study] Malope (2023)	Based on data from 12 participants in 1 study	Some participants had difficulty deciding on abortion and felt pressured by healthcare professionals to make the “right" choice, which they perceived to be abortion. Participants wanted to make the right decision to avoid regret.	As above	

Abortion for fetal anomaly - information to inform decision making [SR] Heaney (2022)	Based on data from participants in 30 studies	26 articles addressed parents need for information and the impact lack of information had on their experiences. While most parents acquired information themselves from various sources, clear and unbiased information from health professionals was valued. When parents were given relevant and timely information, particularly about the anomaly and healthcare procedures, it reduced their fears and worries, helped them understand their choices, and feel more empowered. Parents who felt ill-informed during the process felt less well prepared physically and psychologically about what to expect, and for some their experience was more traumatic. Some studies reported parents' frustration at trying to find information, while others expressed frustration about inconsistent and conflicting information.	**Moderate** Methodological limitation as quality assessments of studies were not used in interpretation of results or conclusions.
Abortion for fetal anomaly - compassionate care [SR] Heaney (2022)	Based on data from participants in 30 studies	Compassionate care was explored in 21 studies. Healthcare providers capacity to provide compassionate and empathetic care was potentially the most influential element in how parents perceived whether their experience was positive or negative. The importance of non-judgmental staff was highlighted in 11 studies.	**Moderate** Methodological limitation as quality assessments of studies were not used in interpretation of results or conclusions.

Clinical Question 2: Safety of Early Medical Abortion delivered by telehealth?

For a woman seeking early medical abortion (up to 10 weeks[xvi] pregnant), are abortion services delivered by telehealth with a trained health practitioner as safe, effective, and acceptable as in-person abortion services?

P: Woman seeking an early medical abortion (< 10 weeks)

I: Abortion service provided by telehealth (package of abortion services), by a health practitioner

Components of abortion services, may include all or some of the following:

- Eligibility assessment via telehealth (including organisation of tests prior to abortion)
- Counselling/instruction for the abortion via telehealth
- Active facilitation to provide medication via telehealth
- Follow-up of the abortion via telehealth

C: In person abortion service by health practitioner

O: Adverse events

- Blood transfusion
- Need for emergency care or hospital admission
- Ongoing pregnancy
- Retained products of conception requiring additional treatment (medical or surgical)

- Access to abortion services – gestational age at time of consult
- Acceptability/satisfaction with abortion services
- Provision of contraceptive advice

Evidence to decision

Benefits and harms

Research evidence

Two Cochrane reviews and a Cochrane Response review inform this recommendation:

- Zhang et al 2022 (Cochrane review)
- Gambir et al 2020 (Cochrane review)
- Sguassero et al 2021 (Cochrane Response review)

An additional single study (a before-and -after cohort study) was identified from literature searches undertaken in the development of the New Zealand Abortion Guideline in 2021.

An additional RCT (Endler 2022) published in August 2022 was identified through updating of literature searching undertaken in November 2022.

Summary

Telehealth compared to in-person abortion care may result in little or no difference in complete abortion, ongoing pregnancies, need for blood transfusions due to haemorrhage, contraception uptake following abortion, satisfaction with the care received, willingness to use the same service again in the future or whether women would recommend the method to a friend.
Provision of abortion care by telehealth may result in a small reduction in receipt of or referral for surgical abortion.

No hospitalisations or deaths were reported in either group at up to 2 months' follow-up. All evidence was GRADEd as low or very low-certainty evidence.

[xvi] Note: Australia: up to 9 weeks (63 days) in accordance with TGA authorisation of MS-2 Step. Aotearoa New Zealand: up to 10 weeks (70 days) based on jurisdictional protocols.

An additional study not included in the meta-analysis findings above (Kerestes 2021) found abortion care provided by telehealth (with medication pickup or mailout was associated with a small benefit (2.8%, 95% CI 0.9% to 4.7%) in successful abortion compared to in-clinic care. This study was a before-and-after cohort study comparing a service model change as a result of COVID-19. This again was GRADEd as very low-certainty evidence.

A further RCT (Endler 2022) published in August 2022 was identified after the above systematic reviews. This non-inferiority study evaluated a telehealth model consisting of a combination of in-person and remote care for women 9 weeks pregnant or less at clinics in low-income areas of Cape Town, South Africa. Participants completed an online abortion consultation on their smartphones while in the clinic, then went on to have an abdominal palpation to assess weeks of pregnancy and an ultrasound if concern was raised about this (11%). 28% of women having an abortion at less than 9 weeks pregnant were excluded from the study owing to not having access to a smartphone, or lacking understanding of English. Little or no difference was found in the proportion of ongoing pregnancy, hospital admission, unscheduled/emergency clinic visits, or blood transfusion between the telehealth and standard care groups. Little or no difference was found in the proportion of women who were satisfied or very satisfied with their experience. Women in the telehealth group were more likely to prefer telehealth care than in-person care.

Certainty of the Evidence

All included studies in the Cochrane reviews/Cochrane Response review were observational. Only two outcomes had narrow confidence intervals; the remainder were wide, and included the null hypothesis.

The RCT evidence was GRADEd as low certainty owing to imprecision (wide confidence intervals) and indirectness (as patient population in urban South Africa were very impoverished with 29% living in shack-type housing and almost half experiencing food insecurity).

Overall certainty of evidence using the GRADE certainty of evidence tool was low to very low.

Values and preferences

Research evidence

An Australian-based qualitative study[73] of 24 women who obtained care via the at-home telehealth medical abortion service reported that women selected at-home telehealth owing to convenience, ability to remain at home and manage personal responsibilities, and desires for privacy.

Additional considerations

Erlank et al 2021 published patient satisfaction outcomes from a survey of 1,243 women who had a telehealth EMA during the introduction of a “no-test” abortion due to the COVID-19 pandemic. 83% of respondents reported preferring telehealth service delivery for their abortion, with 66% of them indicating they would choose telehealth again if COVID-19 were no longer an issue. No respondents indicated having issues finding a private space to have their telehealth consultation.

Summary

The Endler et al (2022) RCT from South Africa finds similar satisfaction scores between telehealth and standard care groups, with both having high satisfaction scores (99 vs 98%).
Non-randomized studies included in the systematic reviews also reported on these outcomes. These studies (included in Gambir et al 2020) indicated that there was little or no difference in satisfaction measures (number of women rating their experience as satisfied or highly satisfied, willingness to use the same service again in the future, and recommendation to a friend) between the two approaches to delivering abortion care, with wide confidence intervals noted. Overall satisfaction was very high in both groups (~98%).

Resources

Economic evaluation was out of the scope of this guideline. However, it is likely that telehealth would be associated with reduced costs as facility costs would not be required. It is acknowledged that the costs might be borne by the individual.

Equity

No studies specifically addressed this domain. However, provision of abortion care via telehealth would probably increase health equity and access to services, particularly for rural women and women from low-income areas who would not be required to travel long distances or incur transportation costs/time off work to attend appointments in-person. Women with disability, childcare needs, domestic violence may have greater access with telehealth. Lack of privacy and confidentiality may be an issue. Lack of access to internet may also be a problem.

Acceptability

Abortion care provided via telehealth (either entirely or components of care) is likely to be acceptable both to women having an abortion and to abortion providers. This will depend on access and other considerations such as distance from a health service. This might lead to hesitancy of the part of the providers.

Feasibility

There may be connectivity issues (i.e., internet or phone access) for rural or low-income women having an abortion.

PICO (2.1)

Population: Women seeking an early medical abortion (less than 10 weeks)
Intervention: Abortion service provided by telehealth (package of abortion services), by a healthcare professional)
Components of abortion services include:

- Eligibility assessment via telehealth
- Counselling/instruction for the abortion via telehealth
- Active facilitation to medication via telehealth
- Follow-up of the abortion only if required via telehealth
- Provision of contraceptive advice

Comparator: In-person abortion assessment by health care professional

Outcome [Author]	Study results and measurements	Absolute effect estimates		Certainty of the evidence (Quality of evidence)	Plain language summary
		In person abortion assessment by health care professional	Abortion service provided by telemedicine		
Medical abortion medication administration: Failure to achieve complete abortion - Home vs hospital [CR: Zhang 2022]	Relative risk: **1.63** (95% CI 0.68 - 3.94) Based on data from 2263 participants in 4 studies	**50** per 1000	**81** per 1000 Difference: **31 more per 1000** (95% CI 16 fewer - 147 more)	**Low** Due to serious risk of bias, serious inconsistency[1]	Little or no difference between in-person and telemedicine medication administration
Medical abortion medication	Relative risk: **1.09** (95% CI 0.74 - 1.61)	**236** per 1000	**257** per 1000	**Low**	

administration: Side effects - Nausea - home vs hospital [CR: Zhang 2022]	Based on data from 1532 participants in 3 studies	Difference: **21 more per 1000** (95% CI 61 fewer - 144 more)		Due to serious risk of bias, serious inconsistency[1]	Little or no difference between in-person and telemedicine medication administration
Medical abortion medication administration: Women's dissatisfaction with the procedure - Home vs hospital [CR: Zhang 2022]	Relative risk: **1.63** (95% CI 0.95 - 2.8) Based on data from 2155 participants in 4 studies	**50** per 1000	**81** per 1000 Difference: **31 more per 1000** (95% CI 3 fewer - 90 more)	**Low** Due to serious risk of bias, serious inconsistency[1]	Little or no difference between in-person and telemedicine medication administration
Medical abortion medication administration: Blood transfusion - Home vs hospital [CR: Zhang 2022]	Relative risk: **0.33** (95% CI 0.01 - 8.18) Based on data from 731 participants in 1 study	**3** per 1000	**1** per 1000 Difference: **2 fewer per 1000** (95% CI 3 fewer - 22 more)	**Very low** Due to very serious risk of bias, serious imprecision[2]	Little or no difference between in-person and telemedicine medication administration
Success of medical abortion self-administered vs provider-administered - NRS [CR: Gambir 2020]	Relative risk: **0.99** (95% CI 0.97 - 1.01) Based on data from 10124 participants in 16 studies	**940** per 1000	**931** per 1000 Difference: **9 fewer per 1000** (95% CI 28 fewer - 9 more)	**Low**	Little or no difference between in-person and telemedicine medication administration
Ongoing pregnancy – self-administered vs provider administered medical abortion - NRS [CR: Gambir 2020]	Relative risk: **1.28** (95% CI 0.65 - 2.49) Based on data from 6691 participants in 11 studies	**8** per 1000	**10** per 1000 Difference: **2 more per 1000** (95% CI 3 fewer - 12 more)	**Very low** Due to serious imprecision[3]	Little or no difference between in-person and telemedicine medication administration
Any complication requiring surgical intervention – self-administered vs provider-administered medical abortion - NRS [CR: Gambir 2020]	Relative risk: **2.14** (95% CI 0.8 - 5.71) Based on data from 2452 participants in 3 studies	**26** per 1000	**56** per 1000 Difference: **30 more per 1000** (95% CI 5 fewer - 122 more)	**Very low** Due to serious imprecision[3]	Little or no difference between in-person and telemedicine medication administration
Satisfied or highly satisfied – self-	Relative risk: **1.01** (95% CI 0.97 - 1.05)	**909** per 1000	**918** per 1000	**Very low**	

administered vs provider-administered medical abortion - NRS [CR: Gambir 2020]	Based on data from 7582 participants in 13 studies		Difference: **9 more per 1000** (95% CI 27 fewer - 45 more)	Due to serious imprecision[3]	Little or no difference between in-person and telemedicine medication administration
Would choose medical abortion again – self-administered vs provider-administered medical abortion - NRS [CR: Gambir 2020]	Relative risk: **1.04** (95% CI 0.96 - 1.14) Based on data from 3515 participants in 6 studies	**536** per 1000	**557** per 1000 Difference: **21 more per 1000** (95% CI 21 fewer - 75 more)	**Very low** Due to serious imprecision[3]	Little or no difference between in-person and telemedicine medication administration
Would recommend to a friend – self-administered vs provider-administered medical abortion - NRS [CR: Gambir 2020]	Relative risk: **1.13** (95% CI 0.97 - 1.31) Based on data from 3513 participants in 6 studies	**527** per 1000	**596** per 1000 Difference: **69 more per 1000** (95% CI 16 fewer - 163 more)	**Very low** Due to serious inconsistency[4]	Little or no difference between in-person and telemedicine medication administration
Complete abortion - all care telemedicine vs all care in-person [CRR: Sguassero 2021]	Relative risk: **1.01** (95% CI 1.0 - 1.02) Based on data from 30813 participants in 3 studies Follow up 2 months	**979** per 1000	**989** per 1000 Difference: **10 more per 1000** (95% CI 0 more - 20 more)	**Very low** Due to very serious risk of bias[5]	Little or no difference between in-person and telemedicine provision of all abortion care
Receipt or referral for surgical abortion - all care telemedicine vs all care in-person [CRR: Sguassero 2021]	Relative risk: **0.4** (95% CI 0.33 - 0.49) Based on data from 34821 participants in 3 studies	**26** per 1000	**10** per 1000 Difference: **16 fewer per 1000** (95% CI 17 fewer - 13 fewer)	**Very low** Due to serious risk of bias[6]	Telemedicine may result in fewer women being referred or having a surgical abortion
Contraception uptake following abortion - All care telemedicine vs all care in-person [CRR: Sguassero 2021]	Relative risk: **0.97** (95% CI 0.87 - 1.07) Based on data from 18677 participants in 2 studies Follow up 4 months	**926** per 1000	**898** per 1000 Difference: **28 fewer per 1000** (95% CI 120 fewer - 65 more)	**Very low** Due to very serious risk of bias, serious inconsistency[7]	Little or no difference in contraception uptake between telemedicine and in-person abortion care
Ongoing pregnancies - All care telemedicine vs	Relative risk: **1.24**	**5** per 1000	**6** per 1000	**Very low**	

All care in-person [CRR: Sguassero 2021]	(95% CI 0.14 - 11.08) Based on data from 34621 participants in 3 studies Follow up 2 months	Difference: **1 more per 1000** (95% CI 4 fewer - 50 more)		Due to very serious risk of bias, serious inconsistency, serious imprecision[8]	Little or no difference between in-person and telemedicine provision of all abortion care
Overall satisfaction: very or somewhat satisfied - all care telemedicine vs all care in-person [CRR: Sguassero 2021]	Relative risk: **1.01** (95% CI 0.98 - 1.04) Based on data from 431 participants in 1 study	**977** per 1000 Difference: **10 more per 1000** (95% CI 20 fewer - 39 more)	**987** per 1000	**Very low** Due to serious inconsistency, serious imprecision, very serious risk of bias[9]	Little or no difference between in-person and telemedicine provision of all abortion care
Successful abortion - TM + mail out medication vs in clinic [COHORT Kerestes et al 2021]	Relative risk: **1.03** (95% CI 1.01 – 1.05) Based on data from 163 participants in 1 study	**940** per 1000 Difference: **28 more per 1000** (95% CI 9 more – 47 more)	**968** per 1000	**Very low** Due to serious risk of bias, serious imprecision[10]	We are uncertain whether abortion service provided by telemedicine with mail out of medications increases or decreases successful abortion
Successful abortion – TM + pick-up medication vs in clinic [COHORT Kerestes et al 2021]	Relative risk: **1.03** (95% CI 1.01 - 1.05) Based on data from 218 participants in 1 study	**936** per 1000 Difference: **28 more per 1000** (95% CI 9 more - 47 more)	**964** per 1000	**Very low** Due to serious risk of bias, serious imprecision[10]	We are uncertain whether abortion service provided by telemedicine with in-person pick-up of medications increases or decreases successful abortion
Ongoing pregnancy - telemedicine vs standard care [RCT: Endler 2022]	Odds ratio: **1.9** (95% CI 0.47 - 7.64) Based on data from 747 participants in 1 study	**9** per 1000 Difference: **8 more per 1000** (95% CI 5 fewer - 56 more)	**17** per 1000	**Low** Due to serious indirectness, serious imprecision[11]	Abortion service provided by telemedicine may increase or decrease ongoing pregnancy when compared to standard in-person care
Admission to hospital - telemedicine vs standard care [RCT: Endler 2022]	Odds ratio: **1.43** (95% CI 0.36 - 8.62) Based on data from 747 participants in 1 study	**6** per 1000 Difference: **3 more per 1000** (95% CI 4 fewer - 458 more)	**9** per 1000	**Low** Due to serious indirectness, serious imprecision[11]	Abortion service provided by telemedicine may increase or decrease admission to hospital compared to standard in-person care
Unscheduled/emergency clinic visits with 2 days	Odds ratio: **1.13** (95% CI 0.34 - 3.74)	**14** per 1000	**16** per 1000	**Low**	Abortion service provided by telemedicine may increase or

of abortion - telemedicine vs standard care [RCT: Endler 2022]	Based on data from 747 participants in 1 study	Difference: **2 more per 1000** (95% CI 9 fewer - 261 more)		Due to serious indirectness, serious imprecision[11]	decrease unscheduled/emergency clinic visits with 2 days of abortion compared to standard in-person care slightly
Blood transfusion - telemedicine vs standard care [RCT: Endler 2022]	Odds ratio: **1.91** (95% CI 0.17 - 21.15) Based on data from 747 participants in 1 study	**3** per 1000	**6** per 1000 Difference: **3 more per 1000** (95% CI 2 fewer - 677 more)	**Low** Due to serious indirectness, serious imprecision[11]	Abortion service provided by telemedicine may increase or decrease blood transfusion compared to standard in-person care slightly
Satisfied or very satisfied - telemedicine vs standard care [RCT: Endler 2022]	Odds ratio: **5.39** (95% CI 0.63 - 46.41) Based on data from 747 participants in 1 study	**986** per 1000	**997** per 1000 Difference: **11 more per 1000** (95% CI 8 fewer - 11 more)	**Low** Due to serious indirectness, serious imprecision[11]	Abortion service provided by telemedicine may increase or decrease ratings of satisfied or very satisfied compared to standard in-person care slightly

1. **Risk of Bias: serious.** no allocation concealment, no blinding; **Inconsistency: serious.** inconsistency of intervention.
2. **Risk of Bias: very serious.** unclear randomization method, no allocation concealment, no blinding.; **Imprecision: serious.** 95% confidence intervals are wide and overlaps no effect.
3. **Imprecision: serious.** wide confidence intervals.
4. **Inconsistency: serious.** The magnitude of statistical heterogeneity was high.
5. **Risk of Bias: very serious.** No randomised studies. Largest study has risks of confounding and selection bias. No adjustment for confounders was made.
6. **Risk of Bias: serious.**
7. **Risk of Bias: very serious. Inconsistency: serious.** The magnitude of statistical heterogeneity was high, with I^2: 85%.
8. **Risk of Bias: very serious.** non-randomised studies, largest study risk of confounding and selection bias; **Inconsistency: serious.** The magnitude of statistical heterogeneity was high, with I^2: 68%.; **Imprecision: serious.** Few cases.
9. **Risk of Bias: very serious.** non-randomised, confounders not controlled for; **Inconsistency: serious.** single study so could not be assessed; **Imprecision: serious.** small sample size.
10. **Risk of Bias: serious.** Patients self-selected their abortion mode; **Imprecision: serious.** Low number of patients.
11. **Indirectness: serious.** Differences between the population of interest and those studied; **Imprecision: serious.** Wide confidence intervals.

Clinical Question 3a: Routine tests before an abortion: abortion without prior testing of haemoglobin, Rh D status

3a: For a woman seeking a medical or surgical abortion up to 14 weeks pregnant, is selective or no testing of haemoglobin, Rh D status, prior to abortion as safe, acceptable and accessible as routine testing of haemoglobin, Rh D status?

P: Woman having a medical abortion up to 10 weeks or surgical abortion before 13 weeks pregnant

I: Routine testing of haemoglobin and Rh D status prior to abortion

C: i) no haemoglobin/ Rh D status blood test prior to abortion

ii) haemoglobin/ Rh D status blood test for selected women as indicated by medical history or clinical situation (history/risk of anaemia, or risk of bleeding)

O: Adverse events

- blood transfusion
- need for emergency care or hospital admission
- rhesus sensitisation

- Access to abortion services
- Acceptability/satisfaction with abortion services

Evidence to decision

Benefits and harms

Additional considerations

It is the standard of care in the UK to not perform pre-procedure haemoglobin testing for all day-stay procedures including abortion, hence this was not addressed in the NICE systematic review.

Summary

The guideline development group identified no direct evidence to inform this recommendation. In the absence of evidence, the precise benefits and risks of pre-procedure haemoglobin or Rh D testing are unclear.

A systematic review (Schmidt-Hansen et al. 2021) was conducted to inform the NICE 2019 Abortion Care guideline regarding Anti-D prophylaxis for women having an abortion. It identified no studies of Anti-D prophylaxis among women having an abortion (medical or surgical) prior to 14 weeks. The NICE recommendation was developed from clinical practice consensus.

Indirect evidence to inform the recommendation regarding Rh D testing was drawn from several studies considering the likelihood and consequences of sensitisation:

- Simonovits et al. (1974) compared the incidence of Rh D alloimmunisation (at subsequent pregnancy after induced abortion) assessed with papain-treated cells or indirect Coombs test between those given Anti-D compared to those with no sensitising event RR 0.76, 95% CI (0.07 to 8.21), baseline risk with no sensitising event 14 per 1000 - very low certainty evidence
- Wiebe et al (2019) was a comparison of alloimmunisation rates from Canada, where Anti-D is routinely given, and the Netherlands, where it is not recommended for abortion under 7 weeks pregnant or miscarriage under 10 weeks pregnant, and found that Canada had a higher prevalence of alloimmunisation.
- Horvath et al (2020), using flow cytometry to quantify the degree of feto-maternal haemorrhage during abortion, has shown that volumes of feto-maternal haemorrhage are lower than had been calculated in earlier studies which used Kleihauer–Betke testing. Using flow cytometry all 37 participating women undergoing uterine aspiration for induced or spontaneous abortion at 5–12 weeks pregnant, had lower amounts of feto-maternal haemorrhage than the threshold needed for sensitisation in gestations up to 12 weeks.
- The Serious Hazards of Transfusion (SHOT) database (UK national surveillance system) monitors Rh D sensitisation events and began in 2012. The numbers of sensitisations arising following a previous first trimester loss have been minimal. As of 2022 the database has recorded 133 cases of Rh D sensitisation that was identified in the first trimester indicating sensitisation in the preceding pregnancy. Of these, three cases of sensitisation were identified as arising following a previous first trimester loss.

Certainty of the Evidence

No direct evidence was identified

Values and preferences

No studies including patient satisfaction outcomes were identified. Qualitative research suggests that women undergoing an abortion have a clear preference not to prolong wait times; any requirement for pre-procedure testing that may delay receiving an abortion is therefore less likely to be preferred.

Resources
Out of scope

Equity

Women relying on telehealth or traveling long distances for abortion care may incur the logistical and possibly financial burdens of finding a local clinical setting for Rh testing and administration, as well as the potential burdens associated with stigma and undesired disclosure of their abortion.

Acceptability
No issues highlighted

Feasibility
No issues highlighted

Clinical Question 3b: Routine tests before an abortion: Abortion without prior ultrasound

3b: For a woman seeking a medical or surgical abortion in the first trimester, is an ultrasound prior to abortion as safe, acceptable and accessible as no ultrasound prior to abortion?

P: Woman having a medical < 10 weeks or surgical abortion < 14 weeks gestation

I: Routine ultrasound prior to abortion

C: i) no ultrasound prior to abortion

ii) ultrasound for selected women as indicated by medical history or clinical situation (uncertain gestation, previous caesarean section/risk of ectopic pregnancy)

O: Adverse events

- blood transfusion
- need for emergency care or hospital admission
- failed abortion (ongoing pregnancy)
- incomplete abortion (retained products of conception requiring additional treatment [medical or surgical])
- wrong gestation (pregnancy too advanced for abortion method)
- death

- Access to abortion services – gestational age at time of consultation
- Acceptability/satisfaction with abortion services

Evidence to decision

Benefits and harms

No ultrasound prior to abortion: Two systematic reviews, Kulier & Kapp (2011) and Kapp et al (2013), did not identify any randomised or comparative studies of the use of pre-procedure ultrasound with no use of ultrasound prior to an abortion.

A systematic review comparing initiation of surgical or medical abortion "before there is definitive evidence of an intrauterine pregnancy" and initiation of surgical or medical abortion "when there is definitive evidence of an intrauterine pregnancy" conducted as part of the NICE Abortion Care Guideline development (2019) was included in this summary of evidence. All participants in the included studies had an ultrasound before the abortion but differed by whether evidence of an intrauterine pregnancy was available before the abortion or not. The authors found that having a medical or surgical abortion before there was ultrasound evidence of an intrauterine pregnancy was not associated with statistically significant differences in rates of "ectopic pregnancy" or "complete abortion without (repeat) surgical intervention".

Aiken et al (2021) published a larger cohort study following the NICE systematic review. It contains a no-test abortion group that includes no ultrasound pre-abortion. This study was a large retrospective cohort study conducted in England, representing 85% of all abortions in England and Wales over the study time period, comparing two months before and after a service model change due to COVID-19 restrictions. Using a treatment decision flowchart, a no-test abortion was deemed appropriate for 61% of women having an early medical abortion (n=18,435), based on risk factors for ectopic pregnancy or uncertain pregnancy dates. Compared to the telehealth hybrid model (n=11,549) that included in-clinic assessment and ultrasound, the no-test group had a statistically significantly higher rate of successful abortions. There were no significant differences in rates of haemorrhage, and neither group had any incidence of infection requiring hospitalisation, major surgery, or death.

Certainty of the Evidence

All studies included in this domain were observational. Using the GRADE certainty of evidence tool, studies were rated low or very low certainty.

Values and preferences

No included studies included patient satisfaction outcomes. However, qualitative research suggests that women undergoing an abortion have a clear preference not to prolong wait times, and therefore should be offered immediate treatment if this is their preferred option.

Resources

Access to ultrasound services in particular can be a barrier and ultrasounds likely contribute significantly to the overall cost of abortion provision.

Equity

Ultrasound testing prior to an abortion can be a barrier for abortion access, particularly for rural or low-income women.

Acceptability

Abortion providers may be uncomfortable not to have an established intrauterine pregnancy or gestational age of the pregnancy by ultrasound prior to undertaking an abortion. Clinical history and examination may not provide a sufficient level of certainty that gestation is correct and ectopic pregnancy is not present. Provider acceptability was not an outcome reported in evidence to support this recommendation. Clinicians should however be reassured that missed ectopic pregnancy was a rare outcome with little or no difference between no-test or pre-procedure testing requirement groups.

PICO (3.2)

Population: Woman having a medical abortion up to 10 weeks or a surgical abortion before 13 weeks gestation
Intervention: Routine ultrasound prior to an abortion
Comparator: i) No ultrasound prior to abortion ii) ultrasound for selected women as indicated by medical history or clinical situation (uncertain gestation, previous caesarean section, risk of ectopic pregnancy)

Outcome Timeframe	Study results and measurements	Absolute effect estimates		Certainty of the evidence (Quality of evidence)	Plain language summary
		i) No testing, ii) selective testing	Routine testing prior to abortion		
Missed diagnosis of ectopic pregnancy - Medical termination of pregnancy - pre-procedure intrauterine pregnancy on USS vs no intrauterine pregnancy on USS [SR NICE 2019]	Relative risk: **0.26** (95% CI 0.03 - 2.12) Based on data from 3716 participants in 2 studies Follow up 7-42 days	**1.6** per 1000	**0.8** per 1000 Difference: **1.6 fewer per 1000** (95% CI 1.55 fewer - 1.79 more)	**Very low** Due to very serious imprecision[1]	Little or no difference between pre-procedure intrauterine pregnancy on ultrasound and no pre-procedure intrauterine pregnancy on ultrasound
Ongoing pregnancy - Medical termination of pregnancy - pre-procedure intrauterine pregnancy on USS vs no intrauterine pregnancy on USS [SR NICE 2019]	Relative risk: **1.06** (95% CI 0.34 - 3.34) Based on data from 3785 participants in 2 studies Follow up 7-42 days	**3.9** per 1000	**2.8** per 1000 Difference: **0.0 more per 1000** (95% CI 3.0 fewer - 9.0 more)	**Very low** Due to very serious imprecision[1]	Little or no difference between pre-procedure intrauterine pregnancy on ultrasound and no pre-procedure intrauterine pregnancy on ultrasound

Ongoing pregnancy - Surgical termination of pregnancy - pre-procedure intrauterine pregnancy on USS vs no intrauterine pregnancy on USS [SR NICE 2019]	Relative risk: **0.56** (95% CI 0.03 - 11.59) Based on data from 1530 participants in 1 study Follow up 7-42 days	**1.5** per 1000	**0.0** per 1000 Difference: **fewer per 1000**	**Very low** Due to serious risk of bias, Due to very serious imprecision[2]	Little or no difference between pre-procedure intrauterine pregnancy on ultrasound and no pre-procedure intrauterine pregnancy on ultrasound
Complete termination of pregnancy without the need surgical intervention - Medical termination of pregnancy -pre-procedure intrauterine pregnancy on USS vs no intrauterine pregnancy on USS [SR NICE 2019]	Relative risk: **1.0** (95% CI 0.98 - 1.02) Based on data from 3785 participants in 2 studies Follow up 7-42 days	**982** per 1000	**982** per 1000 Difference: **0 fewer per 1000** (95% CI 20 fewer - 20 more)	**Very low** Due to serious inconsistency[3]	Little or no difference between pre-procedure intrauterine pregnancy on ultrasound and no pre-procedure intrauterine pregnancy on ultrasound
Complete termination of pregnancy without the need for repeat surgical intervention - Surgical termination of pregnancy - pre-procedure intrauterine pregnancy on USS vs no intrauterine pregnancy on USS [SR NICE 2019]	Relative risk: **1.0** (95% CI 0.99 - 1.01) Based on data from 1530 participants in 1 study Follow up 7-42 days	**1000** per 1000	**996** per 1000 Difference: **0 fewer per 1000** (95% CI 10 fewer - 10 more)	**Very low** Due to serious risk of bias[4]	Little or no difference between pre-procedure intrauterine pregnancy on ultrasound and no pre-procedure intrauterine pregnancy on ultrasound
Successful abortion - no-test EMA vs telemedicine-hybrid model of EMA [COHORT Aiken 2021]	Relative risk: **1.01** (95% CI 1.0 - 1.02) Based on data from 52142 participants in 1 study	**981** per 1000	**992** per 1000 Difference: **9 more per 1000** (95% CI 0 fewer - 20 more)	**Low**	Little or no difference between pre-procedure intrauterine pregnancy on ultrasound and no pre-procedure intrauterine pregnancy on ultrasound
Haemorrhage requiring transfusion - no-test EMA vs telemedicine-hybrid model of EMA [COHORT Aiken 2021]	Relative risk: **0.67** (95% CI 0.11 - 3.98) Based on data from 52142 participants in 1 study	**3** per 1000	**2** per 1000 Difference: **1 fewer per 1000** (95% CI 3 fewer - 9 more)	**Low**	Little or no difference between pre-procedure intrauterine pregnancy on ultrasound and no pre-procedure intrauterine pregnancy on ultrasound

1. **Imprecision: very serious**. Wide confidence intervals.
2. **Risk of Bias: serious.** assessed using the Newcastle-Ottawa scale for cohort studies and the overall quality of this study was medium quality due to unclear comparability**; Imprecision: very serious.** Wide confidence intervals.
3. **Inconsistency: serious.** The magnitude of statistical heterogeneity was high, with I^2: 74%.
4. **Risk of Bias: serious.** assessed using the Newcastle-Ottawa scale for cohort studies and the overall quality of this study was medium quality due to unclear comparability.

Clinical Question 4: Optimal treatment regimen for Early Medical Abortion up to 10 weeks pregnant

For a woman seeking early medical abortion (EMA) (up to 10 weeks or 70 days from LMP), what medication regimen (including type of medication, dosage, and dose interval) is the safest, and most effective, accessible, and acceptable?

P: Woman seeking an early medical abortion (up to 10 weeks)

I: i) mifepristone plus misoprostol

C: i) misoprostol dosage A vs dosage B
ii) misoprostol/ mifepristone interval A vs interval B

O: Adverse events

- ectopic pregnancy
- need for emergency care or hospital admission
- failed abortion (ongoing pregnancy)
- incomplete abortion (retained products of conception)
- wrong gestation (too advanced for abortion method)
- pain

- Access to abortion services
- Acceptability/satisfaction with abortion services

Evidence to decision

Benefits and harms

Research evidence

Research evidence taken from Cochrane systematic review Zhang et al 2022 - literature searches up to February 2021.

A search of the Cochrane library for additional RCTS conducted in November 2022 yielded no further studies meeting inclusion criteria.

This systematic review included studies with a gestation up to 13 weeks, inconsistent with the ≤ 10 weeks included in this PICO. The gestation included in studies contributing to each outcome was examined and where gestations beyond 10 weeks were included in an outcome this evidence has been downgraded for indirectness.

Summary

This recommendation is informed by evidence from a Cochrane review (Zhang et al) 2022.

Compared to any of the combination regimens (mifepristone plus misoprostol), misoprostol alone appears to increase the risk for failure to achieve complete abortion (RR of failure 2.39, 95% CI 1.89 to 3.02), however, the effect remains uncertain owing to very low certainty evidence. In a combined regimen, misoprostol 800 mcg dose is likely to be most effective.

Administration of misoprostol 24-48 hours following mifepristone is the most effective dosing interval for completion of abortion. There was no difference in the occurrence of side effects (vomiting, diarrhoea, abdominal pain, ongoing pregnancy, and women's dissatisfaction with the procedure) among the different time interval groups of misoprostol.

Assessing different routes of administration of misoprostol:

- oral administration (swallowing the tablet) resulted in a higher rate of ongoing pregnancy compared to vaginal administration
- No difference was noted between administration of misoprostol buccally and vaginally in rates of successful abortion, safety and satisfaction outcomes. Higher rates of diarrhoea with vaginal administration

- Sublingual administration resulted in lower failure rates, with similar side effect and satisfaction rates compared to oral administration
- No difference was noted between administration of misoprostol sublingually and vaginally in rates of successful abortion, safety and satisfaction outcomes.
- No difference was noted between administration of misoprostol sublingually and buccally administration in rates of successful abortion, safety and satisfaction outcomes. Lower rates of vomiting in the sublingual administration group

Certainty of the evidence

Moderate certainty of evidence to support dosage and route outcomes. Downgraded for inconsistency.

Values and preferences

Little or no difference was found in levels of dissatisfaction among route of misoprostol administration, or timing of misoprostol dose after mifepristone in the Cochrane review.

Simultaneous administration of medications eliminating an additional clinic visit is likely to be preferred by women if effectiveness and serious side effects are broadly comparable with non-simultaneous administration.

Women undergoing an early medical abortion are likely to desire the least invasive route of administration of misoprostol, however, self-administration of vaginal misoprostol is likely to be acceptable to women, particularly if this route is associated with less gastro-intestinal side-effects than oral and sublingual routes.

Resources

No economic evaluation was undertaken as part of this guideline development.

Equity

Evidence supports a 24-48 hour interval dosing of misoprostol following mifepristone administration. The more convenient simultaneous administration should be balanced against an increased likelihood of failure to complete abortion and the need for an additional course of medications or surgical procedure to complete. No states in Australia or in Aotearoa New Zealand require this now

Acceptability

No issues highlighted

Feasibility

Combined regimen and interval dosing are the standard of care in Australia and New Zealand currently.
Buccal misoprostol via MS-2 Step is the only route of administration currently approved in Australia.

PICO (4.1)

Population: woman seeking an early medical abortion (less than 10 weeks)
Intervention: misoprostol in combined regimen
Comparator: i) misoprostol dosage A vs dosage B ii) misoprostol/ mifepristone interval A vs interval B

Outcome [Author]	Study results and measurements	Absolute effect estimates		Certainty of the evidence (Quality of evidence)	Plain language summary
		Comparison (listed second)	Intervention (listed first)		

Combined regimen: Failure to achieve complete abortion - misoprostol 800 µg vs 400 µg all [CR: Zhang 2022]	Relative risk: **0.63** (95% CI 0.51 - 0.78) Based on data from 4424 participants in 3 studies	**94** per 1000	**59** per 1000 Difference: **35 fewer per 1000** (95% CI 46 fewer - 21 fewer)	**Moderate** Due to serious inconsistency[1]	Misoprostol 800 mcg as part of a combined regimen is associated with a lower proportion of incomplete abortion compared to misoprostol 400 mcg
Combined regimen: Failure to achieve complete abortion - mifepristone 600 mg vs 200 mg [CR: Zhang 2022]	Relative risk: **1.07** (95% CI 0.87 - 1.33) Based on data from 3494 participants in 4 studies	**86** per 1000	**92** per 1000 Difference: **6 more per 1000** (95% CI 11 fewer - 28 more)	**Moderate** Due to serious inconsistency[1]	Little or no difference between mifepristone 200 mg and 600 mg as part of a combined dosing regimen
Combined regimen: Side effects - Nausea - mifepristone 600 mg vs 200 mg [CR: Zhang 2022]	Relative risk: **1.02** (95% CI 0.95 - 1.09) Based on data from 2432 participants in 2 studies	**450** per 1000	**459** per 1000 Difference: **9 more per 1000** (95% CI 23 fewer - 41 more)	**Moderate** Due to serious inconsistency[1]	Little or no difference between mifepristone 200 mg and 600 mg as part of a combined dosing regimen
Combined regimen: Nausea - misoprostol 800 µg vs 400 µg [CR: Zhang 2022]	Relative risk: **0.99** (95% CI 0.94 - 1.05) Based on data from 4424 participants in 3 studies	**479** per 1000	**474** per 1000 Difference: **5 fewer per 1000** (95% CI 29 fewer - 24 more)	**Moderate** Due to serious inconsistency[1]	Little or no difference between misoprostol 800 mcg and 400 mcg as part of a combined dosing regimen
Combined regimen: Side effects - Nausea - misoprostol oral vs vaginal [CR: Zhang 2022]	Relative risk: **1.14** (95% CI 1.03 - 1.26) Based on data from 1380 participants in 2 studies	**482** per 1000	**549** per 1000 Difference: **67 more per 1000** (95% CI 14 more - 125 more)	**Low** Due to serious risk of bias, Due to serious inconsistency[2]	Less nausea experienced by women having Misoprostol vaginally as part of a combined regimen compared to oral
Combined regimen: Women's dissatisfaction with the procedure - misoprostol 800 µg vs 400 µg [CR: Zhang 2022]	Relative risk: **0.75** (95% CI 0.6 - 0.93) Based on data from 4420 participants in 3 studies	**82** per 1000	**62** per 1000 Difference: **21 fewer per 1000** (95% CI 33 fewer - 6 fewer)	**Moderate** Due to serious inconsistency[1]	Women receiving misoprostol 800 mcg as part of a combined regimen we less dissatisfied compared to misoprostol 400 mcg
Combined regimen: Failure to achieve	Relative risk: **2.38** (95% CI 1.46 - 3.87)	**43** per 1000	**102** per 1000	**Very low**	We are uncertain if whether oral misoprostol in combination with

complete abortion - misoprostol oral vs vaginal [CR: Zhang 2022]	Based on data from 1704 participants in 3 studies	Difference: **59 more per 1000** (95% CI 20 more - 123 more)		Due to serious risk of bias, Due to serious inconsistency, Due to serious indirectness[3]	mifepristone increases or decreases failure to achieve complete abortion compared to vaginal misoprostol
Combined regimen: Failure to achieve complete abortion - misoprostol sublingual vs vaginal [CR: Zhang 2022]	Relative risk: **0.68** (95% CI 0.22 - 2.11) Based on data from 3229 participants in 2 studies	**86** per 1000	**58** per 1000 Difference: **28 fewer per 1000** (95% CI 67 fewer - 95 more)	**Moderate** Due to serious inconsistency[1]	Little or no difference in incomplete abortion between sublingual and vaginal routes of misoprostol administration as part of a combined regimen
Combined regimen: Side effects - Nausea - misoprostol sublingual vs vaginal [CR: Zhang 2022]	Relative risk: **1.11** (95% CI 0.93 - 1.33) Based on data from 3543 participants in 3 studies	**536** per 1000	**595** per 1000 Difference: **59 more per 1000** (95% CI 38 fewer - 177 more)	**Moderate** Due to serious inconsistency[1]	Little or no difference in nausea between sublingual and vaginal routes of misoprostol administration as part of a combined regimen
Combined regimen: Women's dissatisfaction with the procedure - misoprostol sublingual vs vaginal [CR: Zhang 2022]	Relative risk: **1.67** (95% CI 0.8 - 3.5) Based on data from 3303 participants in 2 studies	**66** per 1000	**110** per 1000 Difference: **44 more per 1000** (95% CI 13 fewer - 165 more)	**Moderate** Due to serious inconsistency[1]	Little or no difference in dissatisfaction between sublingual and vaginal routes of misoprostol administration as part of a combined regimen
Combined regimen: Failure to achieve complete abortion - misoprostol buccal vs vaginal [CR: Zhang 2022]	Relative risk: **0.71** (95% CI 0.34 - 1.46) Based on data from 479 participants in 2 studies	**71** per 1000	**50** per 1000 Difference: **21 fewer per 1000** (95% CI 47 fewer - 33 more)	**Moderate** Due to serious risk of bias[4]	Buccal misoprostol in combination with mifepristone probably has little or no difference on failure to achieve complete abortion compared to vaginal misoprostol
Prostaglandin alone vs combined regimen: Failure to achieve complete abortion [CR: Zhang 2022]	Relative risk: **2.39** (95% CI 1.89 - 3.02) Based on data from 3471 participants in 18 studies	**135** per 1000	**323** per 1000 Difference: **188 more per 1000** (95% CI 120 more - 273 more)	**Very low** Due to serious risk of bias, Due to serious inconsistency, Due to serious indirectness[5]	We are uncertain whether a greater proportion of incomplete abortion for women having prostaglandin alone compared to a combined regimen
Prostaglandin alone vs combined regimen: Side	Relative risk: **0.9** (95% CI 0.74 - 1.1)	**412** per 1000	**371** per 1000	**Very low**	We are uncertain whether there is little or no difference in nausea

effects - Nausea [CR: Zhang 2022]	Based on data from 2722 participants in 12 studies	Difference: **41 fewer per 1000** (95% CI 107 fewer - 41 more)		Due to serious risk of bias, Due to serious inconsistency, Due to serious indirectness[6]	between prostaglandin alone and combined regimen
Failure to achieve complete abortion - Day 3 vs day 1 [CR: Zhang 2022]	Relative risk: **1.94** (95% CI 1.05 - 3.58) Based on data from 1489 participants in 1 study	**20** per 1000	**39** per 1000 Difference: **19 more per 1000** (95% CI 1 more - 52 more)	**Low** Due to serious risk of bias, Due to serious imprecision[7]	More failure to achieve complete abortion if misoprostol given on day 3 after mifepristone compared to day 1
Failure to achieve complete abortion - Day 2 vs day 0 [CR: Zhang 2022]	Relative risk: **0.53** (95% CI 0.25 - 1.09) Based on data from 711 participants in 3 studies	**145** per 1000	**77** per 1000 Difference: **68 fewer per 1000** (95% CI 109 fewer - 13 more)	**Moderate** Due to serious risk of bias[4]	Little or no difference in failure to achieve complete abortion if misoprostol given on day 0 after mifepristone compared to day 2
Side effects - Diarrhoea day 3 vs day 1 [CR: Zhang 2022]	Relative risk: **1.21** (95% CI 0.99 - 1.48) Based on data from 1358 participants in 1 study	**196** per 1000	**237** per 1000 Difference: **41 more per 1000** (95% CI 2 fewer - 94 more)	**Low** Due to serious risk of bias, Due to serious imprecision[8]	Little or no difference in diarrhoea if misoprostol given on day 3 after mifepristone compared to day 1
Failure to achieve complete abortion - Day 1 vs day 0 (all) [CR: Zhang 2022]	Relative risk: **0.65** (95% CI 0.46 - 0.91) Based on data from 2236 participants in 3 studies	**70** per 1000	**45** per 1000 Difference: **25 fewer per 1000** (95% CI 38 fewer - 6 fewer)	**Moderate** Due to serious risk of bias[4]	More failure to achieve complete abortion if misoprostol given on day 0 after mifepristone compared to day 1
Side effects - Nausea day 3 vs day 1 [CR: Zhang 2022]	Relative risk: **1.05** (95% CI 0.96 - 1.14) Based on data from 1358 participants in 1 study	**605** per 1000	**635** per 1000 Difference: **30 more per 1000** (95% CI 24 fewer - 85 more)	**Low** Due to serious risk of bias, Due to serious imprecision[8]	Little or no difference in nausea if misoprostol given on day 3 after mifepristone compared to day 1
	Relative risk: **0.75** (95% CI 0.58 - 0.98)	**282** per 1000	**212** per 1000	**Moderate**	

Side effects - Nausea day 2 vs day 0 [CR: Zhang 2022]	Based on data from 644 participants in 3 studies	Difference: **71 fewer per 1000** (95% CI 118 fewer - 6 fewer)		Due to serious risk of bias[4]	Less nausea if misoprostol given on day 2 after mifepristone compared to day 0
Side effects - Vomiting day 2 vs day 0 [CR: Zhang 2022]	Relative risk: **0.95** (95% CI 0.66 - 1.38) Based on data from 644 participants in 3 studies	**155** per 1000	**147** per 1000 Difference: **8 fewer per 1000** (95% CI 53 fewer - 59 more)	**Moderate** Due to serious risk of bias[4]	Little or no difference in vomiting if misoprostol given on day 0 after mifepristone compared to day 2
Side effects - Nausea day 1 vs day 0 [CR: Zhang 2022]	Relative risk: **1.03** (95% CI 0.81 - 1.32) Based on data from 2217 participants in 3 studies	**102** per 1000	**105** per 1000 Difference: **3 more per 1000** (95% CI 19 fewer - 33 more)	**Moderate** Due to serious risk of bias[4]	Little or no difference in nausea if misoprostol given on day 0 after mifepristone compared to day 2
Side effects - Vomiting day 1 vs day 0 [CR: Zhang 2022]	Relative risk: **1.16** (95% CI 0.82 - 1.63) Based on data from 2217 participants in 3 studies	**52** per 1000	**60** per 1000 Difference: **8 more per 1000** (95% CI 9 fewer - 33 more)	**Moderate** Due to serious risk of bias[4]	Little or no difference in vomiting if misoprostol given on day 1 after mifepristone compared to day 0
Side effects - Diarrhoea day 1 vs day 0 [CR: Zhang 2022]	Relative risk: **0.85** (95% CI 0.6 - 1.21) Based on data from 2217 participants in 3 studies	**59** per 1000	**50** per 1000 Difference: **9 fewer per 1000** (95% CI 24 fewer - 12 more)	**Moderate** Due to serious risk of bias[4]	Little or no difference in diarrhoea if misoprostol given on day 1 after mifepristone compared to day 0
Side effects - Abdominal pain day 1 vs day 0 [CR: Zhang 2022]	Relative risk: **0.67** (95% CI 0.12 - 3.78) Based on data from 80 participants in 1 study	**75** per 1000	**50** per 1000 Difference: **25 fewer per 1000** (95% CI 66 fewer - 208 more)	**Low** Due to serious risk of bias, Due to serious imprecision[7]	Uncertain difference in abdominal pain if misoprostol given on day 1 after mifepristone compared to day 0 due to wide confidence interval
Women's dissatisfaction with the procedure -	Relative risk: **0.99** (95% CI 0.8 - 1.23)	**120** per 1000	**119** per 1000	**Moderate**	Little or no difference in dissatisfaction if misoprostol

day 2 vs day 0 [CR: Zhang 2022]	Based on data from 1429 participants in 2 studies	Difference: **1 fewer per 1000** (95% CI 24 fewer - 28 more)		Due to serious risk of bias[4]	given on day 1 after mifepristone compared to day 0
Combined regimen: Failure to achieve complete abortion - misoprostol sublingual vs oral [CR: Zhang 2022]	Relative risk: **0.26** (95% CI 0.1 - 0.68) Based on data from 564 participants in 2 studies	**71** per 1000	**18** per 1000 Difference: **53 fewer per 1000** (95% CI 64 fewer - 23 fewer)	**Moderate** Due to serious risk of bias[4]	Sublingual misoprostol probably increases the rate of failure to achieve a complete abortion compared to oral misoprostol
Combined regimen: Side effects - Diarrhoea - misoprostol sublingual vs vaginal [CR: Zhang 2022]	Relative risk: **1.83** (95% CI 1.33 - 2.5) Based on data from 3543 participants in 3 studies	**138** per 1000	**253** per 1000 Difference: **115 more per 1000** (95% CI 46 more - 207 more)	**Moderate** Due to serious inconsistency[1]	Sublingual misoprostol probably increases the side effects of diarrhoea compared to vaginal misoprostol
Combined regimen: dissatisfaction with the procedure - misoprostol sublingual vs oral [CR: Zhang 2022]	Relative risk: **1.96** (95% CI 0.94 - 4.09) Based on data from 471 participants in 1 study	**43** per 1000	**84** per 1000 Difference: **41 more per 1000** (95% CI 3 fewer - 133 more)	**Low** Due to serious imprecision, Due to serious risk of bias[8]	Little or no difference in dissatisfaction between sublingual and oral routes of misoprostol administration as part of a combined regimen
Combined regimen: side effects: nausea - misoprostol sublingual vs oral [CR: Zhang 2022]	Relative risk: **0.62** (95% CI 0.27 - 1.41) Based on data from 564 participants in 2 studies	**516** per 1000	**320** per 1000 Difference: **196 fewer per 1000** (95% CI 377 fewer - 212 more)	**Low** Due to serious risk of bias, Due to serious imprecision[9]	Little or no difference in side effect of nausea between sublingual and oral routes of misoprostol administration as part of a combined regimen
Combined regimen: side effects: diarrhoea - misoprostol sublingual vs oral [CR: Zhang 2022]	Relative risk: **0.32** (95% CI 0.09 - 1.09) Based on data from 93 participants in 1 study	**208** per 1000	**67** per 1000 Difference: **141 fewer per 1000** (95% CI 189 fewer - 19 more)	**Low** Due to serious risk of bias, Due to serious imprecision[8]	Little or no difference in side effect of diarrhoea between sublingual and oral routes of misoprostol administration as part of a combined regimen
Combined regimen: Failure to achieve complete abortion - misoprostol sublingual vs buccal [CR: Zhang 2022]	Relative risk: **1.43** (95% CI 0.64 - 3.23) Based on data from 640 participants in 2 studies	**31** per 1000	**44** per 1000 Difference: **13 more per 1000** (95% CI 11 fewer - 69 more)	**Moderate** Due to serious imprecision[10]	Little or no difference in rate of failure to complete abortion between sublingual and buccal routes of misoprostol administration as part of a combined regimen

Combined regimen: dissatisfaction with the procedure - misoprostol sublingual vs buccal [CR: Zhang 2022]	Relative risk: **2.54** (95% CI 1.14 - 5.66) Based on data from 550 participants in 1 study	**29** per 1000	**74** per 1000 Difference: **45 more per 1000** (95% CI 4 more - 135 more)	**Moderate** Due to serious imprecision[11]	Sublingual misoprostol probably increases dissatisfaction with the procedure compared to buccal misoprostol
Combined regimen: side effects: nausea - misoprostol sublingual vs buccal [CR: Zhang 2022]	Relative risk: **1.06** (95% CI 0.88 - 1.27) Based on data from 640 participants in 2 studies	**553** per 1000	**586** per 1000 Difference: **33 more per 1000** (95% CI 66 fewer - 149 more)	**High**	Little or no difference in side effect of nausea between sublingual and oral routes of misoprostol administration as part of a combined regimen
Combined regimen: side effects: diarrhoea - misoprostol sublingual vs buccal [CR: Zhang 2022]	Relative risk: **2.19** (95% CI 0.56 - 8.51) Based on data from 640 participants in 2 studies	**56** per 1000	**123** per 1000 Difference: **67 more per 1000** (95% CI 25 fewer - 421 more)	**Low** Due to very serious imprecision[10]	Sublingual misoprostol probably increases the side effect of diarrhoea compared to buccal misoprostol

1. **Inconsistency: serious**. inconsistency of intervention.
2. **Risk of Bias: serious**. no allocation concealment, no blinding; **Inconsistency: serious**. inconsistency of intervention.
3. **Risk of Bias: serious**. no allocation concealment, no blinding**; Inconsistency: serious**. inconsistency of intervention; **Indirectness: serious**. Differences between the population of interest and those studied - includes women with pregnancies up to 16 weeks.
4. **Risk of Bias: serious**. Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias.
5. **Risk of Bias: serious**. no allocation concealment, no blinding; **Inconsistency: serious**. The magnitude of statistical heterogeneity was high, with I^2: 62%; **Indirectness: serious**. Differences between the population of interest and those studied - included gestations greater than 10 weeks and women with missed miscarriage as well as abortion.
6. **Risk of Bias: serious**. no allocation concealment, no blinding; **Inconsistency: serious**. inconsistency of intervention; **Indirectness: serious.** Differences between the population of interest and those studied - included gestations greater than 10 weeks and women with missed miscarriage as well as abortion.
7. **Risk of Bias: serious**. No blinded; **Imprecision: serious.** Only data from one study.
8. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias**; Imprecision: serious.** Only data from one study.
9. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias; **Imprecision: serious.** Wide confidence intervals.
10. **Imprecision: serious.** Wide confidence intervals.
11. **Imprecision: serious.** Wide confidence intervals, only data from one study.

Clinical Question 5: Routine follow-up after Early Medical Abortion up to 10 weeks pregnant

For a woman who has undergone an early medical abortion up to 10 weeks pregnant is assessment of completion of the abortion by urine ß-hCG test as safe, effective, accessible, and acceptable as blood ß-hCG testing?

P: Woman having an early medical abortion up to 10 weeks

I: Assessment of completion of abortion by urine β-hCG testing (low sensitivity/semi-quantitative)

C: Assessment of completion of abortion by serum β-hCG testing

O: Adverse events

- pain
- allergy
- blood transfusion
- need for emergency care or hospital admission
- failed abortion (ongoing pregnancy)
- incomplete abortion (retained products of conception)

- Access to abortion services
- Acceptability/satisfaction with abortion services

Evidence to decision

Benefits and harms

Research evidence

MEDLINE search conducted June 2022 and updated on 17th January 2023. Search terms (abortion, induced/ or abortion) AND (follow-up) limited to RCTs, and human studies.

295 results identified and screened for inclusion. Twelve (12) articles were retrieved for full text review. No articles were identified that compared the effectiveness of urine β-hCG testing to serum β-hCG testing following EMA.

A systematic review Baiju et al (2019) was identified that compared remote follow-up with urine pregnancy tests (± symptom review by various methods of communication) to in-clinic follow-up. This review included 4 studies (Iyengar 2015, Ngoc 2014, Oppegaard 2015, Platais 2015) that compared at home low-sensitivity or semi-quantitative pregnancy test (and questionnaire) follow-up after EMA to in-clinic follow-up (assessments included interview ± examination ± ultrasound ± serum β-hCG). Only one of the studies included in this review (Oppegaard 2015) was identified that compared the effectiveness of at-home urine β-hCG testing to routine clinic follow-up protocols that included serum β-hCG testing in addition to follow-up interview and clinician assessment.

Additional considerations

An RCT comparing in-person β-hCG blood test and remote follow-up using an at-home low-sensitivity urine pregnancy test is planned to commence in 2023 in New Zealand led by Dr Michelle Wise.

Raymond et al 2018 conducted a systematic review of diagnostic accuracy of low-sensitivity pregnancy tests in identifying ongoing pregnancy after medical abortion at gestation of 9 weeks or less.

- LSUPT versus standard assessment in same women - three studies
- Studies each enrolled between 158 - 4091 women, of whom 77%–100% had both an LSUPT result and a standard evaluation (serum β-hCG or ultrasound) result from their follow-up visit at 2 weeks post-abortion. Studies had small numbers of women who had an ongoing pregnancy (22, 1, and 3 respectively). The sensitivity of the LSUPT for detecting an ongoing pregnancy ranged from 67% to 100%.
- Test β-hCG detection thresholds ranged from 1000–2000 mIU/mL. No obvious relationship was apparent between the β-hCG detection threshold of the LSUPT and the test's sensitivity for detecting ongoing pregnancy.

Whitehouse et al. 2022 conducted a retrospective observational study of 558 women who had a medical abortion between 9 and 10 weeks pregnant. Participants were scheduled to return to the clinic 14 ± 3 days after mifepristone administration to perform a low-sensitivity pregnancy test and have an ultrasound to determine the abortion completion status. Most participants (79.6%) attended for follow-up at the scheduled time; with 22 (3.9%) attending earlier than 11 days and 92 (16.5%) later than 17 days. Thirteen participants (2.3%) had an ongoing pregnancy. The LSUPT correctly identified all the ongoing pregnancies (sensitivity = 100%; specificity = 84.8%; negative predictive value = 100%; positive predictive value = 13.5%).

Blum et al. 2016 conducted a randomized trial comparing a multilevel urine pregnancy test (MLPT) or a high sensitivity urine pregnancy test (HSPT) for follow-up of medical abortion up to 9 weeks. At day 14 post-mifepristone the MLPT correctly identified all the ongoing pregnancies (sensitivity = 100%; specificity = 97.1%; negative predictive value = 100%; positive predictive value = 46.7%). At day 14 post mifepristone the HSPT correctly identified all the ongoing pregnancies (sensitivity = 100%; specificity = 62.2%; negative predictive value = 100%; positive predictive value = 6.5%). Both tests had a number of false positive results.

Pocius et al. 2017 conducted a prospective, physiologic study of women ≤63 days pregnant who underwent medical abortion with mifepristone 200 mg and misoprostol 800 mcg buccally. The mean serum β-hCG decline among subjects with complete medical abortion was 70.0 ±10.6% [range 36.9-98.6%] on day 3 and 91.4 ±4.4% [range 68.4 to 97.7%] on day 5. The mean serum β-hCG decline from day 1 to day 12-14 was 98.7±2.8% [range 86.7 to 99.9%]. There was no difference in percent β-hCG decline stratified by initial β-hCG or gestation.

Fiala et al. (2003) conducted an observational study of 217 women undergoing medical abortion less than 7 weeks pregnant. Participants had a serum β-hCG test and an ultrasound before treatment and at follow-up 8-16 days later. A drop in serum β-hCG of 80% from pretreatment levels by day 8 to 16 accurately predicted successful expulsion in 98.5% of cases and had a sensitivity of 98.59% (95% CI 95.94-99.71%) and specificity of 75% (95% CI 19.41-99.37%).

Summary

No evidence was identified that directly compared the effectiveness of urine β-hCG testing to serum β-hCG testing.

One article (Oppegaard et al 2015) compared the effectiveness of at-home urine β-hCG testing (semi-quantitative with thresholds of 5 and 1000 IU/L performed at 1-3 weeks after abortion) to routine clinic follow-up protocols which included serum β-hCG testing at some sites vs urine pregnancy tests at other sites, in addition to follow-up interview and clinician assessment at 1-3 weeks after abortion. The authors of this study do not report the proportion of the routine clinic follow-up group who received serum β-hCG testing. Three women in the at home urine β-hCG testing group (3/458, 0.7%) versus no women in the routine clinic follow-up group (0/466, 0%) had undetected continuing pregnancies. No statistically significant difference was found in loss to follow-up rates between the routine clinic follow-up group (108/466, 23%) and the at home urine β-hCG testing group (90/458, 20%).

A total of four studies (Iyengar 2015, Ngoc 2014, Oppegaard 2015, Platais 2015) were identified in the Biaju (2019) systematic review which compared at-home low-sensitivity or semi-quantitative pregnancy test (and questionnaire) follow-up after EMA to in-clinic follow-up (assessments included interview ± examination ± ultrasound ± serum β-hCG). In-clinic assessments included history (5/5), examination (unclear, at least 1/5), urine pregnancy test (1/5), serum β-hCG level (1/5), or ultrasound scan (4/5 if outcome uncertain on clinical assessment).

Little or no difference was found in ongoing pregnancy between the at-home urine pregnancy test and in-clinic follow-up groups (RR 0.90 95% CI 0.50 - 1.62), however the rate of missed ongoing pregnancies was not reported in this review.

The loss to follow-up rate in the in-clinic follow-up group was almost double that of the at-home pregnancy test group (6.49% vs 3.75%).

Three of the four RCTs asked participants which form of follow-up they would prefer if they were to have another abortion. In the at-home pregnancy test group 81.9% (1919/2343) would prefer at-home pregnancy test again, and of the in-clinic follow-up 50.5% (1166/2307) would prefer at-home pregnancy test follow-up.

Certainty of the Evidence

No direct evidence was identified during literature review.

Indirect evidence has been summarized as this may be taken into consideration when developing a recommendation. AMSTAR moderate quality evidence – downgraded for indirectness.

Values and preferences

No direct evidence was identified to indicate patient preference of urine vs serum β-hCG follow-up.

Indirect evidence to support the acceptability of urine β-hCG testing can be found in the acceptability of remote follow-up reported in 4/5 RCTs identified. More women preferred remote follow-up for managing abortion in the future among women who received remote follow-up compared to women who received clinic-based follow-up.

Resources

No economic evaluation was conducted as part of this recommendation. There are likely to be moderate savings with the routine use of urine β-hCG testing.

Despite being more costly than widely available high sensitivity pregnancy tests, low sensitivity urine pregnancy tests are significantly less costly than the laboratory costs for serum β-hCG tests. These costs do not take into account the additional staff time to interpret a serum β-hCG result and contact the woman to inform them of the result.

Equity

Urine β-hCG is able to be performed at home so may offer greater access for rural women and those for whom transportation to a blood-testing facility may be challenging; interpretation/communication of the result can be performed remotely.

Acceptability

Clinicians may have concerns regarding the detection threshold for a urine pregnancy test and the longer delay between abortion and follow-up of 3-4weeks compared to 1-2 weeks for a serum β-hCG test.

Results from additional research to directly compare these two follow-up strategies as planned by Dr Wise is likely to impact clinician acceptability.

A user comprehension survey was carried out by Lynd et al (2013) as part of a study of the test specificity and sensitivity of a semi-quantitative urine pregnancy test for follow-up of EMA. Women reported that the test was easy to use (255/292 [87.3%]) and that provider instructions helped them to use the test (291/292 [99.7%]).

Feasibility

No specific evidence identified but likely to be feasible as blood β-hCG testing is the current standard practice in many centres, and urine testing would not require any additional funding or staffing investment.

PICO (5.1)

Population: Woman having an early medical abortion (less than 10 weeks)
Intervention: Urine β-hCG testing (low sensitivity/semi-quantitative)
Comparator: serum β-hCG testing

Summary

No systematic reviews/studies comparing the effectiveness of urine β-hCG testing to serum β-hCG testing were identified.

Clinical Question 6: The optimal treatment regimen for medical abortion after 10 weeks pregnant

For a woman seeking medical abortion from 10 weeks pregnant, what medication regimen (including dosage, and dose interval) is the safest, and most effective, accessible, and acceptable?

P: Woman seeking medical abortion from 10 weeks

I: i) mifepristone plus misoprostol

C: i) mifepristone and misoprostol route A vs route B
ii) mifepristone and misoprostol dosage A vs dosage B
iii) mifepristone and misoprostol – interval A vs interval B

O: Adverse events

- pain
- ectopic pregnancy
- allergy (to misoprostol)
- blood transfusion
- need for emergency care or hospital admission
- failed abortion (ongoing pregnancy)
- incomplete abortion (retained products of conception)

- Access to abortion services – gestational age at time of consultation
- Acceptability/satisfaction with abortion services

Evidence to decision

Benefits and harms

Research evidence

Research evidence was drawn from the NICE Abortion Care Guideline: J: Misoprostol after mifepristone for inducing medical abortion between 10^{+1} and 24^{+0} weeks' gestation, published in 2019.

Updated search of Cochrane library for RCTs published since the NICE literature searches in 2018, undertaken in November 2022 - 13 studies returned, none met inclusion criteria.

Summary

There are three questions within this PICO:

1. Route of administration: buccal, oral, sublingual, or vaginal

2. Timing of administration of first dose of misoprostol - same time as mifepristone, or delayed (24, 36, or 48 hours)

3. Loading or first dose of misoprostol 400 mcg, 600 mcg, 800 mcg -

Additional comparisons not reported here can be found at: https://www.nice.org.uk/guidance/ng140/evidence/j-misoprostol-after-mifepristone-for-inducing-medical-abortion-between-101-and-240-weeks-gestation-pdf-248581907028

Pooling of results of the trials was not possible owing to the difference in drug regimens, including the loading dose and intervals between two doses. Overall, there is lack of clear evidence regarding the optimal regimen for women undergoing medical abortion after 24 weeks pregnant.

As the uterus becomes more sensitive to misoprostol as gestation advances, lower doses are often used after 14 weeks compared to up to 14 weeks.

Question 1: There was some evidence that vaginal and sublingual routes of administration were associated with a shorter time to expulsion and vaginal route was associated with fewer gastrointestinal side effects, when compared to oral route of administration of misoprostol.

Question 2: Among women receiving buccal misoprostol simultaneously with mifepristone or 24 hours afterwards, little or no difference was reported in the proportion of complete abortion, incomplete abortion requiring surgical procedure, haemorrhage, or patient satisfaction. Time to expulsion was longer in the simultaneous administration group (13 hours vs 8 hours). Among women receiving vaginal misoprostol 24 hours vs 48 hours after mifepristone little or no difference was reported in the proportion of complete abortion, incomplete abortion, or haemorrhage.

The interval of 36 to 48 hours was the most commonly used dosing interval in the included trials, reported in 4 out of 11 included trials.

Question 3: There was some evidence regarding the administration of misoprostol by oral, sublingual and vaginal routes following a loading dose of 800 mcg vaginal misoprostol or 600 mcg sublingual misoprostol. No evidence was identified for buccal misoprostol loading doses.

Certainty of the Evidence

GRADE assessment performed by NICE, ranges from high to low quality.

Values and preferences

Little or no differences were reported in patient satisfaction between varying regimens in included systematic review.

Resources

Out of scope

Equity

No issues highlighted

Acceptability

No issues highlighted

Feasibility

Misoprostol use at this gestation is an off-label use in both Australia and New Zealand.

PICO (6.1)

Population: Woman seeking late medical abortion after 10 weeks pregnant

Intervention: i) mifepristone plus misoprostol

Comparator: i) misoprostol dosage A vs dosage B ii) misoprostol/ mifepristone interval A vs interval B

Outcome [Author]	Study results and measurements	Absolute effect estimates		Certainty of the evidence (Quality of evidence)	Plain language summary
		Comparison of different dosages, and intervals	i) mifepristone plus misoprostol		

Complete abortion at 48hrs - buccal misoprostol 400 mcg 3hrly + mifepristone 200 mg - simultaneous vs 24hrs after mifepristone [SR: NICE 2019]	Relative risk: **0.99** (95% CI 0.95 - 1.02) Based on data from 509 participants in 1 study	**968** per 1000	**958** per 1000 Difference: **10 fewer per 1000** (95% CI 48 fewer - 19 more)	**Moderate** Due to serious risk of bias[1]	From NICE Abortion Care Guideline. Abbas et al 2016 [RR 1.03 (0.98 - 1.09) 13-16 wks] [RR 0.99 (0.95 - 1.03) 17-22 weeks] Little or no difference in complete abortion at 48hrs was found between simultaneous administration of mifepristone 200 mg and misoprostol 400 mcg buccal compared to 24hrs after mifepristone
Incomplete abortion with need for surgical intervention - buccal misoprostol 400 mcg 3hrly + mifepristone 200 mg - simultaneous vs 24hrs after mifepristone [SR: NICE 2019]	Relative risk: **1.98** (95% CI 0.18 - 21.66) Based on data from 509 participants in 1 study	**40** per 1000	**79** per 1000 Difference: **39 more per 1000** (95% CI 33 fewer - 826 more)	**Very low** Due to serious risk of bias, Due to very serious imprecision[2]	Uncertain difference in incomplete abortion with the need for surgical intervention between simultaneous administration of mifepristone 200 mg and misoprostol 400 mcg buccal compared to 24hrs after mifepristone
Haemorrhage >500 mL or requiring blood transfusion - buccal 400 mcg 3hrly + mifepristone 200 mg - simultaneous vs 24hrs after mifepristone [SR: NICE 2019]	Relative risk: **2.96** (95% CI 0.12 - 72.43) Based on data from 509 participants in 1 study	**0** per 1000	**39** per 1000	**Very low** Due to serious risk of bias, Due to very serious imprecision[2]	Uncertain difference in haemorrhage >500 mL or requiring transfusion between simultaneous administration of mifepristone 200 mg and misoprostol 400 mcg buccal compared to 24hrs after mifepristone
Patient satisfaction (satisfactory or very satisfactory) - buccal misoprostol 400 mcg 3hrly + mifepristone 200 mg - simultaneous vs 24hrs after mifepristone [SR: NICE 2019]	Relative risk: **1.0** (95% CI 0.98 - 1.02) Based on data from 509 participants in 1 study	**992** per 1000	**992** per 1000 Difference: **0 fewer per 1000** (95% CI 20 fewer - 20 more)	**Moderate** Due to serious risk of bias[3]	Little or no difference in patient satisfaction between simultaneous administration of mifepristone 200 mg and misoprostol 400 mcg buccal compared to 24hrs after mifepristone
Incomplete abortion with need for surgical intervention - vaginal misoprostol 400 mcg 3hrly - 24hrs vs 48hrs after mifepristone 200 mg [SR: NICE 2019]	Relative risk: **0.69** (95% CI 0.46 - 1.03) Based on data from 227 participants in 1 study	**366** per 1000	**253** per 1000 Difference: **113 fewer per 1000** (95% CI 198 fewer - 11 more)	**Moderate** Due to serious imprecision[4]	Little or no difference in incomplete abortion requiring surgical intervention between vaginal misoprostol 400 mcg administered 24hrs after mifepristone 200 mg compared to 48hrs after mifepristone
Haemorrhage >500 mL or requiring blood	Relative risk: **1.11** (95% CI 0.42 - 2.97)	**63** per 1000	**70** per 1000	**Low**	Little or no difference in haemorrhage >500 mL or need

transfusion - vaginal misoprostol 400 mcg 3hrly - 24hrs vs 48hrs after mifepristone 200 mg [SR: NICE 2019]	Based on data from 227 participants in 1 study	Difference: **7 more per 1000** (95% CI 37 fewer - 124 more)		Due to very serious imprecision[5]	for transfusion between vaginal misoprostol 400 mcg administered 24hrs after mifepristone 200 mg compared to 48hrs after mifepristone
Complete abortion at 48hrs - 200 mcg versus 400 mcg vaginal misoprostol (at 4 hour intervals) 36 to 48 hours after oral mifepristone 200 mg [SR: NICE 2019]	Relative risk: **0.9** (95% CI 0.74 - 1.1) Based on data from 176 participants in 1 study	**733** per 1000	**660** per 1000 Difference: **73 fewer per 1000** (95% CI 191 fewer - 73 more)	**Low** Due to very serious imprecision[5]	Little or no difference in complete abortion at 48hrs between vaginal misoprostol 200 mcg administered 36-48hrs after mifepristone 200 mg and misoprostol 400 mcg administration 36-48hrs after mifepristone
Incomplete abortion with need for surgical intervention - 200 mcg versus 400 mcg vaginal misoprostol (at 4 hour intervals) 36 to 48 hours after oral mifepristone 200 mg [SR: NICE 2019]	Relative risk: **1.26** (95% CI 0.8 - 1.99) Based on data from 176 participants in 1 study	**267** per 1000	**336** per 1000 Difference: **69 more per 1000** (95% CI 53 fewer - 264 more)	**Low** Due to very serious imprecision[5]	Little or no difference in incomplete abortion requiring surgical intervention between vaginal misoprostol 200 mcg administered 36-48hrs after mifepristone 200 mg and misoprostol 400 mcg administration 36-48hrs after mifepristone
Haemorrhage >500 mL or requiring transfusion - 200 mcg versus 400 mcg vaginal misoprostol (at 4 hour intervals) 36 to 48 hours after oral mifepristone 200 mg [SR: NICE 2019]	Relative risk: **1.4** (95% CI 0.32 - 6.05) Based on data from 176 participants in 1 study	**33** per 1000	**46** per 1000 Difference: **13 more per 1000** (95% CI 22 fewer - 167 more)	**Low** Due to very serious imprecision[5]	Little or no difference hemorrhage >500 mL or need for transfusion between vaginal misoprostol 200 mcg administered 36-48hrs after mifepristone 200 mg and misoprostol 400 mcg administration 36-48hrs after mifepristone
Time to expulsion - vaginal misoprostol 400 mcg 3hrly - 24hrs vs 48hrs after mifepristone 200 mg [SR: NICE 2019]	Measured by: Hours Scale: Lower better Based on data from 227 participants in 1 study	Median **7.2**	Median **8.5**	**Moderate** Due to serious imprecision[4]	Uncertain difference between vaginal misoprostol 400 mcg administered 24hrs after mifepristone 200 mg and misoprostol administration 48hrs after mifepristone in time to expulsion due to report of medians rather than means and standard deviations precluding an estimate of effect
Time to expulsion - buccal misoprostol 400 mcg 3hrly + mifepristone 200 mg - simultaneous vs 24hrs after mifepristone [SR: NICE 2019]	Measured by: Hours Scale: Lower better Based on data from 509 participants in 1 study	Median **7.7**	Median **13.0**	**Low** Due to serious risk of bias, Due to serious imprecision[6]	Uncertain difference between buccal misoprostol 400 mcg administered simultaneously with mifepristone 200 mg and misoprostol administration 24hrs after mifepristone in time to expulsion due to report of medians rather than means and standard deviations precluding an estimate of effect

Time to expulsion - 200 mcg versus 400 mcg vaginal misoprostol (at 4 hour intervals) 36 to 48 hours after oral mifepristone 200 mg [SR: NICE 2019]	Measured by: Hours Scale: Lower better Based on data from 176 participants in 1 study	Median **8.0**	Median **9.2**	**Low** Due to very serious imprecision[7]	Uncertain difference between vaginal misoprostol 200 mcg administered 36-48hrs after mifepristone 200 mg and misoprostol 400 mcg administration 36-48hrs after mifepristone in time to expulsion due to report of medians rather than means and standard deviations precluding an estimate of effect

1. **Risk of Bias: serious.** Unclear randomization methods.
2. **Risk of Bias: serious.** Randomisation methods unclear; **Imprecision: very serious.** Wide confidence intervals, only data from one study.
3. **Risk of Bias: serious.** Randomisation methods unclear; **Imprecision: very serious.** Wide confidence intervals.
4. **Imprecision: serious.** Wide confidence intervals.
5. **Imprecision: very serious.** Wide confidence intervals.
6. **Risk of Bias: serious.** Unclear randomisation methods; **Imprecision: serious.** Wide confidence intervals.
7. **Imprecision: very serious.**

Clinical Question 7: The optimal regimen for cervical priming for surgical abortions up to 14 weeks pregnant

For a woman undergoing a surgical abortion up to 14 weeks pregnant, what method of cervical priming is the safest, and most effective, accessible, and acceptable?

P: Woman seeking a surgical abortion up to 14 weeks of gestation

I: Priming

i) misoprostol (any dosage)

ii) misoprostol and mifepristone (together or in succession)

iii) mifepristone alone

C: i) No priming

O: Adverse events

- infection
- cervical injury
- uterine perforation
- blood transfusion
- need for emergency care or hospital admission
- failed abortion (ongoing pregnancy)
- incomplete abortion (retained products of conception)
- need for repeat procedure
- duration of procedure
- efficacy - ease of dilatation
- pain during procedure

- Access to abortion services

- Patient satisfaction/ acceptability

Evidence to decision

Benefits and harms

Research evidence

A Cochrane review (Kapp et al 2010) is relevant to this PICO. This review was updated in 2021 and was under peer review at the time of discussion of this recommendation. Literature searches for this review were included up to October 2021. Data from this updated review was used to inform the WHO Abortion Care Guideline 2022.

A literature search of MEDLINE was performed on 20th January 2023 for RCTs published between October 2021 and 20th January 2023 using the search terms "abortion" OR "termination of pregnancy" AND "cervical priming" OR "ripening", limited to human studies, and RCTs. 3 articles were retrieved and two had full text reviewed. Neither study compared a cervical priming method to no cervical priming/placebo, so both were excluded from this evidence summary.

NOTE: Additional comparisons of misoprostol doses, routes, and comparison of misoprostol plus mifepristone vs misoprostol alone are presented in the updated Cochrane review and WHO Abortion Care Guideline evidence summary, however the parameters of this PICO include a comparison group of no cervical priming/placebo, so those comparisons are not included in this evidence summary.

Those comparisons may be useful to provide indirect evidence to inform this recommendation.

Summary

Comparison - misoprostol alone vs placebo/control:

Benefits: Pre-procedure misoprostol was found to have a lower need for additional mechanical dilatation (1.96% (95% 2.22 to 1.68) difference) and a lower need for re-aspiration/incomplete abortion when compared to placebo (very small but significant difference). Pre-procedure cervical diltation of the women in the misoprostol group was greater (3.4 to 6.0mm) compared to the pre-procedure cervical dilatation of the women in the placebo group.

Little difference was found in cervical dilatation at the start of the procedure between different dosages and routes of administration of misoprostol when compared to placebo.

Cervical injury and uterine perforation were rare in either group with little or no difference found.

Overall fewer women in the any misoprostol group (and vaginally administered misoprostol groups) experienced the side-effects of nausea compared to the women in the placebo group (OR: 0.62 (95% CI 0.47 - 0.81), 20 fewer per 1000).

Harms:

More women in the misoprostol group experienced the side effect of abdominal pain/cramping compared to women in the placebo group (OR 4.19 (95% CI 3.71-4.74), 308 more per 1000).

More women in the misoprostol 400 mcg sublingually group experienced nausea compared to the placebo group (Odds ratio: 10.58 (95% CI 3.38-33.12), 211 more per 1000).

Cervical injury and uterine perforation were rare in either group with high uncertainty of the effects of misoprostol on these outcomes compared to placebo.

Comparison - mifepristone alone vs placebo/control:

One study was included in the Cochrane review which compared mifepristone alone to placebo. Pre-procedure cervical dilatation of the women receiving mifepristone was greater compared to the pre-procedure cervical dilatation of the

women in the placebo group (1.8mm more (95% CI 1.4-2.24mm)). Fewer women in the mifepristone group required further dilatation compared to the women in the placebo group (OR 0.85 (95% CI 0.74 - 0.97), 21 fewer per 1000).

Certainty of the Evidence

Using the GRADE methodology the certainty of evidence ranged from high to low depending on the outcome assessed. Where certainty was downgraded this was owing to inconsistency of intervention and wide confidence intervals indicating imprecision.

Values and preferences

No outcomes reporting satisfaction with misoprostol for cervical priming were identified.
Women may prefer a particular route of misoprostol administration. Some women may choose one route over another because of side effect profile. Studies have reported that women may prefer the oral/buccal/sublingual routes as they find it more private and convenient, however, some women may prefer the vaginal route as they dislike the taste of the misoprostol tablets.

Resources

No economic analyses were conducted as part of this guideline.
In New Zealand the cost of misoprostol is very low. Mifepristone is expensive and not used very often in Aotearoa New Zealand in this gestation. It can be used on a case by case basis in a sparing fashion.
If cervical priming was to be offered to women who are up to and including 13+6 weeks pregnant there would be an increase in contact time with staff. However, the increased cost of staff time to administer/dispense cervical priming medications may be offset in part by savings owing to fewer additional operations needed for incomplete abortion.

Equity

An additional clinic visit to administer mifepristone the day prior may create further inequalities for women living in remote areas. However, the impact of routine cervical priming for surgical termination before 13 weeks may be reduced by recommending the option of sublingual misoprostol administered 1 hour before abortion. This will minimise the time women are required to arrive at hospital before the abortion and may reduce the need for overnight stays. It will also maximise the number of women receiving optimal cervical priming.

Acceptability

Routine pre-procedure cervical priming with misoprostol for surgical abortion before 13 weeks, given on the day of the procedure, would likely add little additional workload to service providers. Any additional workload would likely be offset by improved ease of procedure and reduced need for re-aspiration or incomplete abortion. This is likely to be acceptable to providers.

Feasibility

No feasibility issues are foreseen.

PICO (7.1)

Population: Woman seeking a surgical abortion up to 14 weeks pregnant
Intervention: i) misoprostol (any dosage) ii) misoprostol and mifepristone (together or in succession) iii) mifepristone alone
Comparator: No cervical priming

Outcome [Author]	Study results and measurements	Absolute effect estimates		Certainty of the evidence (Quality of evidence)	Plain language summary
		No priming	Priming		
Any misoprostol: Side-effects: occurrence of nausea [CR: Kapp 2010]	Odds ratio: **0.62** (95% CI 0.47 - 0.81) Based on data from 5660 participants in 6 studies	**54** per 1000	**34** per 1000 Difference: **20 fewer per 1000** (95% CI 28 fewer - 10 fewer)	**Low** Due to very serious inconsistency[1]	Cervical priming with any dose or route of misoprostol may decrease the side-effect occurrence of nausea
Side-effects: occurrence of nausea - misoprostol 400 µg vaginal vs placebo/control [CR: Kapp 2010]	Odds ratio: **0.32** (95% CI 0.22 - 0.47) Based on data from 5172 participants in 3 studies	**47** per 1000	**16** per 1000 Difference: **31 fewer per 1000** (95% CI 36 fewer - 24 fewer)	**Low** Due to very serious inconsistency[1]	Cervical priming with misoprostol 400 mcg vaginally may decrease the side-effect occurrence of nausea compared to placebo/control
Side-effects: occurrence of nausea - misoprostol 400 µg sublingual vs placebo/control [CR: Kapp 2010]	Odds ratio: **10.58** (95% CI 3.38 - 33.12) Based on data from 210 participants in 2 studies	**29** per 1000	**240** per 1000 Difference: **211 more per 1000** (95% CI 63 more - 468 more)	**Moderate** Due to serious risk of bias[2]	Cervical priming with misoprostol 400 mcg sublingual probably increases the side-effect occurrence of nausea compared to placebo/control
Side-effects: occurrence of nausea - misoprostol 600 µg vaginal vs placebo/control [CR: Kapp 2010]	Odds ratio: **0.97** (95% CI 0.53 - 1.8) Based on data from 278 participants in 1 study	**182** per 1000	**178** per 1000 Difference: **4 fewer per 1000** (95% CI 77 fewer - 104 more)	**Low** Due to serious risk of bias, Due to serious imprecision[3]	Cervical priming with misoprostol 600 mcg vaginally may decrease the side-effect occurrence of nausea compared to placebo/control
Need for additional mechanical dilation - misoprostol any dosage/route vs placebo/control [CR: Kapp 2010]	Odds ratio: **0.4** (95% CI 0.36 - 0.45) Based on data from 5720 participants in 3 studies	**773** per 1000	**577** per 1000 Difference: **196 fewer per 1000** (95% CI 222 fewer - 168 fewer)	**Low** Due to very serious inconsistency[1]	Cervical priming with any dose or route of misoprostol may decrease the need for additional mechanical dilation
Cervical laceration/injury - any	Odds ratio: **0.2** (95% CI 0.01 - 4.17)	**1** per 1000	**0** per 1000	**Low**	There were too few who experienced cervical

misoprostol vs placebo/control [CR: Kapp 2010]	Based on data from 4970 participants in 1 study	Difference: **1 fewer per 1000** (95% CI 1 fewer - 3 more)		Due to very serious imprecision[4]	laceration/injury, to determine whether priming made a difference
Need for re-aspiration/incomplete abortion - misoprostol any dosage/route vs placebo/control [CR: Kapp 2010]	Odds ratio: **0.33** (95% CI 0.2 - 0.56) Based on data from 5598 participants in 3 studies	**20** per 1000	**7** per 1000 Difference: **13 fewer per 1000** (95% CI 16 fewer - 9 fewer)	**High**	Cervical priming with misoprostol at any dosage or route decreases need for re-aspiration/incomplete abortion compared to placebo/control
Need for re-aspiration/incomplete abortion - misoprostol 400 µg vaginal vs placebo/control [CR: Kapp 2010]	Odds ratio: **0.34** (95% CI 0.2 - 0.58) Based on data from 5448 participants in 2 studies	**20** per 1000	**7** per 1000 Difference: **13 fewer per 1000** (95% CI 16 fewer - 8 fewer)	**High**	Cervical priming with 400 mcg misoprostol vaginally decreases need for re-aspiration/incomplete abortion compared to placebo/control
Need for re-aspiration/incomplete abortion - misoprostol 400 µg sublingual vs placebo/control [CR: Kapp 2010]	Odds ratio: **0.19** (95% CI 0.01 - 4.12) Based on data from 150 participants in 1 study	**27** per 1000	**5** per 1000 Difference: **22 fewer per 1000** (95% CI 27 fewer - 76 more)	**Very low** Due to serious risk of bias, Due to very serious imprecision[6]	We are uncertain whether cervical priming using misoprostol 400 mcg sublingually increases or decreases need for re-aspiration/incomplete abortion compared to placebo/control
Uterine perforation - any misoprostol vs placebo/control [CR: Kapp 2010]	Odds ratio: **1.25** (95% CI 0.33 - 4.67) Based on data from 5559 participants in 2 studies	**1** per 1000	**1** per 1000 Difference: **0 fewer per 1000** (95% CI 1 fewer - 4 more)	**Low** Due to very serious imprecision[4]	There were too few who experienced uterine perforation, to determine whether priming made a difference
Uterine perforation - misoprostol 400 µg vaginal vs placebo/control [CR: Kapp 2010]	Odds ratio: **1.25** (95% CI 0.33 - 4.67) Based on data from 5559 participants in 2 studies	**1** per 1000	**1** per 1000 Difference: **0 fewer per 1000** (95% CI 1 fewer - 4 more)	**Low** Due to very serious imprecision[4]	There were too few who experienced uterine perforation, to determine whether priming made a difference
Infection - any misoprostol vs placebo/control [CR: Kapp 2010]	Odds ratio: **1.32** (95% CI 0.79 - 2.21) Based on data from 5447 participants in 2 studies	**9** per 1000	**12** per 1000 Difference: **3 more per 1000** (95% CI 2 fewer - 11 more)	**Moderate** Due to serious imprecision[5]	Cervical priming with misoprostol of any dosage or route probably has little or no difference on infection compared to placebo/control

Any misoprostol: Side effects: abdominal pain/cramping [CR: Kapp 2010]	Odds ratio: **4.19** (95% CI 3.71 - 4.74) Based on data from 5710 participants in 3 studies	**194** per 1000	**502** per 1000 Difference: **308 more per 1000** (95% CI 278 more - 176 more)	**Moderate** Due to serious inconsistency[7]	Cervical priming with misoprostol of any dosage or route probably increases the side effect of abdominal pain/cramping compared to placebo
Side effects: abdominal pain/cramping - misoprostol 400 mcg vaginally vs placebo/control [CR: Kapp 2010]	Odds ratio: **4.24** (95% CI 3.74 - 4.79) Based on data from 5560 participants in 2 studies	**197** per 1000	**510** per 1000 Difference: **313 more per 1000** (95% CI 281 more - 177 more)	**Moderate** Due to serious inconsistency[7]	Cervical priming with misoprostol400 mcg vaginally probably increases the side effect of abdominal pain/cramping compared to placebo
Side effects: abdominal pain/cramping - misoprostol 400 mcg sublingually vs placebo/control [CR: Kapp 2010]	Odds ratio: **1.98** (95% CI 0.69 - 5.66) Based on data from 150 participants in 1 study	**80** per 1000	**147** per 1000 Difference: **67 more per 1000** (95% CI 23 fewer - 301 more)	**Very low** Due to serious risk of bias, Due to very serious imprecision[6]	We are uncertain whether cervical priming using misoprostol 400 mcg sublingually increases or decreases the side effect of abdominal pain/cramping compared to placebo/control
Need for additional mechanical dilation - mifepristone alone vs placebo/control [CR: Kapp 2010]	Odds ratio: **0.85** (95% CI 0.74 - 0.97) Based on data from 168 participants in 3 studies	**857** per 1000	**836** per 1000 Difference: **21 fewer per 1000** (95% CI 41 fewer - 453 fewer)	**Low** Due to very serious imprecision, Due to serious inconsistency[8]	Cervical priming using mifepristone alone at any dosage may decrease need for additional mechanical dilation compared to placebo/control
Cervical dilation at start - misoprostol any dosage/route vs placebo/control [CR: Kapp 2010]	Measured by: mm Scale: High better Based on data from 6249 participants in 8 studies		Difference: **MD 1.39 higher** (95% CI 1.22 higher - 1.56 higher)	**Low** Due to very serious inconsistency[1]	Cervical priming using misoprostol of any dosage or route may increase cervical dilation at the start of the procedure compared to placebo/control
Cervical dilation at procedure start - misoprostol 400 µg vaginal vs placebo/control [CR: Kapp 2010]	Measured by: mm Scale: High better Based on data from 5731 participants in 4 studies		Difference: **MD 0.9 higher** (95% CI 0.7 higher - 1.1 higher)	**Low** Due to very serious inconsistency[1]	Cervical priming using misoprostol 400 mcg vaginally may increase cervical dilation at procedure start compared to placebo/control, slightly
Cervical dilation at procedure start -	Measured by: mm Scale: High better			**Moderate**	Cervical priming using misoprostol 400 mcg sublingually

misoprostol 400 µg sublingual vs placebo/control [CR: Kapp 2010]	Based on data from 210 participants in 2 studies	Difference: **MD 3.87 higher** (95% CI 3.39 higher - 4.34 higher)	Due to serious risk of bias[10]	probably increases cervical dilation at the start of the procedure compared to placebo/control
Cervical dilation at procedure start - misoprostol 600 µg oral vs placebo/control [CR: Kapp 2010]	Measured by: mm Scale: High better Based on data from 30 participants in 1 study	Mean **4.5** mm Difference: **MD 1.40 higher** (95% CI 0.51 higher - 2.29 higher)	**High**	Cervical priming using misoprostol 600 mcg oral increases cervical dilation at the start of the procedure compared to placebo/control
Cervical dilation at procedure start - misoprostol 600 µg vaginal vs placebo/control [CR: Kapp 2010]	Measured by: mm Scale: High better Based on data from 278 participants in 1 study	Mean **6.0** mm Difference: **MD 1.60 higher** (95% CI 1.14 higher - 2.06 higher)	**Moderate** Due to serious risk of bias[10]	Cervical priming using misoprostol 600 mcg vaginally probably increases cervical dilation at the start of the procedure compared to placebo/control
Procedure length - misoprostol 400 µg vaginal vs placebo/control [CR: Kapp 2010]	Measured by: minutes Scale: High better Based on data from 761 participants in 3 studies	Difference: **MD 0.31 lower** (95% CI 0.66 lower - 0.04 lower)	**Moderate** Due to serious inconsistency[7]	Cervical priming using misoprostol 400 mcg vaginally probably decreases procedure length - compared to placebo/control, slightly
Procedure length - misoprostol, 400 µg sublingual vs placebo/control [CR: Kapp 2010]	Measured by: minutes Scale: Lower better Based on data from 210 participants in 2 studies	Difference: **MD 3.65 lower** (95% CI 4.22 lower - 3.09 lower)	**Moderate** Due to serious risk of bias[2]	Cervical priming using misoprostol 400 mcg sublingually probably decreases procedure length - compared to placebo/control
Cervical dilation at procedure start - mifepristone alone vs placebo/control [CR: Kapp 2010]	Measured by: mm Scale: High better Based on data from 232 participants in 4 studies	Difference: **MD 1.82 higher** (95% CI 1.40 higher - 2.24 higher)	**Low** Due to serious inconsistency, Due to serious imprecision[1]	Cervical priming using mifepristone alone has little or no difference on cervical dilation at procedure start compared to placebo/control

Note: Author and year of publication of this Cochrane review likely to change on publication.

1. **Inconsistency: very serious**. The magnitude of statistical heterogeneity was high, with I^2>90%.
2. **Risk of Bias: serious**. no blinding.
3. **Risk of Bias: serious**. inadequate allocation concealment; **Imprecision: serious**. Wide confidence intervals.
4. **Inconsistency: very serious**. The magnitude of statistical heterogeneity was high, with I^2>90%.

5. **Risk of Bias: serious**. no blinding; **Imprecision: very serious**. Wide confidence intervals.
6. **Imprecision: serious.** Wide confidence intervals.
7. **Inconsistency: serious**. The magnitude of statistical heterogeneity was high, with I^2: >50%.
8. **Risk of Bias: serious.** Lack of blinding; **Imprecision: very serious**. Wide confidence intervals.
9. **Inconsistency: serious**. The direction of the effect is not consistent between the included studies; **Imprecision: serious**. Low number of patients.
10. **Risk of Bias: serious**. Inadequate concealment of allocation during randomization process, resulting in potential for selection bias.
11. **Inconsistency: serious**. Point estimates vary widely; **Imprecision: serious**. Low number of patients.

Clinical Question 8: The optimal regimen for cervical priming for surgical abortions from 14 weeks pregnant

For a woman undergoing a surgical abortion from 14 weeks pregnant, what method of cervical priming is the safest, and most effective, accessible, and acceptable?

P: Woman seeking a surgical abortion from 14 weeks pregnant

I: i) osmotic cervical dilators (Laminaria, Dilapan) alone
ii) osmotic cervical dilators (Laminaria, Dilapan) and medications (mifepristone/ misoprostol)
ii) other mechanical cervical dilator – Foley catheter

C: Medical methods
i) osmotic/mechanical method vs mifepristone and misoprostol
ii) osmotic/mechanical method vs mifepristone alone
iii) osmotic/mechanical method vs misoprostol alone
iv) osmotic/mechanical method vs other osmotic/mechanical method

O: Adverse events

- infection
- cervical injury
- uterine perforation
- blood transfusion
- need for emergency care or hospital admission
- failed abortion (ongoing pregnancy)
- incomplete abortion (retained products of conception)
- need for repeat procedure
- pre-procedure expulsion of pregnancy
- duration of procedure
- efficacy – ease of dilatation
- pain during procedure

- Access to abortion services – gestational age at time of consultation
- Patient satisfaction/acceptability

Evidence to decision

Benefits and harms

Research evidence

A Cochrane review (Newmann et al 2010) is relevant to this PICO. This review was updated in 2021 and is currently under peer review. Literature searches for this review were up to December 2021. It is expected that this updated Cochrane review will be published prior to the publication of the RANZCOG Clinical Guideline for Abortion Care.

A literature search of MEDLINE was performed on 20th January 2023 for RCTs published between December 2021 and January 2023 using the search terms “abortion” OR “termination of pregnancy” AND “cervical priming” OR “ripening”, limited to human studies, and RCTs. 2 articles were retrieved, and both had full text reviewed. Neither study compared a cervical priming method to no cervical priming/placebo, so both were excluded from this evidence summary.

Summary

For ease of interpretation evidence has been split into three evidence summary tables:

Medical methods of cervical priming vs osmotic dilators:

Medical methods (misoprostol) versus osmotic dilators (4 studies, 373 participants; include gestations from 12+6 to 20 weeks)

Medical methods (misoprostol) may result in little or no difference in the ability to perform a procedure (RR (risk ratio) 0.99, 95% confidence interval (CI) 0.95 to 1.03; moderate-certainty) but probably leads to less dilatation achieved (MD (mean difference) 3.58 mm, 95% CI -4.58 to -2.58; moderate-certainty) compared to osmotic dilators. However, it is uncertain if medical methods (misoprostol) alone impact procedure time or need for additional dilatation.

It is uncertain if medical methods (misoprostol) alone have any effect on pain prior to the procedure compared to misoprostol plus dilators.

Mifepristone plus 400 mcg buccal misoprostol versus osmotic dilators (1 study, 49 participants; included gestations from 15 to 18 weeks; low-certainty)

The use of mifepristone plus misoprostol may have little or no effect on the ability to perform procedure compared to osmotic dilators (RR 1.00, 95% CI 0.92 to 1.08) and does not appear to impact procedure time. This combination may lead to less dilatation achieved (MD -1.67 mm, 95% CI -3.19 to -0.15) and increased need for additional dilatation (RR 1.92, 95% CI 1.16 to 3.18) compared to osmotic dilators (RR 1.00, 95% CI 0.92 to 1.08).

Osmotic cervical dilators plus medical method vs medical method alone of cervical priming:

Misoprostol 400 mcg buccally or vaginally plus dilators versus misoprostol 400 mcg buccally or vaginally (1 study, 163 participants; included gestations from 14 to 19+6 weeks; moderate-certainty)

Compared to buccal or vaginal misoprostol alone, buccal or vaginal misoprostol plus dilators probably makes no difference in the ability to perform procedure (RR 1.00, 95% CI 0.98 to 1.02). Misoprostol plus dilators likely increases dilatation (MD 3.9 mm, 95% CI 3.1 to 4.7) and reduces the need for additional dilatation (RR 0.77, 95% CI 0.63 to 0.93). The overall dilatation and evacuation procedure time was not different between the two groups.

Osmotic cervical dilators combined with medical method vs osmotic cervical dilators combined with a different medical method/placebo

Misoprostol 400 mcg buccal plus dilators versus placebo plus dilators (4 studies, 545 participants; included gestations from 13 to 23+6 weeks; moderate certainty)

Misoprostol plus dilators probably has no effect on ability to perform procedure (RR 0.99, 95% CI 0.96 to 1.20), but may increase dilatation achieved (MD mm 1.83, 95% CI 0.27 to 3.39), and reduce the need for additional dilatation (RR 0.65, 95% CI 0.50 to 0.84) and procedure time (MD -0.99 minutes, 95% CI -2.05 to 0.06) compared to placebo plus dilators.

The number of cervical lacerations requiring suturing, haemorrhage requiring transfusion, emergency hospitalizations, and uterine perforations was too low to determine if misoprostol plus dilators made any difference.

Two studies (589 participants) reported pre-procedure expulsions of the fetus. Both instances occurred in the buccal misoprostol plus dilator group in the studies (46/1000 vs 26/1000).

Mifepristone plus dilators versus placebo plus dilators (1 study, 198 participants; included gestations from 16 to 23+6 weeks)

Compared to placebo plus dilators, mifepristone plus dilators probably has little or no effect on ability to perform procedure (RR 1.00, 95% CI 0.97 to 1.03; moderate certainty). Mifepristone plus osmotic dilators probably increases dilatation achieved (MD 2.00 mm, 95% CI 0.60 to 3.40; moderate certainty). Mifepristone plus dilators does not appear to have any effect on need for additional dilatation.

No instances of pre-procedure expulsion were reported.

Mifepristone plus misoprostol 400 mcg buccal plus dilators compared to misoprostol 400 mcg buccally plus dilators (1 study, 48 participants; included gestations from 19 to 23+6 weeks)

It is uncertain if mifepristone plus misoprostol plus dilators has any effect on dilatation achieved or need for additional dilatation compared to misoprostol plus dilators.

No studies were identified that compared mechanical dilatation methods other than osmotic dilators (such as, Foley catheter) to medical methods or osmotic methods.

Certainty of the evidence

GRADE certainty of evidence ranged from moderate to very low. Studies were most often marked down for having few participants and very wide confidence intervals.

Values and preferences

No evidence on acceptability was identified from the systematic review and up-dated literature search used to inform this recommendation.

Resources

Out of scope

Equity

Osmotic dilators are usually required to be inserted at least 24 hours prior to procedure requiring a longer stay near a clinic. There may be an increase in costs associated with accommodation needed for women travelling for an abortion.

Acceptability

Two-stage procedure may be a challenge for rural people. Sometimes two procedures under general anaesthetic (GA), for insertion of dilators and then for the procedure. Pain and cramping may be experienced with osmotic dilators.

Feasibility

Feasibility issues with training and procedure may limit their use. Insertion under sedation/GA also may have an impact on feasibility and acceptability

PICO (8.1)

Population: Woman seeking a surgical abortion from 14 weeks
Intervention: Medications: i) mifepristone and misoprostol ii) mifepristone alone iii) misoprostol alone
Comparator: i) non-synthetic osmotic cervical dilators (Laminaria) alone

Outcome [Author]	Study results and measurements	Absolute effect estimates		Certainty of the evidence (Quality of evidence)	Plain language summary
		Osmotic dilators alone	Medical method (alone or in combined regimen)		
Misoprostol vs osmotic dilators - need for	Relative risk: **1.85** (95% CI 0.45 - 7.52)	**271** per 1000	**501** per 1000	**Very low**	We are uncertain whether medical methods of cervical

additional dilation [CR: Newman 2010]	Based on data from 167 participants in 2 studies	Difference: **230 more per 1000** (95% CI 149 fewer - 1767 more)		Due to very serious imprecision, Due to serious inconsistency[1]	priming increase or decrease the need for additional dilation compared to osmotic dilators
Misoprostol vs osmotic dilators - Ability to perform procedure (number completed on first attempt) [CR: Newman 2010]	Relative risk: **0.99** (95% CI 0.95 - 1.03) Based on data from 167 participants in 2 studies	**1000** per 1000	**990** per 1000 Difference: **10 fewer per 1000** (95% CI 50 fewer - 30 more)	**Moderate** Due to serious imprecision[2]	Medical methods of cervical priming probably have little or no difference on the ability to perform the procedure (number completed on first attempt) compared to osmotic dilators
Mifepristone plus 400 mcg buccal misoprostol vs osmotic dilators - need for additional dilation [CR: Newman 2010]	Relative risk: **1.92** (95% CI 1.16 - 3.18) Based on data from 149 participants in 1 study	**450** per 1000	**864** per 1000 Difference: **414 more per 1000** (95% CI 72 more - 981 more)	**Low** Due to very serious imprecision[3]	Mifepristone plus 400 mcg buccal misoprostol may increase need for additional dilation compared to osmotic dilators
Mifepristone plus 400 mcg buccal misoprostol vs osmotic dilators - Ability to perform procedure [CR: Newman 2010]	Relative risk: **1.0** (95% CI 0.92 - 1.08) Based on data from 149 participants in 1 study	**1000** per 1000	**1000** per 1000 Difference: **0 fewer per 1000** (95% CI 80 fewer - 0 more)	**Low** Due to very serious imprecision[3]	Mifepristone plus 400 mcg buccal misoprostol may have little or no difference on the ability to perform procedure (number completed on first attempt) compared to osmotic dilators
Misoprostol vs osmotic dilators - Pain experienced by women between initiation of cervical preparation method and abortion procedure [CR: Newman 2010]	Relative risk: **2.59** (95% CI 0.23 - 28.94) Based on data from 206 participants in 2 studies	**301** per 1000	**780** per 1000 Difference: **479 more per 1000** (95% CI 232 fewer - 8410 more)	**Very low** Due to serious inconsistency, Due to very serious imprecision[4]	We are uncertain whether misoprostol vs osmotic dilators increases or decreases pain experienced by women between initiation of cervical preparation method and abortion procedure
Misoprostol vs osmotic dilators - dilation achieved [CR: Newman 2010]	Measured by: mm Scale: High better Based on data from 217 participants in 3 studies		Difference: **MD 3.58 lower** (95% CI 4.58 lower - 2.58 lower)	**Moderate** Due to serious imprecision[2]	Medical methods probably decrease dilation achieved compared to osmotic dilators
Procedure time - mifepristone plus 400	Measured by: mins Scale: Lower better	Mean **14.3**		**Low**	mifepristone plus 400 mcg buccal misoprostol may have little or no

mcg buccal misoprostol vs osmotic dilators [CR: Newman 2010]	Based on data from 149 participants in 1 study	Difference: **MD 0.3 lower** (95% CI 3.46 lower - 2.86 higher)	Due to very serious imprecision[5]	effect on procedure time compared to osmotic dilators
Mifepristone plus 400 mcg buccal misoprostol vs osmotic dilators - dilation achieved [CR: Newman 2010]	Measured by: mm Scale: High better Based on data from 149 participants in 1 study	Mean **15.67** Difference: **MD 1.67 lower** (95% CI 3.19 lower - 0.15 lower)	**Low** Due to very serious imprecision[3]	Mifepristone plus 400 mcg buccal misoprostol may decrease dilation achieved compared to osmotic dilators

Note: Author and year of publication of this Cochrane review likely to change on publication.

1. **Inconsistency: serious.** The direction of the effect is not consistent between the included studies; **Imprecision: very serious.** Wide confidence intervals.
2. **Imprecision: serious**. Low number of patients.
3. **Imprecision: very serious.** Low number of patients.
4. **Inconsistency: serious**. Point estimates vary widely; **Imprecision: very serious**. Wide confidence intervals.
5. **Imprecision: very serious**. Low number of patients, Wide confidence intervals.

PICO (8.2)

Population: person seeking a surgical abortion from 14 weeks
Intervention: Osmotic cervical dilators and medications
Comparator: Medications

Outcome [Author]	Study results and measurements	Absolute effect estimates		Certainty of the evidence (Quality of evidence)	Plain language summary
		Medical method	Osmotic dilator + Medical method		
Osmotic dilator plus 400 mcg misoprostol buccally or vaginally vs 400 mcg misoprostol buccally or vaginally - need for additional dilation [CR: Newman 2010]	Relative risk: **0.77** (95% CI 0.63 - 0.93) Based on data from 161 participants in 1 study	**829** per 1000	**638** per 1000 Difference: **191 fewer per 1000** (95% CI 307 fewer - 58 fewer)	**Moderate** Due to serious imprecision[1]	Osmotic dilator plus 400 mcg misoprostol buccally or vaginally probably decreases need for additional dilation compared to 400 mcg misoprostol buccally or vaginally
Osmotic dilator plus 400 mcg misoprostol buccally or vaginally vs 400 mcg misoprostol buccally or vaginally - ability to perform procedure [CR: Newman 2010]	Relative risk: **1.0** (95% CI 0.98 - 1.02) Based on data from 161 participants in 1 study	**1000** per 1000	**1000** per 1000 Difference: **0 fewer per 1000** (95% CI 20 fewer - 0 more)	**Moderate** Due to serious imprecision[2]	Osmotic dilator plus 400 mcg misoprostol buccally probably has little or no difference on ability to perform procedure compared to 400 mcg misoprostol buccally or vaginally alone
Osmotic dilator plus 400 mcg misoprostol	Measured by: mins Scale: Lower better	Mean **10.8**		**Moderate**	Osmotic dilator plus 400 mcg misoprostol buccally or vaginally

buccally or vaginally vs 400 mcg misoprostol buccally or vaginally - procedure time [CR: Newman 2010]	Based on data from 161 participants in 1 study	Difference: **MD 3.2 higher** (95% CI 1.77 higher - 4.63 higher)	Due to serious imprecision[3]	probably increases procedure time compared to 400 mcg misoprostol buccally or vaginally alone
Osmotic dilator plus 400 mcg misoprostol buccally or vaginally vs 400 mcg misoprostol buccally or vaginally - dilation achieved [CR: Newman 2010]	Measured by: mm Scale: Higher better Based on data from 161 participants in 1 study	Mean **11.7** Difference: **MD 3.9 higher** (95% CI 3.1 higher - 4.7 higher)	**Moderate** Due to serious imprecision[4]	Osmotic dilator plus 400 mcg misoprostol buccally or vaginally probably increases dilation achieved compared to 400 mcg misoprostol buccally or vaginally

1. **Imprecision: serious.** Low number of patients.

PICO (8.3)

Population: person seeking a surgical abortion from 14 weeks
Intervention: Osmotic cervical dilators and medications (combination A)
Comparator: Osmotic cervical dilators and medications (combination B)

Outcome [Author]	Study results and measurements	Absolute effect estimates		Certainty of the evidence (Quality of evidence)	Plain language summary
		Osmotic cervical dilators and medications (combination B)	Osmotic cervical dilators and medications (combination A)		
400 mcg buccal misoprostol plus dilators vs placebo plus dilators - need for additional dilation [CR: Newman 2010]	Relative risk: **0.65** (95% CI 0.5 - 0.84) Based on data from 546 participants in 4 studies	**313** per 1000 Difference: **110 fewer per 1000** (95% CI 156 fewer - 50 fewer)	**203** per 1000	**Moderate** Due to serious imprecision[1]	400 mcg buccal misoprostol plus dilators probably decreases the need for additional dilation compared to placebo plus dilators
400 mcg buccal misoprostol plus dilators vs placebo plus dilators - ability to perform procedure [CR: Newman 2010]	Relative risk: **0.99** (95% CI 0.96 - 1.02) Based on data from 199 participants in 1 study	**990** per 1000 Difference: **10 fewer per 1000** (95% CI 40 fewer - 20 more)	**980** per 1000	**Moderate** Due to serious imprecision[2]	400 mcg buccal misoprostol plus dilators probably has little or no difference on ability to perform procedure compared to placebo plus dilators
Mifepristone + dilators vs placebo + dilators -	Relative risk: **0.61** (95% CI 0.35 - 1.06)	**265** per 1000	**162** per 1000	**Low**	Mifepristone + dilators may have little or no difference on need for

need for additional dilation [CR: Newman 2010]	Based on data from 197 participants in 1 study	Difference: **103 fewer per 1000** (95% CI 172 fewer - 16 more)		Due to very serious imprecision[3]	additional dilation compared to placebo + dilators
Mifepristone + dilators vs placebo + dilators - ability to perform procedure [CR: Newman 2010]	Relative risk: **1.0** (95% CI 0.97 - 1.03) Based on data from 198 participants in 1 study	**990** per 1000	**990** per 1000 Difference: **0 fewer per 1000** (95% CI 30 fewer - 30 more)	**Moderate** Due to serious imprecision[4]	Mifepristone + dilators probably has little or no difference on ability to perform procedure compared to placebo + dilators
Mifepristone plus 400 mcg buccal misoprostol plus dilators vs 400 mcg buccal misoprostol plus dilators - need for additional dilation [CR: Newman 2010]	Relative risk: **1.17** (95% CI 0.38 - 3.61) Based on data from 48 participants in 1 study	**190** per 1000	**222** per 1000 Difference: **32 more per 1000** (95% CI 118 fewer - 496 more)	**Low** Due to very serious imprecision[3]	We are uncertain whether mifepristone plus 400 mcg buccal misoprostol plus dilators increases or decreases the need for additional dilation compared to 400 mcg buccal misoprostol plus dilators
400 mcg buccal misoprostol plus dilators vs placebo plus dilators - need for blood transfusion [CR: Newman 2010]	Relative risk: **2.34** (95% CI 0.35 - 15.69) Based on data from 394 participants in 2 studies	**5** per 1000	**12** per 1000 Difference: **7 more per 1000** (95% CI 3 fewer - 73 more)	**Low** Due to very serious imprecision[5]	There were too few who experienced the need for blood transfusion, to determine whether 400 mcg buccal misoprostol plus dilators made a difference
400 mcg buccal misoprostol plus dilators vs placebo plus dilators - uterine perforation [CR: Newman 2010]	Relative risk: **1.01** (95% CI 0.06 - 15.92) Based on data from 195 participants in 1 study	**10** per 1000	**10** per 1000 Difference: **0 fewer per 1000** (95% CI 9 fewer - 149 more)	**Low** Due to very serious imprecision[3]	There were too few who experienced uterine perforation, to determine whether 400 mcg buccal misoprostol plus dilators made a difference
400 mcg buccal misoprostol plus dilators vs placebo plus dilators - need for emergency hospitalization [CR: Newman 2010]	Relative risk: **1.26** (95% CI 0.34 - 4.59) Based on data from 394 participants in 2 studies	**20** per 1000	**25** per 1000 Difference: **5 more per 1000** (95% CI 13 fewer - 72 more)	**Low** Due to very serious imprecision[5]	There were too few who experienced the need for emergency hospitalization, to determine whether 400 mcg buccal misoprostol plus dilators made a difference
400 mcg buccal misoprostol plus	Relative risk: **1.0** (95% CI 0.14 - 7.03)	**10** per 1000	**10** per 1000	**Low**	There were too few who experienced the need for re-

dilators vs placebo plus dilators - need for re-aspiration [CR: Newman 2010]	Based on data from 394 participants in 2 studies	Difference: **0 fewer per 1000** (95% CI 9 fewer - 60 more)		Due to very serious imprecision[5]	aspiration, to determine whether 400 mcg buccal misoprostol plus dilators made a difference
400 mcg buccal misoprostol plus dilators vs placebo plus dilators - cervical tear requiring suturing [CR: Newman 2010]	Relative risk: **1.62** (95% CI 0.76 - 3.46) Based on data from 423 participants in 3 studies	**42** per 1000	**68** per 1000 Difference: **26 more per 1000** (95% CI 10 fewer - 103 more)	**Low** Due to very serious imprecision[5]	There were too few who experienced a cervical tear requiring suturing, to determine whether 400 mcg buccal misoprostol plus dilators made a difference
400 mcg buccal misoprostol plus dilators vs placebo plus dilators - pre-procedure expulsion [CR: Newman 2010]	Based on data from 589 participants in 2 studies	**20** per 1000	**46** per 1000 Difference: **26 more per 1000** (95% CI 19 fewer - 111 more)	**Moderate** Due to serious imprecision[6]	There were too few who experienced a pre-procedure fetal expulsion, to determine whether 400 mcg buccal misoprostol plus dilators made a difference
400 mcg buccal misoprostol plus dilators vs placebo plus dilators - procedure time [CR: Newman 2010]	Measured by: mins Scale: Lower better Based on data from 545 participants in 4 studies		Difference: **MD 0.99 lower** (95% CI 2.05 lower - 0.06 lower)	**Moderate** Due to serious inconsistency[7]	400 mcg buccal misoprostol plus dilators probably decreases procedure time compared to placebo plus dilators
400 mcg buccal misoprostol plus dilators vs placebo plus dilators - dilation achieved [CR: Newman 2010]	Measured by: mm Scale: High better Based on data from 484 participants in 4 studies		Difference: **MD 1.83 higher** (95% CI 0.27 higher - 3.30 higher)	**Moderate** Due to serious inconsistency[8]	400 mcg buccal misoprostol plus dilators probably increases dilation achieved compared to placebo plus dilators
Mifepristone + dilators vs placebo + dilators - dilation achieved [CR: Newman 2010]	Measured by: mm Scale: High better Based on data from 196 participants in 1 study	Mean **22**	Difference: **MD 2 higher** (95% CI 0.6 higher - 3.4 higher)	**Moderate** Due to serious imprecision[9]	Mifepristone + dilators probably increases dilation achieved compared to placebo + dilators

1. **Imprecision: serious.** Low event rate.

2. **Imprecision: serious.** Low number of patients.
3. **Imprecision: very serious.** Low number of patients, wide confidence intervals.
4. **Imprecision: serious.** Low number of patients.
5. **Imprecision: very serious.** Wide confidence intervals.
6. **Imprecision: serious.** Wide confidence intervals.
7. **Inconsistency: serious.** Differences in size of effect.
8. **Inconsistency: serious.** The direction of the effect is not consistent between the included studies.
9. **Imprecision: serious.** Low number of patients.

Clinical Question 9: The optimal surgical approach for surgical abortion

For a woman undergoing surgical abortion up to 14 weeks pregnant, is the use of manual vacuum aspiration (MVA) more acceptable than electric vacuum aspiration (EVA)?

P: Woman having surgical abortion (up to 14 weeks)

I: Electric vacuum aspiration

C: Manual vacuum aspiration

O: Adverse events

- infection
- cervical injury
- uterine perforation
- blood transfusion
- emergency care or hospitalisation
- failed abortion
- incomplete abortion
- need for repeat procedure
- procedure duration
- efficacy – ease of dilatation
- pain during procedure

- Patient satisfaction/ acceptability

Evidence to decision

Benefits and harms

Research evidence

A Cochrane review was available from 2001 with an updated search in 2009.

An additional search was undertaken on 26th May 2022 by University of Auckland for studies published after 2009. Two authors independently screened 368 studies. Three studies met the inclusion criteria (Dean 2015, Mittal 2011, and Grentzer 2022) and were GRADEd.

This search was updated on 17th February 2023 with no further studies included.

Additional considerations

WHO refer to Cochrane review (Kulier 2009) when addressing evidence for surgical abortion method in the first trimester.

Summary

Cochrane review: little or no difference was found in rates of uterine perforation, febrile morbidity, need for repeat uterine evacuation, and patient preference between MVA and EVA. A higher proportion of women among EVA patients reported severe pain. No instances of cervical injury were found in included studies with either MVA or EVA.

Additional studies: Dean 2016 and Mittal 2011 both report little or no difference in completion of abortion between MVA and EVA methods. Little or no difference was found in satisfaction (both those selecting satisfied or very satisfied, or those who would opt for the same method in future) between MVA and EVA between 10-14 weeks pregnant in Grentzer 2022. Although procedure time was increased in the EVA group in Mittal 2011, the mean difference was less than 1 minute. Although blood loss was increased in the EVA group in Mittal 2011, the mean difference was less than 7 mL. The clinical significance of these findings is likely to be negligible.

Certainty of the evidence

GRADE was completed for Cochrane review studies. Evidence quality was rated as low.
Three additional included studies were GRADEd as moderate or high quality.

Values and preferences

Little or no difference was found in patient preference or satisfaction between MVA and EVA in both the Cochrane review and additional studies.

Resources

No economic evidence was included in the literature search.
MVA can be performed without operating theatre requirements so implementation would be unlikely to attract additional costs.
Consider impact on the environment as MVA can be reused in some settings.

Equity

MVA can be performed without operating theatre requirements so has potential to increase access to surgical abortions for rural people.

Acceptability

Training would need to be provided to practitioners not familiar with MVA devices. Once trained in MVA use no acceptability concerns would be expected by abortion providers. Later gestations may not be acceptable to providers owing to the prolonged period that may be required for aspiration.

Feasibility

Many MVA syringes are able to be sterilised and reused, while the catheter itself is disposable. Some MVA syringes, particularly those available in Australia, are intended for single use, increasing the environmental burden of the procedure.

PICO (9.1)

Population: Woman having surgical abortion less than 14 weeks
Intervention: Manual vacuum aspiration (MVA)
Comparator: Electric vacuum aspiration (EVA)

Outcome [Author]	Study results and measurements	Absolute effect estimates		Certainty of the evidence (Quality of evidence)	Plain language summary
		Electric vacuum aspiration (EVA)	Manual vacuum aspiration (MVA)		
	Relative risk: **0.06** (95% CI 0.0 - 1.01)	**8** per 1000	**0** per 1000	**Low**	MVA may have little or no difference on uterine perforation

Uterine perforation - less than 9 weeks - MVA vs EVA [Kulier 2009 CR]	Based on data from 789 participants in 4 studies	Difference: **8 fewer per 1000** (95% CI 8 fewer - 0 fewer)		Due to serious risk of bias, Due to serious risk of bias, Due to serious imprecision[1]	compared to EVA for abortion less than 9 weeks
Cervical injury - less than 9 weeks - MVA vs EVA [Kulier 2009 CR]	Relative risk (95% CI -) Based on data from 600 participants in 3 studies	0 per 1000 Difference: **fewer per 1000** (95% CI 0 fewer - fewer)	0 per 1000	**Low** Due to serious risk of bias, Due to serious imprecision[1]	There were too few who experienced cervical injury, to determine whether MVA made a difference
Febrile morbidity - less than 9 weeks - MVA vs EVA [Kulier 2009 CR]	Relative risk: **0.97** (95% CI 0.14 - 6.72) Based on data from 179 participants in 1 study	2 per 1000 Difference: **0 fewer per 1000** (95% CI 2 fewer - 11 more)	2 per 1000	**Low** Due to serious risk of bias, Due to serious imprecision[2]	MVA may have little or no difference on febrile morbidity compared to EVA for abortion less than 9 weeks
Repeat uterine evacuation procedure - less than 9 weeks - MVA vs EVA [Kulier 2009 CR]	Relative risk: **0.99** (95% CI 0.4 - 2.48) Based on data from 779 participants in 4 studies	9 per 1000 Difference: **0 fewer per 1000** (95% CI 5 fewer - 13 more)	9 per 1000	**Low** Due to serious risk of bias, Due to serious inconsistency[3]	MVA may have little or no difference on the need for a repeat uterine evacuation procedure compared to EVA for abortion less than 9 weeks
Severe pain - less than 9 weeks - MVA vs EVA [Kulier 2009 CR]	Relative risk: **0.02** (95% CI 0.0 - 0.15) Based on data from 300 participants in 2 studies	48 per 1000 Difference: **47 fewer per 1000** (95% CI 48 fewer - 41 fewer)	0 per 1000	**Low** Due to serious risk of bias, Due to serious imprecision[4]	MVA may decrease severe pain compared to EVA for abortion less than 9 weeks
Women's preference (would choose same method again) - MVA vs EVA [Kulier 2009 CR]	Relative risk: **1.17** (95% CI 0.9 - 1.53) Based on data from 83 participants in 1 study	28 per 1000 Difference: **5 more per 1000** (95% CI 3 fewer - 15 more)	32 per 1000	**Low** Due to serious risk of bias, Due to serious imprecision[2]	MVA may have little or no difference on women's preference (would choose same method again) compared to EVA
Complete abortion - less than 10 weeks -	Relative risk: **0.98** (95% CI 0.95 - 1.01)	979 per 1000	959 per 1000	**High**	MVA has little or no difference on complete abortion compared

MVA vs EVA [Mittal 2011 RCT]	Based on data from 600 participants in 1 study	Difference: **20 fewer per 1000** (95% CI 49 fewer - 10 more)			to EVA for abortion less than 10 weeks
Satisfaction (very or somewhat satisfied) - 10-14 weeks - MVA vs EVA [Grentzer 2022 RCT]	Relative risk: **0.98** (95% CI 0.88 - 1.08) Based on data from 141 participants in 1 study	**926** per 1000	**907** per 1000 Difference: **19 fewer per 1000** (95% CI 111 fewer - 74 more)	**Moderate** Due to serious imprecision[5]	MVA probably has little or no difference on satisfaction (very or somewhat satisfied) compared to EVA for abortion 10-14 weeks
Satisfaction - would you choose the same method again (very or somewhat likely) [Grentzer 2022 RCT]	Relative risk: **0.99** (95% CI 0.87 - 1.14) Based on data from 141 participants in 1 study	**853** per 1000	**844** per 1000 Difference: **9 fewer per 1000** (95% CI 111 fewer - 119 more)	**Moderate** Due to serious imprecision[5]	MVA probably has little or no difference on satisfaction (would choose the same method again - very or somewhat likely) compared to EVA
Complete abortion - less than 6 weeks - MVA vs EVA [Dean 2015 RCT]	Relative risk: **0.99** (95% CI 0.96 - 1.01) Based on data from 438 participants in 1 study	**991** per 1000	**977** per 1000 Difference: **14 fewer per 1000** (95% CI 40 fewer - 10 more)	**Moderate** Due to risk of bias[6]	MVA probably has little or no difference on complete abortion compared to EVA for abortion less than 6 weeks
Initial cervical dilation - less than 10 weeks - MVA vs EVA [Mittal 2011 RCT]	Measured by: mm Scale: High better Based on data from 600 participants in 1 study	Mean **5.62**	Mean **5.88**	**High**	MVA has little or no difference on initial cervical dilation compared to EVA for abortion less than 10 weeks
Duration of procedure - less than 10 weeks - MVA vs EVA [Mittal 2011 RCT]	Measured by: Minutes Scale: Lower better Based on data from 600 participants in 1 study	Mean **3.82**	Mean **2.99**	**High**	MVA slightly decreases the duration of procedure (in minutes) compared to EVA for abortion less than 10 weeks
	Measured by: mL Scale: Lower better	Mean **17.88**	Mean **11.1**	**High**	

Blood loss - less than 10 weeks - MVA vs EVA [Mittal 2011 RCT]	Based on data from 600 participants in 1 study				MVA slightly decreases blood loss in mL compared to EVA for abortion less than 10 weeks
Procedure time - 10-14 weeks - MVA vs EVA [Grentzer 2022 RCT]	Measured by: Minutes Scale: Lower better Based on data from 141 participants in 1 study	Median 2.4	Median 2.6	**Moderate** Due to serious imprecision[5]	MVA probably increases procedure time slightly compared to EVA for abortion 10-14 weeks

1. **Risk of Bias: serious.** Inadequate sequence generation/ generation of comparable groups, resulting in potential for selection bias, Inadequate concealment of allocation during randomization process, resulting in potential for selection bias; **Imprecision: serious.** Low number of patients with outcome.
2. **Risk of Bias: serious.** Inadequate sequence generation/ generation of comparable groups, resulting in potential for selection bias, Inadequate concealment of allocation during randomization process, resulting in potential for selection bias; **Imprecision: serious.** Low number of patients.
3. **Risk of Bias: serious.** Inadequate sequence generation/ generation of comparable groups, resulting in potential for selection bias, Inadequate concealment of allocation during randomization process, resulting in potential for selection bias; **Imprecision: serious.** Only data from one study.
4. **Risk of Bias: serious.** Inadequate sequence generation/ generation of comparable groups, resulting in potential for selection bias, Inadequate concealment of allocation during randomization process, resulting in potential for selection bias; **Inconsistency: serious.** Point estimates vary widely.
5. **Imprecision: serious.** Low number of patients.
6. **Risk of Bias: serious.** Incomplete data and/or large loss to follow up (12% of patients lost to follow-up).

Clinical Question 10a: Medical or surgical abortion and pain relief

For a woman undergoing a medical or surgical abortion up to 14 weeks what pain relief regimen is the safest, most effective, and acceptable?

P: Woman undergoing a medical or surgical abortion up to 14 weeks

I: Any type of pharmacological pain control administered via mucosa (oral, vaginal, paracervical, buccal/sublingual), intramuscular, or intravenous route

C: i) medication A vs no pain control/placebo
ii) medication A vs medication B
iii) dosage A medication vs dosage B medication
iv) nonpharmacological pain relief

O: Patient satisfaction/acceptability: (would choose again)/ patient-reported efficacy of pain control on perceived pain during or after abortion

Safety:

- adverse effects
- side effects (including if pain control method caused pain)

Evidence to decision

Benefits and harms

Research evidence

Evidence was obtained from:

- Analgesia for surgical abortion: WHO Abortion Care Guideline evidence summaries 2022 (searches up to date to December 2020)
- Cochrane Review: Reynolds-Wright et al 2022 - Pain management for medical abortion before 14 weeks' gestation (searches up to date to Aug 2019).

Additional literature search undertaken on 16th February 2023 to identify articles published after the above systematic reviews.

Search terms: abortion OR abortion (induced) OR "termination of pregnancy" AND pain OR "pain relief" OR analgesia

- Limited to humans and published after 2019
- Identified 59 articles of which 12 were retrieved for full text review. 1 met inclusion criteria for abortion <14 weeks. 2 met inclusion for abortion after 14 weeks, and two met inclusion criteria for non-pharmacological methods

Additional considerations

From Acute Pain Management: Scientific Evidence (5th Edition) 2020 - produced and published by the Australian and New Zealand College of Anaesthetists & Faculty of Pain Medicine:

'*Paracetamol: There is no good evidence for a dose-dependent analgesic effect of oral paracetamol; the effects of 500 mg (NNT 3.5; 95%CI 2.7 to 4.8), 600/650 mg (NNT 4.6; 95%CI 3.9 to 5.5) and 1,000 mg (NNT 3.6; 95%CI 3.2 to 4.1) show no statistically significant difference (Moore 2015b Level I, 53 RCTs, n=5,679). Although in clinical practice there is no clear evidence of a dose-response relationship, experimental surgical models have shown that the maximal effective dose is 1000 mg.*

'*Paracetamol and NSAID combination: The combination of paracetamol and NSAIDs is more effective than either paracetamol or NSAID alone (Martinez 2017 Level I [NMA], 2 RCTs, n=85 [paracetamol/NSAID]; 60 RCTs, n=3,259 [NSAIDs]; 20 RCTs, n=699 [paracetamol]; Ong 2010 Level I, 21 RCTs, n=1,909).*'

Evidence of safety of higher doses of simple analgesics

Ibuprofen: Use of ibuprofen at low doses has a rate of adverse gastrointestinal (GI) events similar to that of placebo. At higher doses, the rate of adverse GI events increases. A meta-analysis (Lewis et al 2002) of three case-controlled studies of women with acute upper GI bleeding (n=2472) versus controls (n=5877) found the odds ratio of upper GI bleeding with ibuprofen at doses≤1200 mg/day compared to no use of ibuprofen was 1.1. As doses increased from 1200 to 1799 mg/day, the odds ratio increased to 1.8, and the highest doses of≥1800 mg/day had an odds ratio of 4.6.

Summary

Surgical abortion:

Pre-procedure - pain scores during and after abortion were lower if ibuprofen 600 mg was taken prior to surgical abortion with para-cervical block (PCB) compared to placebo + PCB.

Procedure - Lower mean pain score within 24 hours when PCB used compared to placebo. However, little or no difference was found in use of additional narcotics when comparing PCB to placebo.

PCB plus sedation had lower pain scores and greater satisfaction than PCB alone. No safety outcomes were reported.

No studies were identified which compared sedation alone vs PCB and sedation.

Medical abortion:

Little or no difference in pain score or reported side effects when comparing ibuprofen 800 mg to placebo, nor when comparing therapeutic versus prophylactic administration of ibuprofen 800 mg. One study reported increased vomiting with ibuprofen compared to placebo. No safety outcomes were reported.

Worst pain score reported within 24 hours of abortion was higher in women receiving ibuprofen 1600 mg compared to paracetamol 2000 mg. Little or no difference was found in the completion of abortion. These doses of medication are above recommended dosage levels in Australia and New Zealand.

No studies were identified which compared use of opiates for first trimester medical abortion to other analgesia options or placebo.

Non-pharmacological pain relief interventions:

Two studies identified that compare a pharmacological method and a non-pharmacological method for surgical abortion less than 14 weeks.

Ng et al (2022) conducted an RCT comparing acupuncture plus oral diazepam and IM pethidine to the medications alone without acupuncture. No sham acupuncture was used introducing a risk of bias as participants were not blinded. Acupuncture plus oral diazepam and IM pethidine probably decreases worst pain during procedure compared to oral diazepam and IM pethidine alone (p-value 0.03).

Lerma et al (2021) conducted an RCT comparing TENS plus PCB to IV sedation plus PCB. Little or no difference was found in the worst pain levels reported nor in the need for additional IV pain relief. Satisfaction scores were lower in the TENS group than the IV sedation group.

Certainty of the evidence

Certainty of evidence ranged from high to low using GRADE methodology, with the most commonly cited issue being broad confidence intervals resulting in imprecision.

Values and preferences

Additional considerations

Surgical abortion can be perceived by some women as a less painful method of abortion.

Summary

Women undergoing an abortion value pain control provided this is balanced with potential side effects. Satisfaction scores were higher among women receiving PCB plus sedation compared to PCB alone when undergoing a surgical abortion. Preferences are likely to vary.

Two satisfaction outcomes were reported: PCB probably has little or no difference on satisfaction with pain relief compared to placebo for surgical abortion <14 weeks. Combined sedation plus PCB improves satisfaction with pain relief compared to PCB alone for surgical abortion <14 weeks.

Resources

Non-opioid oral analgesia is associated with negligible cost for providers.
Any additional costs incurred by the routine use of PCB are negated by reduced use of general anaesthesia for surgical abortion.

Equity

No direct evidence from which to inform this domain.
Reduced use of general anaesthesia for surgical termination less than 13 weeks may mean that this procedure is able to be offered in areas where theatre space and anaesthetist availability can limit service provision.

Acceptability

Reduced staff required to deliver surgical abortion services when general anaesthesia not used. May require training for abortion providers in PCB and sedation administration.

Feasibility

Likely to be feasible.

PICO (10.1)

Population: Woman undergoing surgical or medical abortion up to 14 weeks
Intervention: Any type of pharmacological pain control administered via mucosa (oral, vaginal, paracervical, buccal/sublingual), intramuscular, or intravenous route
Comparator: i) medication A vs no pain control/placebo
ii) medication A vs medication B
iii) dosage A medication vs dosage B medication

Outcome [Author]	Study results and measurements	Absolute effect estimates		Certainty of the evidence (Quality of evidence)	Plain language summary
		Comparison (listed second)	Intervention (listed first)		
Surgical abortion <14 weeks - worst pain within 24hrs - PCB vs general anaesthesia [WHO 2022]	Relative risk: **10.84** (95% CI 1.5 - 78.11) Based on data from 59 participants in 1 study	**36** per 1000	**390** per 1000 Difference: **354 more per 1000** (95% CI 18 more - 2776 more)	**Moderate** Due to serious imprecision[1]	PCB probably increases report of the worst pain within 24hrs compared to general anaesthesia for surgical abortion less than 14 weeks
Surgical abortion <14 weeks - use of additional narcotics - PCB vs placebo [WHO 2022]	Relative risk: **1.57** (95% CI 0.9 - 2.73) Based on data from 210 participants in 2 studies	**162** per 1000	**254** per 1000 Difference: **92 more per 1000** (95% CI 16 fewer - 280 more)	**Low** Due to serious inconsistency, Due to serious imprecision[2]	PCB may have little or no difference on the use of additional narcotics compared to placebo for surgical abortion <14 weeks
Surgical abortion <14 weeks - satisfaction - PCB vs placebo [WHO 2022]	Relative risk: **1.2** (95% CI 0.66 - 2.2) Based on data from 89 participants in 1 study	**295** per 1000	**354** per 1000 Difference: **59 more per 1000** (95% CI 100 fewer - 354 more)	**Moderate** Due to serious imprecision[3]	PCB probably has little or no difference on satisfaction with pain relief compared to placebo for surgical abortion <14 weeks
Surgical abortion <14 weeks - satisfaction - Sedation (fentanyl and midazolam) + PCB vs PCB alone [WHO 2022]	Relative risk: **2.5** (95% CI 1.35 - 4.65) Based on data from 100 participants in 1 study	**200** per 1000	**500** per 1000 Difference: **300 more per 1000** (95% CI 70 more - 730 more)	**High**	Combined sedation and PCB improves satisfaction with pain relief compared to PCB alone for surgical abortion <14 weeks
Medical abortion <14 weeks - side effects (nausea/ vomiting) - therapeutic vs prophylactic pain relief (ibuprofen 800 mg) [Reynolds-Wright 2022 CR]	Relative risk: **1.67** (95% CI 0.99 - 2.83) Based on data from 228 participants in 1 study	**378** per 1000	**504** per 1000 Difference: **253 more per 1000** (95% CI 2 fewer - 255 more)	**Low** Due to serious risk of bias, Due to serious imprecision[4]	Therapeutic ibuprofen 800 mg may have little or no difference on side effects of nausea/ vomiting compared to prophylactic ibuprofen 800 mg, although this nears statistical significance
Medical abortion <14 weeks - side effects	Odds ratio: **0.19** (95% CI 0.04 - 0.97)	**281** per 1000	**69** per 1000	**Low**	Ibuprofen 800 mg may decrease the side effect of vomiting

(vomiting) - ibuprofen 800 mg vs placebo [Reynolds-Wright 2022 CR]	Based on data from 61 participants in 1 study	Difference: **212 fewer per 1000** (95% CI 266 fewer - 6 fewer)	Due to very serious imprecision[5]	compared to placebo for medical abortion <14 weeks
Surgical abortion <14 weeks - worst pain within 24hrs with conscious sedation - PCB vs placebo [WHO 2022]	Measured by: mm on pain scale Scale: 0 - 100 Lower better Based on data from 376 participants in 3 studies	Mean **65** Difference: **MD 8.7 lower** (95% CI 13.6 lower - 3.94 lower)	**Moderate** Due to serious inconsistency[6]	PCB probably decreases the level of worst pain within 24hrs compared to placebo for surgical abortion <14 weeks who received conscious sedation
Surgical abortion <14 weeks - pain during procedure - PCB + 600 mg ibuprofen vs PCB + placebo [WHO 2022]	Measured by: Scale: Lower better Based on data from 193 participants in 1 study	Mean **5.85** Difference: **MD 0.78 lower** (95% CI 1.52 lower - 0.04 lower)	**Low**	PCB + ibuprofen 800 mg may decrease level of pain during the procedure compared to PCB + placebo for surgical abortion <14 weeks
Surgical abortion <14 weeks - pain after procedure - PCB + 600 mg ibuprofen vs PCB + placebo [WHO 2022]	Measured by: Scale: Lower better Based on data from 193 participants in 1 study	Mean **3.74** Difference: **MD 0.93 lower** (95% CI 1.62 lower - 0.24 lower)	**Low**	PCB + ibuprofen 800 mg may decrease level of pain after procedure compared to PCB + placebo for surgical abortion <14 weeks
Surgical abortion <14 weeks - worst pain within 24hrs without conscious sedation - PCB vs placebo [WHO 2022]	Measured by: mm on pain scale Scale: 0 - 100 Lower better Based on data from 155 participants in 3 studies	Mean **85** Difference: **MD 30.86 lower** (95% CI 36.48 lower - 25.25 lower)	**Moderate** Due to serious inconsistency[6]	PCB probably decreases the level of worst pain within 24hrs compared to placebo for surgical abortion <14 weeks who did not receive conscious sedation
Medical abortion <14 weeks - worst pain within 24hrs - prophylactic pain relief vs therapeutic pain relief (ibuprofen 800 mg) [WHO 2022]	Measured by: pain scale Scale: 1 - 10 Lower better Based on data from 228 participants in 1 study	Mean **7.3** Difference: **MD 0.2 lower** (95% CI 1.73 lower - 1.33 lower)	**Low** Due to serious risk of bias, Due to serious imprecision[7]	Prophylactic pain relief with ibuprofen 800 mg may decrease worst pain within 24hrs compared to therapeutic pain relief for medical abortion <14 weeks, however the clinical significance of this is negligible

Medical abortion <14 weeks - worst pain score - ibuprofen 800 mg vs placebo [WHO 2022]	Measured by: pain score Scale: 1 - 10 Lower better Based on data from 61 participants in 1 study	Mean **5.4** Difference: **MD 1.4 lower** (95% CI 3.33 lower - 0.53 lower)	**Low** Due to very serious imprecision[8]	Pain relief with ibuprofen 800 mg may decrease worst pain within 24hrs compared to placebo for medical abortion <14 weeks, however the clinical significance of this is likely negligible
Medical abortion <14 weeks - worst pain score - ibuprofen 1600 mg vs paracetamol 2000 mg [WHO 2022]	Measured by: pain score Scale: 1 - 10 Lower better Based on data from 108 participants in 1 study	Mean **5.67** Difference: **MD 2.26 lower** (95% CI 3 lower - 1.52 lower)	**Moderate** Due to serious imprecision[9]	Pain relief with ibuprofen 1600 mg may decrease worst pain within 24hrs compared to paracetamol 200 mg for medical abortion <14 weeks, however these doses are higher than those licensed in Australia/Aotearoa New Zealand

1. **Imprecision: serious.** Wide confidence intervals.
2. **Inconsistency: serious.** The magnitude of statistical heterogeneity was high; **Imprecision: serious.** Wide confidence intervals.
3. **Imprecision: serious.**
4. **Risk of Bias: serious.** Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias; **Imprecision: serious.** Wide confidence intervals.
5. **Imprecision: very serious.** Wide confidence intervals, small sample size.
6. **Inconsistency: serious.**
7. **Risk of Bias: serious.** no blinding; **Imprecision: serious.** Wide confidence intervals.
8. **Imprecision: very serious.**
9. **Imprecision: serious.** small sample size.

PICO (10.2)

Population: Person undergoing surgical or medical abortion second trimester
Intervention: Any type of pharmacological pain control administered via mucosa (oral, vaginal, paracervical, buccal/sublingual), intramuscular, or intravenous route
Comparator: Non-pharmacological pain control

Outcome [Author]	Study results and measurements	Absolute effect estimates		Certainty of the evidence (Quality of evidence)	Plain language summary
		Comparison (listed second)	Intervention (listed first)		
Surgical abortion <10 weeks - satisfaction (satisfactory or excellent) - Acupuncture combined with oral diazepam and IM pethidine vs oral diazepam and IM pethidine alone [RCT Ng 2022]	Relative risk: **0.93** (95% CI 0.72 - 1.19) Based on data from 60 participants in 1 study	**900** per 1000 Difference: **63 fewer per 1000** (95% CI 252 fewer - 171 more)	**837** per 1000	**Moderate** Due to serious risk of bias[1]	Acupuncture combined with oral diazepam and IM pethidine probably has little or no difference on satisfaction (rating of pain relief as satisfactory or excellent) compared to oral diazepam and IM pethidine alone for surgical abortion <10 weeks

Surgical abortion <10 weeks - need for additional pain relief - TENS + PCB vs IV sedation (fentanyl + midazolam) + PCB [RCT Lerma 2021]	Relative risk: **8.83** (95% CI 1.16 - 67.39) Based on data from 109 participants in 1 study	**19** per 1000 Difference: **149 more per 1000** (95% CI 3 more - 1261 more)	**168** per 1000	**Moderate** Due to serious risk of bias[1]	TENS + PCB is probably associated with an increase in the need for additional pain relief compared to sedation (fentanyl + midazolam) + PCB, however there is high uncertainty as to the degree of this effect
Surgical abortion <10 weeks - worst pain during procedure - Acupuncture combined with oral diazepam and IM pethidine vs oral diazepam and IM pethidine alone [RCT Ng 2022]	Measured by: mm on VAS Scale: 0 - 100 Lower better Based on data from 60 participants in 1 study	Median **80**	Median **66**	**Moderate** Due to serious risk of bias[1]	Acupuncture in combination with oral diazepam and IM pethidine probably decreases worst pain during procedure compared to oral diazepam and IM pethidine alone for surgical abortion <10 weeks
Surgical abortion <10 weeks - worst pain during procedure - TENS + PCB vs IV sedation (fentanyl + midazolam) + PCB [RCT Lerma 2021]	Measured by: mm on VAS Scale: 0 - 100 Lower better Based on data from 109 participants in 1 study	Median **66** Difference: **MD 4.8 higher** (95% CI 5.9 lower - 13.5 higher)	Median **73**	**Moderate** Due to serious risk of bias[1]	TENS + PCB probably is not inferior to IV sedation (fentanyl + midazolam) + PCB for worst pain during procedure for surgical abortion <12 weeks
Surgical abortion <10 weeks - likelihood to recommend - TENS + PCB vs IV sedation (fentanyl + midazolam) + PCB [RCT Lerma 2021]	Measured by: mm on VAS Scale: 0 - 100 High better Based on data from 109 participants in 1 study	Median **95**	Median **89**	**Moderate** Due to serious risk of bias[1]	TENS + PCB probably decreases the likelihood to recommend this pain relief option to others compared to sedation (fentanyl + midazolam) + PCB for surgical abortion <12 weeks

1. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias.

Clinical Question 10b: Medical or surgical abortion and pain relief

For a woman undergoing a medical or surgical abortion from 14 weeks pregnant what pain relief regimen is the safest, most effective, and acceptable?

P: Woman undergoing medical or surgical abortion after 14 weeks

I: Any type of pharmacological pain control administered via mucosa (oral, vaginal, paracervical, buccal/sublingual), intramuscular, or intravenous route,

C: i) medication A vs no pain control/placebo
ii) medication A vs medication B
iii) dosage A medication vs dosage B medication
iv) Non pharmacological pain relief

O: Patient satisfaction/acceptability

- (would choose again) / patient-reported efficacy of pain control on perceived pain during or after abortion
- Safety
  - adverse effects
  - side effects (including if pain control method caused pain)

Evidence to decision

Benefits and harms

Research evidence

Evidence was obtained from:

- Analgesia for surgical abortion: WHO Abortion Care Guideline evidence summaries 2022 (searches up to date to December 2020)
- Systematic review by Jackson and Kapp 2020: Pain management for medical and surgical termination of pregnancy between 13 and 24 weeks of gestation: a systematic review 2020 (searches up to date to June 2019)

Additional literature search undertaken on 16th February 2023 to identify articles published after the above systematic reviews.

- Search terms: abortion OR abortion (induced) OR “termination of pregnancy” AND pain OR “pain relief” OR analgesia
- Limited to humans and published after 2019

Identified 59 articles of which 12 were retrieved for full text review. 2 met inclusion for abortion after 14 weeks.

Summary

Differences in interventions and comparators largely preclude meta-analysis for medical or surgical abortion.

Medical abortion after 14 weeks:

Pregabalin in addition to a patient-controlled epidural probably decreases pain slightly (MD -9.5mm, 95% CI -16.94 to -2.06), however, the clinical significance of this on a 0-100 VAS is probably negligible. Little or no difference was found between pain ratings and satisfaction scores for patient-controlled epidural anaesthesia (PCEA) compared to patient-controlled analgesia (PCA). Little or no difference was found in pain scores between PCB and oral pain relief.

Little or no difference was found in the need for additional narcotic pain relief between NSAIDs and non-NSAIDs/placebo, however the need for additional narcotic pain relief was high in both groups (~65%).

Little or no difference was found in nausea or vomiting side effects between diclofenac compared to paracetamol + codeine, PCB compared to oral pain relief, and celecoxib compared to placebo.

Dilator placement for surgical abortion after 14 weeks:

Little or no difference was found in worst pain rating between lignocaine spray and placebo; PCB and placebo, and 12 mL and 20 mL PCB volume for dilator placement prior to surgical abortion. PCB may be associated with worse reported pain when compared to intra-vaginal lignocaine gel (MD 12 mm, 95% CI 7.35-31.35).

Procedure pain management surgical abortion after 14 weeks:

A single study addressed this question, comparing PCB plus GA with no PCB plus GA. PCB in addition to GA may decrease the level of worst pain post-procedure slightly (MD 0.4mm), however the clinical significance of this on a 0-100 VAS is probably negligible. Little or no difference was found in the need for additional analgesia.

Certainty of the evidence

GRADE assessments ranged from high to low; studies were downgraded for lack of blinding and imprecision.

Values and preferences

Women undergoing an abortion value pain control provided this is balanced with potential side effects.

Resources

Economic evaluation is outside of the scope of this guideline.

Acceptability

Clinicians and women are likely to value the highest level of pain relief achievable without intolerable side effects. Side effects such as nausea appear to be common and may be ameliorated by offering anti-nausea medications at the time of discussing pain relief options.

Feasibility

No feasibility issues are foreseen

PICO (10.3)
Population: Woman undergoing surgical or medical abortion second trimester
Intervention: Any type of pharmacological pain control administered via mucosa (oral, vaginal, paracervical, buccal/sublingual), intramuscular, or intravenous route
Comparator: i) Medication A vs no pain control/placebo
ii) medication A vs medication B
iii) dosage A medication vs dosage B medication

Summary

No studies consider pain management during D&C procedure for surgical abortion after 14 weeks (only consider pain management during osmotic dilator placement)

Outcome Timeframe	Study results and measurements	Absolute effect estimates		Certainty of the evidence (Quality of evidence)	Plain language summary
		Comparison (listed second)	Intervention (listed first)		
Medical abortion >14 weeks - Worst pain within 24 hours (pain above VAS 7) - PCB vs oral pain relief [SR WHO 2022]	Relative risk: 1.22 (95% CI 0.93 - 1.59) Based on data from 102 participants in 1 study	640 per 1000	781 per 1000 Difference: **141 more per 1000** (95% CI 45 fewer - 378 more)	**Moderate** Due to serious imprecision[1]	We are uncertain whether PCB improves or worsens report of worst pain in 24hrs as VAS > 7 compared to oral pain relief for medical abortion >14 weeks
Medical abortion >14 weeks - Side effects (vomiting) - diclofenac vs paracetamol and codeine [SR WHO 2022]	Relative risk: **0.66** (95% CI 0.35 - 1.26) Based on data from 74 participants in 1 study	421 per 1000	278 per 1000 Difference: **143 fewer per 1000** (95% CI 274 fewer - 109 more)	**Moderate** Due to serious imprecision[1]	Diclofenac probably has little or no difference on side effects (vomiting)compared to paracetamol and codeine for medical abortion >14 weeks
Medical abortion >14 weeks - use of supplemental narcotic - NSAID (diclofenac or celecoxib) vs non-NSAID (paracetamol + codeine)/placebo [SR WHO 2022]	Relative risk: **0.99** (95% CI 0.78 - 1.25) Based on data from 130 participants in 2 studies	652 per 1000	645 per 1000 Difference: **7 fewer per 1000** (95% CI 143 fewer - 163 more)	**High**	NSAIDs have little or no difference on use of supplemental narcotic compared to non-NSAIDs (paracetamol + codeine)/placebo for medical abortion >14 weeks
Medical abortion >14 weeks - Side effects (nausea) - PCB vs oral pain relief [SR WHO 2022]	Relative risk: **0.96** (95% CI 0.39 - 2.36) Based on data from 102 participants in 1 study	160 per 1000	154 per 1000 Difference: **6 fewer per 1000** (95% CI 98 fewer - 218 more)	**Low** Due to very serious imprecision[2]	PCB may have little or no difference on the side effect of nausea compared to oral pain relief for medical abortion >14 weeks
Medical abortion >14 weeks - Side effects (vomiting) - Celecoxib vs placebo [SR WHO 2022]	Relative risk: **0.75** (95% CI 0.3 - 1.88) Based on data from 56 participants in 1 study	286 per 1000	215 per 1000 Difference: **71 fewer per 1000** (95% CI 200 fewer - 252 more)	**Moderate** Due to serious imprecision[2]	Celecoxib probably has little or no difference on report of the side effects of vomiting compared to placebo for medical abortion >14 weeks
Surgical abortion >14 weeks - side effects	Relative risk: **0.34** (95% CI 0.07 - 1.6)	130 per 1000	44 per 1000	**High**	PCB 12 mL lignocaine has little or no difference on side effects (any

(any reported) - PCB 12 mL vs PCB 20 mL during dilator placement [RCT Shaw 2021]	Based on data from 91 participants in 1 study	Difference: **86 fewer per 1000** (95% CI 121 fewer - 78 more)			reported) compared to PCB 20 mL during dilator placement for surgical abortion
Surgical abortion >14 weeks - requirement for additional analgesia - PCB + GA vs no PCB + GA [SR Jackson & Kapp 2020 SR]	Relative risk: **0.71** (95% CI 0.35 - 1.41) Based on data from 72 participants in 1 study	**340** per 1000	**241** per 1000 Difference: **99 fewer per 1000** (95% CI 221 fewer - 139 more)	**Low** Due to serious imprecision, Due to serious risk of bias[3]	PCB in addition to GA may have little or no difference in requirement for additional analgesia compared to GA without PCB for surgical abortion >14 weeks
Surgical abortion >14 weeks - Worst pain within 24 hours - PCB vs placebo during dilator placement [SR WHO 2022]	Measured by: mm on VAS Scale: 0 - 100 Lower better Based on data from 41 participants in 1 study	Mean **0** Difference: **MD 41 lower** (95% CI 56.95 lower - 25.05 lower)		**Moderate** Due to serious imprecision[4]	PCB probably decreases the report of worst pain within 24 hours compared to placebo during dilator placement for surgical abortion >14 weeks
Surgical abortion >14 weeks - Worst pain within 24 hours - PCB vs intravaginal lignocaine during dilator placement [SR WHO 2022]	Measured by: mm on VAS Scale: 0 - 100 Lower better Based on data from 69 participants in 1 study	Mean **0** Difference: **MD 12 higher** (95% CI 7.35 higher - 31.35 higher)		**Low** Due to serious risk of bias, Due to serious imprecision[5]	PCB may increase the report of worst pain within 24 hours compared to intravaginal lignocaine during dilator placement for surgical abortion >14 weeks
Surgical abortion >14 weeks - Worst pain after first laminaria insertion - Lignocaine spray vs placebo spray during dilator placement [RCT Meyer 2020]	Measured by: mm on VAS Scale: 0 – 100 Lower better Based on data from 134 participants in 1 study	Median **20**	Median **20**	**Moderate** Due to serious risk of bias[6]	Lignocaine spray probably has little or no difference on worst pain after first laminaria insertion compared to placebo spray during dilator placement for surgical abortion >14 weeks
Surgical abortion >14 weeks – Worst pain at time of dilator insertion – PCB 12 mL vs PCB 20 mL during dilator placement [RCT Shaw 2021]	Measured by: mm on VAS Scale: 0 - 100 Lower better Based on data from 91 participants in 1 study	Median **49** Difference: **MD 1.36 lower** (95% CI 12.56 lower - 9.85 higher)	Median **41**	**High**	PCB with 12 mL lignocaine has little or no difference on worst pain at time of dilator insertion compared to PCB with 20 mL lignocaine during dilator placement for surgical abortion >14 weeks

Surgical abortion >14 weeks - satisfaction - PCB vs placebo during dilator placement [SR WHO 2022]	Measured by: mm on satisfaction scale Scale: Higher better Based on data from 41 participants in 1 study	Mean **88** Difference: **MD 4 higher** (95% CI 12.23 lower - 20.23 lower)		**Moderate** Due to serious imprecision[7]	PCB probably has little or no difference on satisfaction with pain relief compared to placebo for during dilator placement for surgical abortion >14 weeks
Surgical abortion >14 weeks - worst pain post-procedure - PCB + GA vs no PCB + GA [SR Jackson & Kapp 2020 SR]	Measured by: mm on VAS Scale: Lower better Based on data from 72 participants in 1 study	Mean **1.6**	Mean **1.2** Difference: **MD 0.4 lower**	**Low** Due to serious risk of bias, Due to serious imprecision[8]	PCB in addition to GA may decrease report of worst pain post-procedure compared to GA without PCB for surgical abortion >14 weeks
Medical abortion >14 weeks - Worst pain within 24 hours - antiepileptic (pregabalin) + patient controlled epidural vs anxiolytic (prazepam) + patient-controlled epidural [SR WHO 2022]	Measured by: mm on VAS Scale: 0 - 100 Lower better Based on data from 48 participants in 1 study	Mean **73** Difference: **MD 9.5 lower** (95% CI 16.94 lower - 2.06 lower)		**Moderate** Due to serious imprecision[1]	Anti-epileptic medication (pregabalin) in addition to a patient-controlled epidural probably decreases report of worst pain within 24 hours compared to anxiolytic medication (prazepam) combined with patient-controlled epidural for medication abortion, however the 95% CI for the MD crosses into a clinically insignificant effect
Medical abortion >14 weeks - Worst pain within 24 hours - patient controlled epidural (PCEA - bupivicaine + fentanyl) vs patient controlled IV fentanyl (PCA) [SR WHO 2022]	Measured by: mm on VAS Scale: 0 - 100 Lower better Based on data from 37 participants in 1 study	Mean **0** Difference: **MD 17 lower** (95% CI 34 lower - 0.4 higher)		**Moderate** Due to serious imprecision[1]	PCEA probably has little or no difference on worst pain within 24 hours compared to PCA for medication abortion >14 weeks
Medical abortion >14 weeks - satisfaction with pain relief - patient controlled epidural (PCEA - bupivicaine + fentanyl) vs patient controlled IV fentanyl (PCA) [SR WHO 2022]	Measured by: rating scale (1-10) Scale: 1 - 10 Higher better Based on data from 37 participants in 1 study	Mean **7.8** Difference: **MD 0.6 higher** (95% CI 0.43 lower - 1.63 higher)		**Moderate** Due to serious imprecision[9]	PCEA probably has little or no difference on satisfaction with pain relief compared to PCA for medication abortion >14 weeks

1. **Imprecision: serious.** Wide confidence intervals.

2. **Imprecision: very serious.** Wide confidence intervals.
3. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias; **Imprecision: serious.** Only data from one study.
4. **Imprecision: serious.** Only data from one study.
5. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias; **Imprecision: serious.** Wide confidence intervals, only data from one study.
6. **Risk of Bias: serious.** Unclear sequence generation/ generation of comparable groups, resulting in potential for selection bias.
7. **Imprecision: serious.** Wide confidence intervals, only data from one study.
8. **Risk of Bias: serious.** Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias; **Imprecision: serious.** Only data from one study.
9. **Imprecision: serious.** Wide confidence intervals, only data from one study.

Clinical Question 11: Abortion and antibiotic prophylaxis

For a woman undergoing a medical or surgical abortion what antibiotic prophylaxis regimen (including no antibiotic prophylaxis) is the safest, most effective, and acceptable?

P: Woman undergoing a medical or surgical abortion (at any gestation)

I: Routine antibiotic prophylaxis: any antibiotic regimen, including preoperative, perioperative, or postoperative doses

C: i) Screen-and-treat only strategy
ii) No screening/no antibiotics
iii) screen negative but give antibiotics

O: Proportion of women diagnosed with post-abortion upper genital tract infection

- Other antibiotic treatments provided within 6 weeks of the abortion
- Hospitalisation due to infectious complications
- Adverse effects of antibiotic prophylaxis or screening
- Patient satisfaction

Evidence to decision

Benefits and harms

Research evidence

Evidence obtained from:

- NICE Abortion Care Guideline [NG 140] 2019
- Low N, Mueller M, Van Vliet HA et al: Perioperative antibiotics to prevent infection after first-trimester abortion. Cochrane Database of Systematic Reviews 2012

An updated search for literature published after the NICE Abortion Care Guideline was undertaken on 17th February 2023 for studies published since 2019. 104 studies were identified, however none met criteria for inclusion.

Additional considerations

Evidence from the NICE Abortion Care Guideline indicates that is unclear whether or not there are important differences in the rates of post-abortion pelvic inflammatory disease, or gastro-intestinal side effects of vomiting and diarrhoea with a 3-day course of doxycycline compared to a 7-day course of doxycycline as antibiotic prophylaxis for surgical abortion, as evidence is from a single study reporting this outcome with very wide confidence intervals. It is also uncertain if a regimen of metronidazole and doxycycline is superior to doxycycline alone as antibiotic prophylaxis for surgical abortion, for the same reasons.

As antibiotic prophylaxis is standard of care for surgical abortion in the UK, no comparison of antibiotics to placebo/no antibiotics or their selected use was included in the NICE Abortion Care Guideline.

Summary

Antibiotics for abortion less than 14 weeks:

Medical abortion: There were lower rates of severe infection with antibiotic prophylaxis (7-day course of doxycycline) compared to no antibiotic prophylaxis. However, rates of severe infection were noted to be very low in either arm of the study (<1%). This evidence included medical abortion less than 9 weeks pregnant. No identified studies addressed routine antibiotic prophylaxis in medical abortion greater than 9 weeks.

Evidence from a separate trial showed higher rates of severe nausea, severe vomiting, and vomiting lasting more than 1 day with antibiotic prophylaxis compared to no antibiotic prophylaxis.

Surgical abortion: In a systematic review of 15 placebo-controlled RCTs there was an effect of non-universal antibiotic prophylaxis compared to placebo/no prophylaxis for surgical abortion in the first trimester (pooled RR 0.59, 95% CI 0.46 to 0.75). One study compared universal antibiotic prophylaxis to placebo, demonstrating a reduction in the number of upper genital tract infections. A single study was identified that compared the incidence of post-abortion upper genital tract infections between a screen-and-treat approach and universal antibiotic prophylaxis. This study showed a potential benefit of universal prophylaxis however the confidence interval does cross the line of no effect.

Antibiotics for abortion after 14 weeks or more:

No studies were identified which addressed routine antibiotic prophylaxis in medical or surgical abortion after 14 weeks.

Certainty of the evidence

Regarding antibiotic prophylaxis for medical abortion, the study authors report different routes of administration of misoprostol used which could confound the results, particularly regarding risk of infection unrelated to sexually transmitted infections. The study of side effects contains a risk of bias given the unblinded study design. Overall, studies were GRADEd as very low certainty evidence.

Values and preferences

No satisfaction outcomes were reported for this domain.

Resources

No economic analysis was taken as part of this guideline.

Equity

Lack of access to antibiotics should not limit access to abortion services.
The importance of screening for sexually transmitted infections is noted regardless of antibiotic prophylaxis to facilitate treatment and notification of sexual partners to minimise reinfection and further transmission.

Evidence included in this review was for abortion in the first trimester. No studies considering medical abortion in the second trimester were identified in the NICE systematic review and the Cochrane review comparison of universal vs screen-and-treat for surgical abortion was limited to the first trimester. Younger, or more deprived women may be more likely to present in the second trimester and be at greater risk for sexually transmitted infections. There was no evidence to support a recommendation for antibiotic prophylaxis in a specific group of high-risk women; however, NICE recommends that clinicians may want to consider prophylaxis for medical abortion where a clinician feels a woman is at high risk. Such risk factors may include women who have a history of sexually transmitted infections or signs of a current infection or who would find it difficult to return to a clinical site to access treatment in the event of screening positive for a sexually transmitted infection, as the consequences of untreated infection can be significant.

Acceptability

Prevention of severe infection needs to be balanced with concerns regarding overprescribing of antibiotics and the development of antibiotic resistance.

PICO (11.1)

Population: Woman undergoing a medical or surgical abortion (at any gestation)

Intervention: Routine antibiotic prophylaxis – any antibiotic regimen, including preoperative, perioperative, or postoperative doses

Comparator: i) Screen-and-treat only strategy

ii) No screening/no antibiotics

iii) screen negative but prescribe antibiotics

Outcome Timeframe	Study results and measurements	Absolute effect estimates		Certainty of the evidence (Quality of evidence)	Plain language summary
		Screen-and-treat only strategy or no antibiotic	Routine antibiotic prophylaxis		
Severe infection within 1 month - medical abortion, doxycycline vs control [NICE 2019 SR]	Relative risk: **0.07** (95% CI 0.02 - 0.2) Based on data from 227823 participants in 1 study	**0.9** per 1000	**0.06** per 1000 Difference: **0.84 fewer per 1000** (95% CI 0.88 fewer - 0.72 fewer)	**Very low** Due to serious risk of bias[1]	We are uncertain whether antibiotic prophylaxis with doxycycline increases or decreases severe infection within 1 month compared to placebo for medical abortion due to very low-quality studies
Nausea - Overall - medical abortion, doxycycline vs control [NICE 2019 SR]	Relative risk: **1.17** (95% CI 0.97 - 1.4) Based on data from 581 participants in 1 study	**409** per 1000	**479** per 1000 Difference: **70 more per 1000** (95% CI 12 fewer - 164 more)	**Very low** Due to serious risk of bias, Due to serious imprecision[2]	We are uncertain whether antibiotic prophylaxis with doxycycline increases or decreases the side effect of nausea compared to placebo for medical abortion
Upper genital tract infection - surgical abortion, routine antibiotics vs placebo [Low 2012 CR]	Relative risk: **0.65** (95% CI 0.49 - 0.87) Based on data from 5168 participants in 15 studies	**96** per 1000	**62** per 1000 Difference: **34 fewer per 1000** (95% CI 49 fewer - 12 fewer)	**Moderate** Due to serious risk of bias[3]	Routine antibiotic prophylaxis probably decreases upper genital tract infection compared to placebo
Upper genital tract infection - surgical abortion, screen-and-treat vs universal antibiotic prophylaxis [Low 2012 CR]	Relative risk: **1.53** (95% CI 0.99 - 2.36) Based on data from 1613 participants in 1 study	**40** per 1000	**61** per 1000 Difference: **21 more per 1000** (95% CI 0 fewer - 54 more)	**Low** Due to serious risk of bias, Due to serious imprecision[4]	Antibiotics given by a screen-and-treat protocol may have little or no difference on upper genital tract infection following surgical abortion compared to universal antibiotic prophylaxis, however, this result nears statistical significance

1. **Risk of Bias: serious.** different methods of mifepristone administration were applied in the 2 arms. Additionally, baseline characteristics of the cohorts were not reported in the paper to assess if the populations were otherwise similar.
2. **Risk of Bias: serious.** the study was not adjusted for confounders and there were statistically significant differences in mean gestational age, race, education, and difficulty paying for the abortion at baseline between the 2 arms; **Imprecision: serious.** 95% CI crosses 1 MID.
3. **Risk of Bias: serious.** Incomplete data and/or large loss to follow up.
4. **Risk of Bias: serious.** Incomplete data and/or large loss to follow up; **Imprecision: serious.** Only data from one study.

Clinical Question 12: Contraception following abortion

For a woman receiving abortion and requesting either contraceptive implant or IUC is provision of this contraception at the same visit for surgical abortion or in-person medical abortion as safe, effective, and acceptable as provision of contraception at a post-abortion follow-up visit?

P: Woman receiving surgical or medical abortion and requesting a long acting contraception

I: Progesterone contraceptive implant insertion, intrauterine device insertion, at the same visit as an abortion (insertion at the start of the first dose of medication for medical abortion, or during or at the end of procedure for surgical abortion).

C: Insertion of LARC (either IUD (any) or implant) after follow-up post EMA

O: Success rate of medical abortion Initiation rate of contraceptive implant or depot at 6 weeks after abortion

- Side effects – bleeding, other
- Continuation rate of contraceptive implant or depot six months after insertion
- Unintended pregnancy within first 6 months and 1 year after abortion

i. Patient satisfaction

Evidence to decision

Benefits and harms

Research evidence

Evidence obtained from:

- Sothornwit J, Eamudomkarn N, Lumbiganon P et al: Immediate versus delayed postabortal insertion of contraceptive implant. Cochrane Database of Systematic Reviews 2022 (searches up to date to March 2021)
- NICE Abortion Care Guideline - only included outcomes for IUCD insertion for medical abortion

One study identified from reference list of Cochrane review Okosanya et al 2014 - Immediate postabortal insertion of intrauterine devices; however this review does not meet inclusion criteria of for the evidence table as it includes induced and spontaneous abortion. RCT by Hohmann et al 2013, included in this Cochrane review, was added to the evidence table as a single study.

Primary literature search undertaken on 21st March 2023 for studies published after the searches undertaken for the NICE Abortion Care Guideline (2018 onwards). Search terms included:

- abortion OR “termination of pregnancy” AND
- contracepti*OR Long-Acting Reversible Contraception/ or LARC OR implant OR “intrauterine device”
- limited to humans, English language, RCTs published 2018-current

29 studies identified, 3 retrieved for full text review. 2 were included in the evidence summary (Hogmark et al 2023, and Constant et al 2022).

Additional considerations

From NICE evidence review for Abortion Care Guideline NG 140 2019: *to assist in development of a Good Practice Point (GPP) regarding timing depot medroxyprogesterone acetate injections*

The evidence showed that it was unclear whether or not there were clinically important differences in the rate of incomplete abortion with the need for surgical intervention, complete abortion without the need for surgical intervention and subsequent unintended pregnancy between the two interventions.

There was also uncertainty on the potentially higher rate of ongoing pregnancy with immediate administration compared to delayed administration of depot medroxyprogesterone acetate intramuscular injection (1 RCT, n=446; RR= 4.11 [95% CI 0.88, 19.14]; moderate certainty). [Higher rates of ongoing pregnancy were seen only in one study and at the 90% CI and

not the 95% CI. This corresponds to a risk difference of approximately 3% in absolute value between the two groups]. The NICE committee agreed that a difference of 3% in ongoing pregnancy was deemed significant and although significant uncertainty surrounded the RR of the single study that the result could not be ignored in view of the criticality of the outcome. The committee therefore agreed that consideration of immediate administration of depot medroxyprogesterone acetate intramuscular injection should be made only after discussing the potential small risk of ongoing pregnancy with the woman.

Summary

Implant:

Evidence drawn from a 2022 Cochrane review: Sothornwit et al 2022, including 3 studies and 1162 participants.

Little or no difference was found in the rate of ongoing pregnancy, or in the rate of incomplete abortion with the need for surgical intervention, between the group with simultaneous administration of mifepristone and the etonorgestrel implant and the group with etonorgestrel implant administration more than 24 hours after mifepristone. However, uncertainty remains over these outcomes owing to wide confidence intervals.

Greater rates of initiation of contraceptive implants were found when the etonorgestrel implant was inserted at the same time as medical abortion (RR 1.26, 95% CI 1.21-1.32, 1014 participants in 2 studies) and surgical abortion (RR 2.32, 95% CI 1.79-3.01, 148 participants from 1 study) compared to delayed implant insertion 6 weeks after the abortion. Higher rates of contraceptive implant utilization at 6 months were found in the simultaneous insertion group (RR 1.10, 95% CI 1.05-1.15, 1103 participants from 3 studies) compared to delayed implant insertion, correspondingly lower rates of unintended pregnancy at 6 months were found in women who received simultaneous administration of mifepristone and the contraceptive implant (RR 0.25, 95% CI 0.08-0.77, 1029 participants from 3 studies).

Little or no difference was found between the two groups in bleeding side effects at 1 month, bleeding side effects at 6 months, and side effects other than bleeding at 6 months. Patient satisfaction was higher immediately following the abortion in the immediate implant group (RR 1.50, 95% CI 1.34-1.68, 464 participants from 1 study), however, by 6 months post-abortion there was little or no difference in patient satisfaction between the two groups.

Intrauterine contraceptive device:

Medical abortion less than 9 weeks:

Evidence obtained from NICE systematic review for the Abortion Care Guideline NG 140 included two studies of timing of LNG-IUS IUCD placement and two studies of Copper IUD placement in medical abortion less than 9 weeks. We are uncertain of the risk of expulsion of LNG-IUS or copper IUD with immediate or early IUCD insertion after medical abortion compared to delayed insertion after at least 1 week. No cases of uterine perforation occurred in either group.

Little or no difference was found between immediate/early insertion and delayed insertion in uptake rates of the LNG-IUS IUCD. We are uncertain of the impact of immediate/early insertion after medical abortion on continuation rates of the LNG-IUS at 6-12 months. An increased uptake rate was found in the immediate/early insertion group for Copper IUDs (RR 1.27, 95% CI 1.12-1.44, 156 participants from 1 study), however, little or no difference was found in continuation rates among this type of IUCD.

An additional RCT (Hogmark et al 2023) was identified. In this study immediate insertion was taken to be within 48 hours of completion of abortion. There was little or no difference in continuation rates of IUCD (either LNG-IUS or Copper IUD types) between immediate insertion and delayed insertion 2-4 weeks after abortion. There is uncertainty regarding the risk of expulsion associated with immediate IUCD insertion owing to very wide confidence intervals.

Medical abortion 9-12 weeks:

Evidence obtained from NICE systematic review for the Abortion Care Guideline NG 140 included one study of timing of IUCD placement in medical abortion between 9 and 12 weeks. An increased rate of expulsion was found in the immediate/early insertion group compared to delayed insertion (RR 2.78, 95% CI 1.19-6.47, 101 participants in 1 study). No cases of uterine perforation in either group.

Immediate/early insertion was associated with higher uptake rates of the LNG-IUS IUCD (RR 1.20, 95% CI 1.04-1.37, 101 participants from 1 study), as well as higher continuation rates at 6-12 months (RR 1.68, 95% CI 1.12-2.38, 101 participants from 1 study) compared to delayed IUCD insertion.

Medical abortion 12-20 weeks:

Evidence obtained from NICE systematic review for the Abortion Care Guideline NG 140 included one study of timing of IUCD placement in medical abortion between 12 and 20 weeks. We are uncertain of the risk of expulsion with immediate/early insertion owing to wide confidence intervals. No cases of uterine perforation occurred in either group.

Little or no difference was found in uptake rates of LNG-IUS IUCDs between the immediate/early and delayed groups, but immediate insertion was associated with higher continuation rates at 6-12 months (RR 2.22, 95% CI 1.08-4.59, 55 participants from 1 study).

An additional RCT (Constant et al 2022) studied immediate insertion of copper IUDs within 24 hours of completion of abortion vs delayed insertion 3 weeks later in medical abortion from 17-20 weeks. Higher continuation rates were found in the immediate insertion group (RR 2.85, 95% CI 1.39-5.85, 112 participants) compared to the delayed group.

Surgical abortion 15-24 weeks:

A single RCT (Hohmann et al 2013) was identified in the population of women undergoing surgical abortion. We are uncertain if there was any difference in expulsion rates owing to wide confidence intervals. Immediate copper IUD insertion was associated with higher uptake rates (RR 2.20, 95% CI 1.59-3.04, 88 participants), however, we are uncertain of effect on continuation rates owing to wide confidence intervals.

Certainty of the Evidence

GRADE ranges from moderate to very-low quality evidence with most outcomes GRADEd as moderate-low certainty. Reasons for downgrading evidence included lack of blinding (unlikely to impact on objective outcomes but impact the certainty of subjective outcomes such as side effects or satisfaction), and imprecision owing to wide confidence intervals or that cross the null hypothesis.

Values and preferences

Additional considerations

Women in the immediate administration group of the study regarding timing of depot medroxyprogesterone acetate injections were significantly more satisfied with their group assignment than those in the delayed group.

Summary

Women are likely to find early insertion more convenient than delayed insertion, and this is more likely to improve accessibility and uptake of long-acting contraception. There is a possibility that immediate insertion may be associated with increased pain from the abortion but no evidence was identified that considered this.

Implant: A higher number of women were “pleased” after the abortion was determined to be complete in the simultaneous administration of mifepristone plus the etonorgestrel implant group compared to the etonorgestrel implant

administration more than 24 hours after mifepristone group. However, little or no difference was found in the rate of women "very satisfied/fairly satisfied" 6 months after the etonorgestrel implant insertion between the two groups possibly owing to problematic implants being taken out by the longer follow-up time frame and further losses to follow-up at 6 months.

Intrauterine contraceptive device: No satisfaction outcomes reported. Use of the IUCD at 6 months post-abortion was significantly higher among women receiving their IUCD immediately vs delayed which could be used as a proxy measure of long-term satisfaction with LARCs.

Resources

Research evidence

A systematic review of the economic literature was conducted by NICE but no relevant studies were identified that were applicable to this review question.

Economic modelling of immediate vs delayed insertion of a contraceptive implant or IUCD was conducted by NICE in the formulation of their abortion guideline. The model estimated that simultaneous administration of an etonogestrel implant at the abortion setting was substantially less expensive per person than delayed administration at the woman's GP.

The model estimated that insertion of an intrauterine contraceptive device as soon as possible after abortion was less expensive per person than later administration at the woman's GP. However, when the higher rate of expulsion in the immediate insertion group is taken into account immediate insertion of an IUS, being a more expensive IUCD, is no longer less expensive than delayed insertion. Given that quality of life would likely be higher amongst the 'as soon as possible' group the immediate insertion of an IUS it could still be cost-effective.

An economic model was developed by the NICE Abortion Care Guideline group to evaluate immediate vs delayed implant insertion. The model estimated that simultaneous administration of an etonogestrel implant at the abortion setting was less expensive per person than delayed administration at the woman's GP. The amount saved per person was approximately £80, when only the costs of administration were considered. When the costs of clinical complications and subsequent pregnancies were considered, this saving reduced to £71. This was a result of the higher rate of continued pregnancies and incomplete abortions in the base case. Quality of life would be assumed to be at least equal but most likely greater in the simultaneous administration group. It was therefore considered given the robust evidence around simultaneous administration being cost-saving that it could be considered the dominant (cost saving and health improving) intervention.

Summary

No economic literature search was conducted as part of this guideline as this falls out of scope.

Equity

The recommendation for early insertion (ideally at the time of contact with health services to undertake the abortion) is likely to benefit vulnerable women who may experience more barriers to accessing LARCs and contraception in general.

Acceptability

May increase the staff time per abortion as time needed to consent and insert LARC however shifts burden from other contraception providers and increases LARC use which may translate to a decreased demand for abortion services over time.

PICO (12.1)

Population: Pregnant women receiving abortion care (irrespective of the type of abortion) and requesting a long-acting reversible contraceptive (LARC)
Intervention: IUCD at the same visit as an abortion (insertion at the start of the first dose of medication for medical abortion, or during or at the end of procedure for surgical abortion)
Comparator: IUCD at/after post abortion follow-up

Outcome Timeframe	Study results and measurements	Absolute effect estimates		Certainty of the evidence (Quality of evidence)	Plain language summary
		IUCD inserted at the post-abortion visit	IUCD inserted immediately following abortion		
Early/immediate (on day or within 7 days since pregnancy expulsion) vs delayed (>7 days) IUCD insertion - expulsion of LNG-IUS within 6-12 months - medical abortion <9 weeks [SR] NICE 2019	Relative risk: **1.25** (95% CI 0.56 - 2.82) Based on data from 169 participants in 2 studies	**110** per 1000	**138** per 1000 Difference: **28 more per 1000** (95% CI 48 fewer - 200 more)	**Low** Due to serious risk of bias, due to serious imprecision[1]	We are uncertain whether IUCD insertion immediately/early following abortion increases or decreases rates of expulsion of LNG-IUS within 6-12 months of medical abortion <9 weeks compared to delayed insertion, due to wide confidence intervals
Early/immediate (on day or within 7 days since pregnancy expulsion) vs delayed (>7 days) IUCD insertion - expulsion of LNG-IUS within 6-12 months - medical abortion 9- <12 weeks [SR] NICE 2019	Relative risk: **2.78** (95% CI 1.19 - 6.47) Based on data from 101 participants in 1 study	**120** per 1000	**334** per 1000 Difference: **214 more per 1000** (95% CI 23 more - 656 more)	**Moderate** Due to serious imprecision[2]	LNG-IUS IUCD insertion immediately following abortion probably increases expulsion within 6-12 months in medical abortion at 9- <12 weeks compared to delayed IUCD insertion
Early/immediate (on day or within 7 days since pregnancy expulsion) vs delayed (>7 days) IUCD insertion - expulsion of LNG-IUS within 6-12 months - medical abortion 12- <20 weeks [SR] NICE 2019	Relative risk: **5.19** (95% CI 0.65 - 41.54) Based on data from 55 participants in 1 study	**36** per 1000	**187** per 1000 Difference: **151 more per 1000** (95% CI 13 fewer - 1459 more)	**Low** Due to very serious imprecision[3]	We are uncertain whether IUCD insertion immediately/early following abortion increases or decreases rates of expulsion of LNG-IUS within 6-12 months of medical abortion 12-20 weeks compared to delayed insertion, due to very wide confidence intervals
Early/immediate (on day or within 7 days since pregnancy expulsion) vs delayed (>7 days) IUCD insertion - expulsion of Copper IUD within 6-12 months - medical abortion <9 weeks [SR] NICE 2019	Relative risk: **1.3** (95% CI 0.53 - 3.17) Based on data from 189 participants in 2 studies	**78** per 1000	**101** per 1000 Difference: **23 more per 1000** (95% CI 37 fewer - 169 more)	**Low** Due to serious risk of bias, Due to serious imprecision[1]	We are uncertain whether IUCD insertion immediately/early following abortion increases or decreases rates of expulsion of Copper IUD within 6-12 months of medical abortion <9 weeks compared to delayed insertion, due to wide confidence intervals

Early/immediate (on day or within 7 days since pregnancy expulsion) vs delayed (>7 days) IUCD insertion - continuation of LNG-IUS within 6-12 months - medical abortion <9 weeks [SR] NICE 2019	Relative risk: **1.02** (95% CI 0.6 - 1.73) Based on data from 169 participants in 2 studies	**549** per 1000 Difference: **11 more per 1000** (95% CI 220 fewer - 401 more)	**560** per 1000	**Very low** Due to serious risk of bias, Due to serious imprecision, Due to serious inconsistency[4]	We are uncertain whether LNG-IUS IUCD insertion immediately/early following abortion increases or decreases rates of continuation rates within 6-12 months of medical abortion <9 weeks compared to delayed insertion, due to very low quality of evidence
Early/immediate (on day or within 7 days since pregnancy expulsion) vs delayed (>7 days) IUCD insertion - continuation of LNG-IUS within 6-12 months - medical abortion 9-<12 weeks [SR] NICE 2019	Relative risk: **1.63** (95% CI 1.12 - 2.38) Based on data from 101 participants in 1 study	**420** per 1000 Difference: **265 more per 1000** (95% CI 50 more - 580 more)	**685** per 1000	**Moderate** Due to serious imprecision[2]	LNG-IUS IUCD insertion immediately/early following abortion probably increases continuation rates within 6-12 months following medical abortion 9- <12 weeks compared to delayed insertion (>7 days after abortion complete)
Early/immediate (on day or within 7 days since pregnancy expulsion) vs delayed (>7 days) IUCD insertion - continuation of LNG-IUS within 6-12 months - medical abortion 12-<20 weeks [SR] NICE 2019	Relative risk: **2.22** (95% CI 1.08 - 4.59) Based on data from 55 participants in 1 study	**250** per 1000 Difference: **305 more per 1000** (95% CI 20 more - 898 more)	**555** per 1000	**Moderate** Due to serious imprecision[2]	LNG-IUS IUCD insertion immediately/early following abortion probably increases continuation rates within 6-12 months following medical abortion 12-20 weeks compared to delayed insertion (>7 days after abortion complete)
Early/immediate (on day or within 7 days since pregnancy expulsion) vs delayed (>7 days) IUCD insertion - continuation of Copper IUD within 6-12 months - medical abortion <9 weeks [SR] NICE 2019	Relative risk: **1.14** (95% CI 0.94 - 1.37) Based on data from 211 participants in 2 studies	**627** per 1000 Difference: **88 more per 1000** (95% CI 38 fewer - 232 more)	**715** per 1000	**Low** Due to serious risk of bias, Due to serious imprecision[1]	Copper IUD insertion immediately following abortion may have little or no difference on continuation rates within 6-12 months of medical abortion <9 weeks compared to delayed insertion
Early/immediate (on day or within 7 days since pregnancy expulsion) vs delayed (>7 days) IUCD insertion - uptake rate of LNG-IUS within 6-12 months - medical abortion <9 weeks [SR] NICE 2019	Relative risk: **1.07** (95% CI 0.99 - 1.17) Based on data from 169 participants in 2 studies	**871** per 1000 Difference: **61 more per 1000** (95% CI 9 fewer - 148 more)	**932** per 1000	**Low** Due to serious risk of bias, Due to serious imprecision[1]	LNG-IUS IUCD insertion immediately following abortion may have little or no difference on uptake rates within 6-12 months of medical abortion <9 weeks compared to delayed insertion
Early/immediate (on day or within 7 days	Relative risk: **1.2** (95% CI 1.04 - 1.37)	**820** per 1000	**984** per 1000	**Moderate**	LNG-IUS IUCD insertion immediately/early following

since pregnancy expulsion) vs delayed (>7 days) IUCD insertion - uptake rate of LNG-IUS within 6-12 months - medical abortion 9- <12 weeks [SR] NICE 2019	Based on data from 101 participants in 1 study	Difference: **164 more per 1000** (95% CI 33 more - 303 more)		Due to serious imprecision[2]	abortion probably increases uptake rates within 6-12 months following medical abortion 9-<12 weeks compared to delayed insertion (>7 days after abortion complete)
Early/immediate (on day or within 7 days since pregnancy expulsion) vs delayed (>7 days) IUCD insertion - uptake rate of LNG-IUS within 6-12 months - medical abortion 12-<20 weeks [SR] NICE 2019	Relative risk: **1.17** (95% CI 0.97 - 1.41) Based on data from 55 participants in 1 study	**821** per 1000	**961** per 1000 Difference: **140 more per 1000** (95% CI 25 fewer - 337 more)	**Moderate** Due to serious imprecision[2]	LNG-IUS IUCD insertion immediately following abortion may have little or no difference on uptake rates within 6-12 months of medical abortion 12-<20 weeks compared to delayed insertion
Early/immediate (on day or within 7 days since pregnancy expulsion) vs delayed (>7 days) IUCD insertion - uptake rate of Copper IUD within 6-12 months - medical abortion <9 weeks [SR] NICE 2019	Relative risk: **1.27** (95% CI 1.12 - 1.44) Based on data from 156 participants in 2 studies	**765** per 1000	**972** per 1000 Difference: **207 more per 1000** (95% CI 92 more - 337 more)	**Moderate** Due to serious imprecision[2]	Copper IUD insertion immediately/early following abortion probably increases uptake rates within 6-12 months following medical abortion <9 weeks compared to delayed insertion (>7 days after abortion complete)
Early (within 48hrs of misoprostol administration) vs delayed (2-4 weeks after abortion) IUCD insertion - expulsion within 6 months - medical abortion <9 weeks [RCT] Hogmark 2023	Relative risk: **2.52** (95% CI 0.82 - 7.8) Based on data from 223 participants in 1 study	**36** per 1000	**91** per 1000 Difference: **55 more per 1000** (95% CI 6 fewer - 245 more)	**Low** Due to serious risk of bias, Due to serious imprecision[5]	We are uncertain whether IUCD insertion within 48hrs following abortion increases or decreases rates of expulsion within 6 months of medical abortion <9 weeks compared to delayed insertion, due to wide confidence intervals
Early (within 48hrs of misoprostol administration) vs delayed (2-4 weeks after abortion) IUCD insertion - continuation rate at 6 months - medical abortion <9 weeks [RCT] Hogmark 2023	Relative risk: **1.06** (95% CI 0.92 - 1.2) Based on data from 223 participants in 1 study	**777** per 1000	**824** per 1000 Difference: **47 more per 1000** (95% CI 62 fewer - 155 more)	**Moderate** Due to serious risk of bias[6]	IUCD insertion within 48hrs following abortion may have little or no difference on continuation rates within 6 months of medical abortion <9 weeks compared to delayed insertion 2-4 weeks after abortion
Immediate vs delayed (3 weeks after abortion)	Relative risk: **2.85** (95% CI 1.39 - 5.85)	**400** per 1000	**1140** per 1000	**Moderate**	Copper IUCD insertion immediately following abortion

Copper IUCD insertion - continuation rate at 6 months - medical abortion 17-20 weeks [RCT] Constant 2022	Based on data from 112 participants in 1 study	Difference: **740 more per 1000** (95% CI 156 more - 1940 more)		Due to serious risk of bias[6]	probably increases continuation rates at 6 months for medical abortion 17-20 weeks compared to delayed insertion 3 weeks after abortion complete
Immediate (at time of surgery) vs delayed (3-6 weeks after abortion) LNG-IUS IUCD insertion - continuation rate at 6 months - surgical abortion 15-24 weeks [RCT] Hohmann 2013	Relative risk: **1.35** (95% CI 0.85 - 2.16) Based on data from 88 participants in 1 study	**386** per 1000	**521** per 1000 Difference: **135 more per 1000** (95% CI 58 fewer - 448 more)	**Low** Due to serious risk of bias, Due to serious imprecision[5]	We are uncertain whether immediate LNG-IUS insertion following abortion increases or decreases rates of continuation at 6 months for surgical abortion 15-24 weeks compared to delayed insertion, due to wide confidence intervals
Immediate (at time of surgery) vs delayed (3-6 weeks after abortion) LNG-IUS IUCD insertion - expulsion within 6 months - surgical abortion 15-24 weeks [RCT] Hohmann 2013	Relative risk: **1.36** (95% CI 0.15 - 12.31) Based on data from 88 participants in 1 study	**50** per 1000	**68** per 1000 Difference: **18 more per 1000** (95% CI 42 fewer - 566 more)	**Very low** Due to serious risk of bias, Due to very serious imprecision[7]	We are uncertain whether immediate LNG-IUS insertion following abortion increases or decreases rates of expulsion within 6 months for surgical abortion 15-24 weeks compared to delayed insertion, due to very wide confidence intervals
Immediate (at time of surgery) vs delayed (3-6 weeks after abortion) LNG-IUS IUCD insertion - uptake rate - surgical abortion 15-24 weeks [RCT] Hohmann 2013	Relative risk: **2.2** (95% CI 1.59 - 3.04) Based on data from 88 participants in 1 study	**455** per 1000	**1000** per 1000 Difference: **545 more per 1000** (95% CI 268 more - 928 more)	**Moderate** Due to serious risk of bias[8]	Immediate LNG-IUS insertion following abortion probably increases rates of IUCD uptake for surgical abortion 15-24 weeks compared to delayed insertion

1. **Risk of Bias: serious.** Incomplete data and/or large loss to follow up; **Imprecision: serious.** Wide confidence intervals.
2. **Imprecision: serious.** Wide confidence intervals.
3. **Imprecision: very serious.** Wide confidence intervals.
4. **Risk of Bias: serious.** Incomplete data and/or large loss to follow up; **Inconsistency: serious.** The magnitude of statistical heterogeneity was high, with I^2: 75%.; **Imprecision: serious.** Wide confidence intervals.
5. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias; **Imprecision: serious.** Wide confidence intervals.
6. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias.
7. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias; **Imprecision: very serious.** Wide confidence intervals.
8. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias; **Imprecision: no serious.** Wide confidence intervals.

PICO (12.2)

Population: Pregnant woman receiving abortion care (irrespective of the type of abortion) and requesting a long-acting reversible contraceptive (LARC)

Intervention: Implant at the same visit as an abortion (insertion at the start of the first dose of medication for medical abortion, or during or at the end of procedure for surgical abortion)

Comparator: Implant at/after post abortion follow-up

Outcome Timeframe	Study results and measurements	Absolute effect estimates		Certainty of the evidence (Quality of evidence)	Plain language summary
		Implant inserted at the post-abortion visit	Implant inserted immediately following abortion		
Immediate vs delayed implant (within 6 weeks) - Utilization rate of contraceptive implant - At 6 months after abortion [CR] Sothornwit 2022	Relative risk: 1.1 (95% CI 1.05 - 1.15) Based on data from 1103 participants in 3 studies	678 per 1000	746 per 1000 Difference: **68 more per 1000** (95% CI 34 more - 102 more)	Low Due to serious inconsistency, Due to serious imprecision[1]	Implant inserted immediately following abortion (medical or surgical) may increase utilization rate of contraceptive implant at 6 months after abortion compared to delayed insertion (within 6 weeks of abortion)
Immediate vs delayed implant (within 6 weeks) - Failure rate of medical abortion - Overall failure rate [CR] Sothornwit 2022	Relative risk: 1.18 (95% CI 0.58 - 2.4) Based on data from 1001 participants in 2 studies	85 per 1000	100 per 1000 Difference: **15 more per 1000** (95% CI 36 fewer - 119 more)	Moderate Due to serious imprecision[2]	We are uncertain whether implant inserted immediately following abortion increases or decreases the overall failure rate of medical abortion compared to delayed insertion (within 6 weeks of abortion) due to wide confidence intervals
Immediate vs delayed implant (within 6 weeks) - Failure rate of medical abortion - Require extra medication for complete abortion [CR] Sothornwit 2022	Relative risk: 1.18 (95% CI 0.44 - 3.2) Based on data from 1001 participants in 2 studies	53 per 1000	63 per 1000 Difference: **10 more per 1000** (95% CI 30 fewer - 117 more)	Low Due to serious inconsistency, Due to serious imprecision[1]	We are uncertain whether implant inserted immediately following abortion increases or decreases the need for additional medication doses to complete medical abortion compared to delayed insertion (within 6 weeks of abortion) due to wide confidence intervals
Immediate vs delayed implant (within 6 weeks) - Failure rate of medical abortion - Require surgery for complete abortion [CR] Sothornwit 2022	Relative risk: 1.28 (95% CI 0.71 - 2.3) Based on data from 1001 participants in 2 studies	38 per 1000	49 per 1000 Difference: **11 more per 1000** (95% CI 11 fewer - 49 more)	Moderate Due to serious imprecision[2]	We are uncertain whether implant inserted immediately following abortion increases or decreases the need for surgical evacuation to complete medical abortion compared to delayed insertion (within 6 weeks of abortion) due to wide confidence intervals
Immediate vs delayed implant (within 6	Relative risk: 1.0 (95% CI 0.88 - 1.14)	675 per 1000	675 per 1000	Low	Implant inserted immediately following abortion may have

weeks) - Bleeding side effects - At 1month postabortion [CR] Sothornwit 2022	Based on data from 463 participants in 1 study	Difference: **0 fewer per 1000** (95% CI 81 fewer - 94 more)		Due to serious imprecision, Due to serious risk of bias[3]	little or no difference on bleeding side effects at 1 month postabortion compared to delayed insertion (within 6 weeks of abortion)
Immediate vs delayed implant (within 6 weeks) - Bleeding side effects - At 6 months postabortion [CR] Sothornwit 2022	Relative risk: 0.74 (95% CI 0.33 - 1.65) Based on data from 462 participants in 1 study	**59** per 1000	**44** per 1000 Difference: **15 fewer per 1000** (95% CI 40 fewer - 38 more)	**Low** Due to serious risk of bias, Due to serious imprecision[3]	Implant inserted immediately following abortion may have little or no difference on bleeding side effects at 6 months postabortion compared to delayed insertion (within 6 weeks of abortion)
Immediate vs delayed implant (within 6 weeks) - Side effects other than bleeding - At 6 months postabortion [CR] Sothornwit 2022	Relative risk: 0.62 (95% CI 0.28 - 1.38) Based on data from 462 participants in 1 study	**64** per 1000	**40** per 1000 Difference: **24 fewer per 1000** (95% CI 46 fewer - 24 more)	**Low** Due to serious risk of bias, Due to serious imprecision[3]	Implant inserted immediately following abortion may have little or no difference on side effects other than bleeding at 6 months postabortion compared to delayed insertion (within 6 weeks of abortion)
Immediate vs delayed implant (within 6 weeks) - Unintended pregnancy - At 6 months after abortion [CR] Sothornwit 2022	Relative risk: 0.25 (95% CI 0.08 - 0.77) Based on data from 1029 participants in 3 studies	**28** per 1000	**7** per 1000 Difference: **21 fewer per 1000** (95% CI 26 fewer - 6 fewer)	**Moderate** Due to serious imprecision[2]	Implant inserted immediately following abortion probably decreases unintended pregnancy at 6 months after abortion compared to delayed insertion (within 6 weeks post abortion)
Immediate vs delayed implant (within 6 weeks) - Patient satisfaction - After complete abortion was determined [CR] Sothornwit 2022	Relative risk: 1.5 (95% CI 1.34 - 1.68) Based on data from 464 participants in 1 study	**601** per 1000	**902** per 1000 Difference: **301 more per 1000** (95% CI 204 more - 409 more)	**Moderate** Due to serious risk of bias[4]	Implant inserted immediately following abortion probably increases patient satisfaction after complete abortion was determined compared to delayed insertion (within 6 weeks post abortion)
Immediate vs delayed implant (within 6 weeks) - Patient satisfaction - At 6 months postabortion [CR] Sothornwit 2022	Relative risk: 1.06 (95% CI 0.93 - 1.21) Based on data from 350 participants in 1 study	**695** per 1000	**737** per 1000 Difference: **42 more per 1000** (95% CI 49 fewer - 146 more)	**Low** Due to very serious risk of bias[5]	Implant inserted immediately following abortion may have little or no difference on patient satisfaction at 6 months postabortion compared to delayed insertion (within 6 weeks of abortion)
Immediate vs delayed implant (within 6	Relative risk: 1.26 (95% CI 1.21 - 1.32)	**772** per 1000	**973** per 1000	**Moderate**	Implant inserted immediately following abortion probably

weeks) - rate of initiation of contraceptive implants - following medical abortion [CR] Sothornwit 2022	Based on data from 1014 participants in 2 studies	Difference: **201 more per 1000** (95% CI 162 more - 247 more)		Due to serious inconsistency[6]	increases the rate of initiation of contraceptive implants following medical abortion compared to delayed insertion (within 6 weeks of abortion)
Immediate vs delayed implant (within 6 weeks) - Rate of initiation of contraceptive implants - Following surgical abortion [CR] Sothornwit 2022	Relative risk: 2.32 (95% CI 1.79 - 3.01) Based on data from 148 participants in 1 study	**427** per 1000	**991** per 1000 Difference: **564 more per 1000** (95% CI 337 more - 858 more)	**Low** Due to serious risk of bias, Due to serious imprecision[7]	Implant inserted immediately following abortion probably increases the rate of initiation of contraceptive implants following surgical abortion compared to delayed insertion (within 6 weeks of abortion)

1. **Inconsistency: serious.** The magnitude of statistical heterogeneity was high, with I^2: >50%.; **Imprecision: serious.** Wide confidence intervals.
2. **Imprecision: serious.** Wide confidence intervals.
3. **Risk of Bias: serious.** risk of detection bias - study provided no criteria to diagnose complete abortion; **Imprecision: serious.** Wide confidence intervals.
4. **Risk of Bias: serious.** Participants were unblinded.
5. **Risk of Bias: very serious.** high rate of attrition (>20%) which was unexplained other than lost to follow-up and women were unblinded to the intervention allocated.
6. **Inconsistency: serious.** The magnitude of statistical heterogeneity was high, with I^2: >50%.
7. **Risk of Bias: serious.** risk of attrition bias; **Imprecision: serious.** Wide confidence intervals.

Clinical Question 13: Choice of medical or surgical abortion up to 14 weeks pregnant

For a woman having an abortion less than 14 weeks pregnant are medical methods safer, more effective, and more acceptable than surgical methods?

P: Woman seeking an abortion less than 14 weeks

I: Medical abortion

C: Surgical abortion

O: Adverse effects

- pain
- failed abortion (ongoing pregnancy)
- incomplete abortion (retained products of conception)
- blood loss – amount and duration
- medication side effects
- cervical injury
- uterine perforation
- infection
- anaesthetic risks

- Patient satisfaction
- Provision of LARCs

Evidence to decision

Benefits and harms

Research evidence

Cochrane review Say et al 2009 used as the primary source of literature for this clinical question.

Literature search from Cochrane review (complete up to 2009) updated using original search terms by University of Auckland (September 2022). Only 1 additional study (Robson 2009) was identified which met the study PICO.

Summary

Cochrane review Say et al 2009 included three studies with medical abortion using a combined regimen mifepristone and prostaglandin (1 study used misoprostol, 2 used gemeprost) compared to surgical (vacuum aspiration), and included abortions up to 13 weeks pregnant. Little or no difference was found in the proportion of abortions completed by the assigned method between medical and surgical abortion.

The duration of bleeding was longer (MD 2.94 days 95% CI 2.10 - 3.78 days), and haemoglobin drop was greater (MD 1.9g/L 95% CI 0.05 - 3.75g/L) in the medical group compared to surgical. Higher rates of side effects were experienced in the medical abortion group, including vomiting (OR 10.54 95% CI 5.77 - 19.23), and diarrhoea (OR 15.87 95% CI 7.38 - 34.15). The proportion of women experiencing any pain was higher in the medical group (OR 4.75 95%CI 1.56 - 14.95), compared to the surgical abortion group, with median pain score reported on a 0-10 VAS in the medical group being 6.2 (range 0-10) and the surgical group 2.5 (range 0-10). Overall, the experience of any pain was high in both groups (>90%).

Pain score findings from the additional randomized study (Robson 2009) identified by additional literature search correlate with that of the single study reporting this outcome in the Cochrane review (MD 28.1mm higher in medical abortion group, 95% CI 22.7-33.5mm).

Additionally, Robson et al (2009) report on acceptability outcomes. Higher satisfaction ratings were reported with the surgical abortion (vacuum aspiration) method at 2 weeks compared to medical abortion (mifepristone and misoprostol) (RR 0.72, 95% CI 0.66-0.78). Women who had surgical abortion were more likely to opt for surgical abortion again in the

future compared to those who had medical abortion (RR 0.76, 95% CI 0.63-0.90). Little or no difference was found in the time taken to return to work (median 3 in both groups, p-value 0.94)

Certainty of the evidence

Risk of bias assessments only were performed for the studies included in the summary of evidence as only single studies were identified for each outcome.

Two of the three studies included in the systematic review were stopped early owing to poor recruitment resulting in a moderate risk of bias, and the additional study identified had issues identified with blinding. This study included a randomised and a preference arm. Only the results from the randomised arm were included in the summary of evidence.

Values and preferences

Additional considerations

Robson et al (2009): A total of 1516 (99%) women in the preference arm gave a reason for their preference. Of these, 232 (15%) stated two reasons.

The most frequently cited reason related to awareness during the procedure; 479 (32%) women who preferred medical abortion wanted to be awake/avoid a general anaesthetic, while 213 (14%) who preferred surgical abortion wanted to be asleep.

A desire not to pass and see the fetus was the principal reason in a further 114 (8%) of women who preferred surgical abortion.

Prior personal experience of abortion or miscarriage/labour was the primary reason stated by 161 (11%) of women, with almost half preferring surgical abortion.

Temporal reasons were reported by 240 (16%) women, with those who wanted the minimum number of visits/length of stay predominantly choosing surgical abortion, while a shorter time to medical abortion was important for some women.

Of the remaining reasons, 156 (10%) related to one procedure (mostly medical abortion) being perceived as ‘easier’, ‘less traumatic’ or being associated with fewer complications/side effects.

Summary

Robson et al 2009 found that medical abortion was associated with more negative experiences and lower acceptability.

Slow recruitment to randomized studies included in the Cochrane review may indicate a strong preference by women for a particular method of abortion. Two included studies stopped prior to achieving their recruitment goal: Henshaw 1994 calculated for a sample size of 360, however only 195 women were randomized; and Rorbye 2004 calculated for a sample size of 802, but only 111 were randomized. The varying reasons for a preference of method were reported by Robson (2009) among women in their study who chose their method of abortion rather than being randomized, indicating the method of abortion is a very personal choice.

Resources

Research evidence

An economic analysis included in Robson et al 2009 indicated that surgical abortion was more costly than medical abortion, even though complication rates were higher with medical abortion.

Summary

Economic analyses were outside of the scope of this literature search.

Equity

The access to medicines and the use of telehealth makes medical abortion more equitable than surgical abortion that relies on the availability of surgical services. However, early medical abortions require access to private shelter, and may not be suitable for women experiencing houselessness or living in shared/multi-generational households.

Acceptability

Under international human rights law, countries must provide essential medicines listed under WHO's Action Programme on Essential Drugs, which include medical abortion medicines.
Most centres would be able to offer both medical and MVA, however theatre access may limit surgical abortion provision in some centres if MVA is not available.

Feasibility

Additional considerations

The guideline development group advised that although there is evidence that medical abortion less than 13 weeks can be safely performed at home, this can be limited by local regulations.

Summary

Most centres would be able to offer both medical abortion and surgical abortion by MVA with appropriate training.

PICO (13.1)

Population: Woman seeking an abortion less than 13 weeks of gestation
Intervention: Medical abortion
Comparator: Surgical abortion

Outcome Timeframe	Study results and measurements	Absolute effect estimates		Certainty of the evidence (Quality of evidence)	Plain language summary
		Surgical abortion	Medical abortion		
Abortion not completed with intended method - mifepristone and prostaglandin vs vacuum aspiration [CR] Say 2009	Relative risk: **2.12** (95% CI 0.37 - 12.06) Based on data from 111 participants in 1 study	**36** per 1000	**72** per 1000 Difference: **40 more per 1000** (95% CI 13 fewer - 398 more)	**Very low** Due to serious risk of bias, Due to very serious risk of bias, Due to serious imprecision[1]	We are uncertain whether medical abortion (with mifepristone and prostaglandin) increases or decreases abortion not completed with intended method compared to surgical abortion (vacuum aspiration)
Pain resulting from procedure -	Odds ratio: **4.75**	**906** per 1000	**979** per 1000	**Moderate**	Medical abortion (with mifepristone and prostaglandin)

mifepristone and prostaglandin vs vacuum aspiration [CR] Say 2009	(95% CI 1.56 - 14.95) Based on data from 366 participants in 1 study		Difference: **73 more per 1000** (95% CI 32 more - 87 more)	Due to serious imprecision[2]	probably increases pain resulting from procedure compared to surgical abortion (vacuum aspiration). There is high uncertainty around the magnitude of this increase - wide confidence interval
Side effects: vomiting - mifepristone and prostaglandin vs vacuum aspiration [CR] Say 2009	Odds ratio: **10.54** (95% CI 5.77 - 19.23) Based on data from 366 participants in 1 study	**83** per 1000	**488** per 1000 Difference: **405 more per 1000** (95% CI 260 more - 552 more)	**Moderate** Due to serious imprecision[2]	Medical abortion (with mifepristone and prostaglandin) probably increases side effects of vomiting compared to surgical abortion (vacuum aspiration). There is high uncertainty around the magnitude of this increase - wide confidence interval
Side effects: diarrhoea - mifepristone and prostaglandin vs vacuum aspiration [CR] Say 2009	Odds ratio: **15.87** (95% CI 7.38 - 34.15) Based on data from 366 participants in 1 study	**44** per 1000	**422** per 1000 Difference: **378 more per 1000** (95% CI 210 more - 567 more)	**Moderate** Due to serious imprecision[2]	Medical abortion (with mifepristone and prostaglandin) probably increases side effects of diarrhoea compared to surgical abortion (vacuum aspiration). There is high uncertainty around the magnitude of this increase - wide confidence interval
Would opt for the same method again (2 weeks)- mifepristone and misoprostol vs vacuum aspiration [RCT] Robson 2009	Relative risk: **0.76** (95% CI 0.63 - 0.9) Based on data from 349 participants in 1 study	**940** per 1000	**714** per 1000 Difference: **226 fewer per 1000** (95% CI 348 fewer - 94 fewer)	**Moderate** Due to serious risk of bias[3]	Medical abortion (with mifepristone and prostaglandin) probably decreases the number of women who would choose the same method again (when asked at 2 weeks after the procedure) compared to surgical abortion (vacuum aspiration)
Satisfaction (rating care as excellent) at 2 weeks - mifepristone and misoprostol vs vacuum aspiration [RCT] Robson 2009	Relative risk: **0.72** (95% CI 0.66 - 0.78) Based on data from 349 participants in 1 study	**611** per 1000	**440** per 1000 Difference: **171 fewer per 1000** (95% CI 208 fewer - 134 fewer)	**Moderate** Due to serious risk of bias[3]	Medical abortion (with mifepristone and prostaglandin) probably decreases the number of women rating their satisfaction with their care as excellent (when asked at 2 weeks after the procedure) compared to surgical abortion (vacuum aspiration)
Bleeding at 2 weeks (self-rated as moderate to excessive) - mifepristone and misoprostol vs vacuum aspiration [RCT] Robson 2009	Relative risk: **1.41** (95% CI1.32 - 1.51) Based on data from 349 participants in 1 study	**557** per 1000	**785** per 1000 Difference: **228 more per 1000** (95% CI 178 more - 284 more)	**Moderate** Due to serious risk of bias[3]	Medical abortion (with mifepristone and prostaglandin) probably increases bleeding (rated as moderate, heavy, or excessive when asked at 2 weeks after the procedure) compared to surgical abortion (vacuum aspiration)

Blood loss (fall in Hb) - mifepristone and prostaglandin vs vacuum aspiration [CR] Say 2009	Measured by: g/L Scale: Lower better Based on data from 195 participants in 1 study	Mean **1.4** g/L		Difference: **MD 1.9 higher** (95% CI 0.05 higher - 3.75 higher)	**Moderate** Due to serious risk of bias[4]	Medical abortion (mifepristone and prostaglandin) probably increases blood loss (fall in haemoglobin) compared to surgical abortion (vacuum aspiration) slightly
Duration of bleeding - mifepristone and prostaglandin vs vacuum aspiration [CR] Say 2009	Measured by: days Scale: Lower better Based on data from 424 participants in 2 studies			Difference: **MD 2.94 higher** (95% CI 2.10 higher - 3.78 higher)	**Moderate** Due to serious risk of bias[5]	Medical abortion (mifepristone and prostaglandin) probably increases duration of bleeding (days) compared to surgical abortion (vacuum aspiration)
Mean pain score during admission - mifepristone and misoprostol vs vacuum aspiration (under GA) [RCT] Robson 2009	Measured by: VAS Scale: 0 - 100 Lower better Based on data from 298 participants in 1 study	**22.9** Mean	**51.0** Mean	Difference: **MD 28.1 higher** (95% CI 22.7 higher - 33.5 higher)	**Moderate** Due to serious risk of bias[3]	Medical abortion (with mifepristone and prostaglandin) probably increases the mean pain score during admission compared to surgical abortion (vacuum aspiration)
Days taken to return to work - mifepristone and misoprostol vs vacuum aspiration (under GA) [RCT] Robson 2009	Measured by: days Scale: 0 - 100 Lower better Based on data from 298 participants in 1 study	Median **3** days	Median **3** days		**Moderate** Due to serious risk of bias[3]	Medical abortion (with mifepristone and prostaglandin) probably has little or no difference in median days taken to return to work compared to surgical abortion (vacuum aspiration)

1. **Risk of Bias: very serious.** Unclear allocation concealment, Trial stopping earlier than scheduled, resulting in potential for overestimating benefits; **Inconsistency: no serious. Imprecision: serious.**
2. **Imprecision: serious.** Wide confidence intervals.
3. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias.
4. **Risk of Bias: serious.** Trial stopping earlier than scheduled due to poor recruitment, resulting in potential for overestimating benefits.
5. **Risk of Bias: serious.** Henshaw 1994 stopping earlier than scheduled due to poor recruitment, resulting in potential for overestimating benefits.

Clinical Question 14: Choice of medical or surgical abortion from 14 weeks pregnant

For a woman having an abortion from 14 weeks pregnant are medical methods safer, more effective, and more acceptable than surgical methods?

P: Woman seeking an abortion from 14 weeks

I: Medical abortion

C: Surgical abortion

O: Adverse effects

- pain
- failed abortion (ongoing pregnancy)
- incomplete abortion (retained products of conception)
- blood loss – amount and duration
- medication side effects
- cervical injury
- uterine perforation
- infection
- anaesthetic-risks
- perforation

- Patient satisfaction
- Provision of LARCs

Evidence to decision

Benefits and harms

Research evidence

Evidence derived from NICE Abortion Care Guideline [K] Medical versus surgical abortion between 13+0 and 24+0 weeks pregnant (literature search up to March 2018) – note includes abortions between 13-14 weeks which are not within the population of interest for this PICO.

Additional search for evidence published since NICE systematic review conducted by University of Auckland on 14th April 2023.

Search terms: “medical abortion” OR “medication abortion” OR mifepristone OR misoprostol OR induction of labour AND “surgical abortion” OR “vacuum aspiration” OR “vacuum curettage” OR “D&C” OR “D&E” AND “second trimester” OR “2nd trimester” limited to 2018 - current, English language, and humans.

49 results returned. None were suitable for inclusion in the evidence table.

Summary

Evidence from two studies in the NICE systematic review showed that there was a lower rate of abortions completed by the intended method in the medical group compared to the surgical group (RR 0.88 95% CI 0.79-0.98, moderate certainty evidence). A higher rate of incomplete abortions requiring surgical intervention was reported in the medical abortion group (13%) compared to the surgical abortion group (3%) (RR 4.58 95% CI 1.07-19.64, moderate certainty evidence).

Little or no difference was reported in the rates of haemorrhage requiring transfusion or ≥ 500 mL blood loss, infection reported within 1 month of abortion, and patient satisfaction of the procedure at 2 weeks, between medical and surgical abortion at 13-24 weeks. There were no instances of uterine injury, cervical injury requiring repair in either group in the included studies.

Higher patient acceptability was reported in the surgical than medical abortion group (RR 0.54 95% CI 0.39-0.76) however, this was very low certainty evidence and thus we are uncertain of the true effect.

Certainty of the evidence

GRADE ratings taken from NICE committee in their appraisal of the evidence for their 2019 Guideline. The quality of the evidence across all outcomes ranged from very low to moderate and was only downgraded for imprecision owing to low event rates, and missing data.

Values and preferences

Additional considerations

Kerns et al 2012: Conducted interviews with 21 women undergoing medical or surgical abortion less than 24 weeks for fetal anomaly or pregnancy complications regarding their reasons for choosing their particular method of abortion. Key themes that emerged from the interviews were: valuing the ability to choose the method; and the importance of religious beliefs, abortion attitudes, and emotional coping style. Women's preferences for a method were largely based on their individual emotional coping styles.

Summary

Medical abortion for pregnancies at gestational ages ≥ 13 weeks has been practiced and researched as a facility-based procedure during which women should remain under observation until the process is complete. Length of hospitalisation was found to be longer for medical abortion which may impact on women's preferences.

The included study had difficulties recruiting women to participate and was terminated early owing to this. The authors of included studies note that recruitment difficulties were because this is an area of very strong patient preferences in terms of which method of abortion wanted.

Resources

Additional considerations

NICE Abortion Care Guideline group conducted their own cost analysis based on UK data. The economic model compared a base case of surgical abortion to that of medical abortion. Based on NHS reference costs the cost of a surgical abortion was greater than that of a medical abortion by £579. Surgical abortion remained the more costly option when adverse event costs, which were higher for medical abortion, were added on. Even when the overnight stays for the medical group, observed in Kelly 2010, were added surgical abortion remained more costly by £236 per procedure.
The economic model did not attempt to estimate these implementation costs given the large variation across the country.

Summary

Economic analysis was outside of scope.
However, there may be greater implementation costs for providing either medical or surgical abortions in some areas than for others where a choice of methods is already provided.

Equity

There may be greater implementation difficulties for providing either medical or surgical abortions in some areas than for others where a choice of methods is already provided. Maintaining proficiency for surgical termination requires a minimum caseload which may not be able to be maintained in smaller regional centres. Where surgical abortion cannot

be offered owing to low case numbers access to this service may require travel to another centre, impacting on equity of care for rural women in particular.

Acceptability

Maintaining proficiency for surgical termination requires a minimum caseload which may not be able to be maintained in smaller regional centres.

Feasibility

There may be greater implementation challenges for providing either medical or surgical abortions in some areas than for others where a choice of methods is already provided. Maintaining proficiency for surgical termination requires a minimum caseload which may not be able to be maintained in smaller regional centres.

PICO (14.1)

Population: woman seeking an abortion from 14 weeks
Intervention: Medical abortion
Comparator: Surgical abortion

Outcome Timeframe	Study results and measurements	Absolute effect estimates		Certainty of the evidence (Quality of evidence)	Plain language summary
		Surgical abortion	Medical abortion		
Abortion completed by intended method - Medical versus surgical abortion between 13^{+0} and 24^{+0} weeks' gestation [SR] NICE 2019	Relative risk: **0.88** (95% CI 0.79 - 0.98) Based on data from 128 participants in 2 studies	**970** per 1000	**854** per 1000 Difference: **116 fewer per 1000** (95% CI 204 fewer - 19 fewer)	**Moderate** Due to serious imprecision[1]	Medical abortion probably decreases abortion completed by intended method compared to surgical abortion between 13^{+0} and 24^{+0} weeks' gestation
Incomplete abortion with need for surgical intervention - Medical versus surgical abortion between 13^{+0} and 24^{+0} weeks' gestation [SR] NICE 2019	Relative risk: **4.58** (95% CI 1.07 - 19.64) Based on data from 140 participants in 2 studies	**28** per 1000	**128** per 1000 Difference: **100 more per 1000** (95% CI 2 more - 522 more)	**Moderate** Due to serious imprecision[1]	Medical abortion probably increases incomplete abortion with need for surgical intervention compared to surgical abortion between 13^{+0} and 24^{+0} weeks' gestation
Infection reported within 1 month of abortion - Medical versus surgical abortion between 13^{+0} and 24^{+0} weeks' gestation [SR] NICE 2019	Relative risk: **7.0** (95% CI 0.41 - 118.69) Based on data from 140 participants in 2 studies	**0** per 1000	**430** per 1000	**Low** Due to very serious imprecision[2]	Medical abortion may have little or no difference on infection reported within 1 month of abortion compared to surgical abortion between 13^{+0} and 24^{+0} weeks' gestation. We are uncertain of its effect due to a very wide confidence interval

Haemorrhage >500 mL or requiring transfusion - Medical versus surgical abortion between 13^{+0} and 24^{+0} weeks' gestation [SR] NICE 2019	Relative risk: **0.21** (95% CI 0.02 - 1.72) Based on data from 140 participants in 2 studies	**70** per 1000 Difference: **55 fewer per 1000** (95% CI 69 fewer - 50 more)	**15** per 1000	**Low** Due to very serious imprecision[2]	Medical abortion may have little or no difference on haemorrhage >500 mL or requiring transfusion compared to surgical abortion between 13^{+0} and 24^{+0} weeks' gestation
Acceptability - Would choose the same method again at 2 weeks - Medical versus surgical abortion between 13^{+0} and 24^{+0} weeks' gestation [SR] NICE 2019	Relative risk: **0.54** (95% CI 0.39 - 0.76) Based on data from 56 participants in 1 study	**1000** per 1000 Difference: **460 fewer per 1000** (95% CI 610 fewer - 240 fewer)	**540** per 1000	**Very low** Due to very serious risk of bias, Due to serious imprecision[3]	We are uncertain whether medical abortion increases or decreases acceptability - would choose the same method again at 2 weeks compared to surgical abortion between 13^{+0} and 24^{+0} weeks' gestation due to very low quality evidence
Patient satisfaction (rating of satisfied with care during abortion) - Medical versus surgical abortion between 13^{+0} and 24^{+0} weeks' gestation [SR] NICE 2019	Relative risk: **1.02** (95% CI 0.95 - 1.11) Based on data from 56 participants in 1 study	**972** per 1000 Difference: **28 more per 1000** (95% CI 49 fewer - 107 more)	**1000** per 1000	**Very low** Due to very serious risk of bias, Due to serious imprecision[4]	We are uncertain whether medical abortion increases or decreases patient satisfaction (rating of satisfied with care during abortion) compared to surgical abortion between 13^{+0} and 24^{+0} weeks' gestation due to confidence interval crossing the null, and very low quality evidence

1. **Imprecision: serious.** Wide confidence intervals.
2. **Imprecision: very serious.** Wide confidence intervals.
3. **Risk of Bias: very serious.** Incomplete data and/or large loss to follow up (>50% missing data in each group); **Imprecision: serious.** Small sample size.
4. **Risk of Bias: very serious.** Incomplete data and/or large loss to follow up (>50% missing data in both groups); **Imprecision: serious.** Wide confidence intervals.

Clinical Question 15: Abortion following uterine surgery

For a woman seeking an abortion who has had previous uterine surgery (including caesarean section, hysterotomy, myomectomy, or perforation) what additional investigations and management is required to ensure safety and efficacy of the abortion procedure?

P: Woman seeking an abortion (any gestation) who has had previous uterine surgery (including previous caesarean section (single/≥2), hysterotomy, myomectomy, or perforation)

I: Additional investigations and management

C: Standard abortion care

O: Adverse effects

- ectopic pregnancy
- hospitalisation or emergency procedure
- blood loss requiring transfusion
- hysterectomy
- death
- failed abortion (ongoing pregnancy)
- incomplete abortion (retained products of conception)

- Patient satisfaction

Evidence to decision

Benefits and harms

Research evidence

A primary literature search was carried out by the University of Auckland on 4th October 2022, using search terms ((abortion OR induced abortion OR termination or pregnancy OR pregnancy termination) AND (caesarean section OR scarred uterus)). 639 studies were screened for inclusion. No studies fitting the PICO population, intervention (additional tests and management), and comparator (standard care) were identified.

Indirect evidence was used from a systematic review of comparative observational studies by Andrikopoulou et al. 2016 comparing the incidence of outcomes of complete abortion, uterine rupture, and other complications among women with no previous caesarean sections (CS) and those with at least 1 previous caesarean section undergoing medical abortion using misoprostol, or surgical abortion with cervical priming using mechanical methods, in the second trimester. No indirect evidence was identified for abortion in the first trimester.

Citations for an additional three cohort studies not identified in the initial literature search were provided by guideline development group member Paddy Moore, two of which have been included in the evidence summary as indirect evidence.

Although case reports were identified of uterine rupture following abortion in the first trimester among women having had previous uterine surgery, research focus appears to be on abortion in the second trimester, when risks of uterine rupture may be higher owing to greater uterine distention.

Summary

No randomised controlled trial evidence was identified comparing additional investigations and management with standard abortion care in women who have had previous uterine surgery.

Systematic review:

A systematic review of observational studies (Andrikopoulou et al 2016) was identified comparing outcomes of vaginal delivery, uterine rupture, and other complications among women with no previous caesarean sections and women with at

least 1 previous caesarean section undergoing abortion in the second trimester. In this meta-analysis studies are grouped by method of induction despite varying dosage and administration protocols among included studies. 15 studies considered PGE1 regimens for medical abortion, while 3 studies considered mechanical methods (Laminaria) prior to surgical abortion. This systematic review includes procedures for intrauterine fetal demise as well as abortion in the second trimester.

Misoprostol in medical abortion second trimester

No differences in the proportion of women achieving vaginal delivery were reported between women with and without previous caesarean section who had abortion using prostaglandin E1 (PGE1) (RR 0.99, 95% CI 0.98-1.00).

The baseline rate of uterine rupture in women having PGE1 in the second trimester with at least 1 caesarean section was 1.3% (Andrikopoulou et al 2016). Compared to women without a prior history of caesarean section, women with a history of at least 1 previous caesarean section that used PGE1 methods had a higher proportion of uterine perforation/rupture (RR 6.57, 95% CI 2.21-19.52, 15 studies), retained placenta (RR 1.21, 95% CI 1.03-3.04, 5 studies), and blood transfusion (RR 1.75, 95% CI 1.10-3.04, 10 studies). On subgroup analysis a history of one previous CS was not associated with higher risk of uterine perforation/rupture compared to no previous CS (RR 2.36 95%CI 0.39-14.32); however, two or more CS were associated with substantial increased risk compared to none (RR 17.55, 95%CI 3.00-102.80).

Mechanical methods in surgical abortion in second trimester

No differences in the proportion of complete abortions reported between women with and without previous caesarean section who had cervical ripening prior to surgical abortion (D&E) using mechanical methods (RR 1.00, 95% CI 0.98-1.01).

The baseline rate of uterine perforation/rupture in women having mechanical methods followed by a D&E in the second trimester with at least 1 caesarean section is 1.4% (Andrikopoulou et al 2016). Women with a history of at least 1 previous caesarean section that used mechanical methods prior to D&E had a higher proportion of uterine perforation/rupture (RR 19.25, 95% CI 3.97-93.38, 3 studies, of which two (Schneider et al 1994, and Ben-Ami 2009) had no events. The third study (Australian) Pridmore et al 1999 reported 3 in 60 having had a prior CS and 3 in 1155 no CS). No difference in blood transfusion (RR 0.74, 95% CI 0.10-5.65, 2 studies) compared to women without a prior history of caesarean section.

Additional cohort studies:

A large US cohort study of 2,973 surgical abortions performed after 14 weeks was published by Frick et al 2010. (GRADE: Low certainty) This study was not included in the above systematic review as the authors were unable to match a history of caesarean section with the incidence of specific complications on which they were conducting a meta-analysis. Frick et al report on the odds of having a major complication if a woman has had 1, or 2 or more, caesarean sections compared to no previous caesarean section. A major complication was defined as need for blood transfusion, diagnosis of disseminated intravascular coagulation (DIC), or reoperation by means of uterine artery embolisation, laparoscopy or laparotomy. Cervical priming was achieved with Laminaria, and all D&E procedures were performed under moderate or deep sedation, with antibiotic prophylaxis, and ultrasound guidance. While little to no difference in the risk of a major complication was found among one previous caesarean compared to no previous, a history of two or more caesareans was associated with a higher risk of major complications (OR 7.37 95%CI 3.35-15.80) compared to no previous caesarean.

An additional large US cohort study of 4,520 surgical abortions from 14-24 weeks was published by Lederle et al 2015. This study was published after the systematic review searches were completed. Lederle et al report on the odds of having any complication and a major complication if a woman has had 1 or more caesarean sections compared to no previous caesarean section. Included complications were: cervical laceration, haemorrhage (>500 mL total loss, requiring blood transfusion, 3x doses of uterotonic, or balloon tamponade, re-aspiration or other intervention), uterine atony, anaesthetic complications, uterine perforation, DIC, or retained products of conception. A major complication was defined as need for blood transfusion, uterine artery embolization, additional surgery, or admission. Cervical priming was achieved with Laminaria, and all D&E procedures were performed under moderate or deep sedation, with antibiotic prophylaxis, and

ultrasound guidance. A history of one or more caesareans was associated with a higher risk of any complications (aOR 1.8 95%CI 1.4-2.3) and major complications (aOR 1.8 95%CI 1.1-3.1) compared to women with no previous caesarean.

Overall summary:

We are uncertain if a history of one previous caesarean section increases the risk of major complications of medical or surgical abortion in the second trimester owing to conflicting results between studies. A history of two or more caesarean sections appears to substantially increase the risk of uterine perforation/rupture among women having medical abortion, and the risk of major complications in women having surgical abortion. The magnitude of these effects differs between studies.

Certainty of the Evidence

As this is a systematic review of observational studies, GRADE is set at low certainty. There were no downgrading or upgrading factors to alter this certainty level identified. AMSTAR of this review was 7/11 (moderate certainty)

Frick et al 2011 was a cohort study of 2,973 2nd trimester surgical abortions and was GRADEd low (upgraded for dose response, downgraded for imprecision).

Lederle et al 2015 was a cohort study of 4,520 2nd trimester surgical abortions and was graded very low using GRADE (downgraded for imprecision).

Values and preferences

No evidence reporting acceptability and patient satisfaction outcomes was identified.

Resources

Economic evaluation was outside of the scope of this guideline.

Equity

No direct evidence was identified from which to inform the equity impacts of this recommendation.

PICO (15.1)

Population: Woman seeking an abortion (any gestation) who has had previous uterine surgery (including caesarean section, hysterotomy, myomectomy, or perforation)
Intervention: Additional investigations and management
Comparator: Standard abortion care

Summary:
There are no studies that reported on outcomes for women having abortion in the first trimester with previous uterine surgery on which to make a recommendation. A systematic review of 18 studies and two additional large cohort studies in the second trimester have informed the corresponding evidence to decision table (Etd).

No studies were identified that compared medical and surgical abortion in women with previous uterine surgery.

The body of evidence from observational studies indicates that there is a small increased risk of perforation or rupture regardless of the method among women having a second trimester abortion with a uterine scar compared to those without a

scar. The proportion of uterine rupture in women who have medical abortion was 1.4% and the proportion in mechanical methods followed by D&E was 1.3%.

Clinical Question 16a: Management of incomplete abortion

For a woman who has undergone an abortion who has an incomplete or partially completed abortion what additional management is required?

P: Woman who has undergone an abortion who has an incomplete abortion (retained products of conception on investigation)
I: Repeat same procedure (medical or surgical)
C: i) alternate abortion method (medical or surgical)
ii) conservative management
O: Adverse effects:

- pain
- incomplete abortion (retained products of conception)
- blood loss – amount and duration
- medication side effects
- cervical injury
- perforation
- infection
- anaesthetic risks

- Patient satisfaction

Evidence to decision

Benefits and harms

Research evidence

A Cochrane network meta-analysis considering management of miscarriage was identified from which it was considered by the research team that the incomplete miscarriage group may provide indirect evidence to inform this recommendation.

Primary literature searches using search terms “abortion” OR “termination of pregnancy” AND “Incomplete” OR “retained products” OR “RPOC” identified 1 RCT (Tzur 2022) for inclusion. This study compares repeat medical management to expectant management in women having undergone medical abortion. No studies comparing medical and surgical management in women having undergone medical abortion nor comparing medical and surgical management in women having undergone surgical abortion were identified.

Additional considerations

Evidence from a network meta-analysis of management of miscarriage using the sub-population of incomplete miscarriage can also be used as indirect evidence to inform this recommendation in the absence of other interventional studies in population of women undergoing abortion. In the Cochrane network meta-analysis of miscarriage management, the highest ranked method for managing incomplete miscarriage for the outcome of complete miscarriage was suction aspiration, followed by dilation & curettage, then misoprostol, followed by mifepristone plus misoprostol. Expectant management was ranked last. For the outcome of days of bleeding, dilatation & curettage was ranked highest followed by suction aspiration, expectant management, misoprostol, and lastly mifepristone plus misoprostol.

Summary

A single randomized controlled trial Tzur et al 2022 was identified. This RCT compares medical management (misoprostol 800 mcg sublingual) with expectant management. 155 women who had undergone medical abortion prior to 63 days gestation (with a combined regimen of mifepristone 600 mg followed by misoprostol 400 mcg 48 hours later) were included in this RCT if they had retained products of conception (RPOC) on transvaginal (TV) ultrasound performed 21

days after mifepristone administration, measuring 12mm or greater in their largest diameter with presence of doppler flow. 80% of included women were also experiencing symptoms suggestive of RPOC (vaginal bleeding). A repeat ultrasound was undertaken 2 weeks later, and for women with ongoing presence of RPOC a further ultrasound 2 weeks later. Women with persistent RPOC on the final ultrasound (8 weeks from randomisation) underwent a hysteroscopy for definitive treatment. Women were telephoned within 3 months of resolution of their RPOC to determine participants' experience of adverse events, pain score, and over-the-counter (OTC) analgesia use. This study reported a loss to follow-up rate of 5.7%.

Overall, 60% (78/131) of participants in this study did not require surgical management. Little or no difference was found in the rate of treatment success (avoidance of surgical management) between women treated with misoprostol (61.8%) and those having expectant management (57.1%) (RR 1.12, 95% CI 0.74-1.70). This finding persisted when adjusted for age, BMI, smoking, nulliparity, and sonographic RPOC length (aRR 0.86, 95% CI 0.39-1.89). No participants received a blood transfusion or experienced endometritis. Little or no difference was reported in need for emergency surgical intervention (0% vs 3.3%), or unscheduled emergency department visits (1.6% vs 7.4%). Little or no difference was found in the number of adverse events, pain score, or OTC analgesia use between the medical and expectant management groups. Regardless of the treatment allocation, for each 1mm increase in RPOC size the likelihood of treatment failure (requirement for surgical management at 8 weeks from start of the procedure) increased by 12%.

Certainty of the evidence

Moderate quality of evidence to support misoprostol, D&C, and suction aspiration as being more effective at achieving complete miscarriage compared to expectant management based on Cochrane certainty of evidence assessment.

Values and preferences

No evidence to inform this domain was identified. It is likely that women's preferences would vary. Women having an abortion may have had a preference for medical or surgical management as their initial management, for varying reasons, and may prefer to repeat this management option in the management of RPOC. Most women would likely value fewer days of bleeding and a quicker resolution of RPOC.

Resources

Economic evaluation was outside of the scope of this guideline.

Equity

Access to surgery management for remote/rural populations may reduce equity, therefore repeat medical management or expectant management may be preferred for these populations.

Acceptability

Both surgical and medical abortion medications/procedures routinely available in most urban centres if an additional medication course/procedure was required.

Feasibility

Both surgical and medical abortion medications/procedures routinely available in most urban centres if an additional medication course/procedure was required. Access to ultrasound in primary care may not always be available.

PICO (16.1)

Population: Woman who has undergone an abortion who has an incomplete abortion (retained products of conception on investigation)

Intervention: repeat same procedure (medical or surgical)
Comparator: i) alternate abortion method (medical or surgical) ii) Conservative management

Outcome Timeframe	Study results and measurements	Absolute effect estimates		Certainty of the evidence (Quality of evidence)	Plain language summary
		i) alternate abortion method ii) Conservative mx	repeat same procedure (medical or surgical)		
Medical management (800 mcg misoprostol sublingual) vs expectant management of RPOC - treatment success (resolution of RPOC on USS within 28 days) [RCT] Tzur 2022	Relative risk: **0.86** (95% CI 0.39 - 1.89) Based on data from 141 participants in 1 study	**571** per 1000	**491** per 1000 Difference: **80 fewer per 1000** (95% CI 348 fewer - 508 more)	**Very low** Due to serious risk of bias, Due to serious indirectness, Due to serious imprecision[1]	We are uncertain whether medical management improves or worsens RPOC treatment success, due to the very low certainty of evidence
Medical management (800 mcg misoprostol sublingual) vs expectant management of RPOC - need for emergent surgical intervention [RCT] Tzur 2022	Based on data from 141 participants in 1 study	**0** per 1000	**33** per 1000	**Very low** Due to serious risk of bias, Due to serious indirectness, Due to serious imprecision[2]	There were too few who experienced the need for emergent surgical intervention (0 events in one arm, 3 in the other) to determine whether medical management with 800mch misoprostol sublingual made a difference compared to expectant management
Medical management (800 mcg misoprostol sublingual) vs expectant management of RPOC - unscheduled emergency department visit [RCT] Tzur 2022	Based on data from 141 participants in 1 study	**16** per 1000	**74** per 1000	**Very low** Due to serious risk of bias, Due to serious indirectness, Due to serious imprecision[2]	There were too few who experienced the need for emergent surgical intervention (1 in one arm and 5 in the other) to determine whether medical management with 800mch misoprostol sublingual made a difference compared to expectant management

1. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias; **Indirectness: serious.** Differences between the intervention/comparator of interest and those studied; **Imprecision: serious.** Only data from one study.
2. **Risk of Bias: serious.** Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias; **Indirectness: serious.** Differences between the intervention/comparator of interest and those studied; **Imprecision: serious.** few events.

Clinical Question 16b: Management of ongoing pregnancy

For a woman who has undergone an abortion who has an ongoing pregnancy what investigations and management is required?

P: Woman who has undergone an abortion who has an ongoing pregnancy (failed abortion)

I: Additional investigations and management

C: Standard abortion care

O: Adverse effects:

- Miscarriage
- Fetal anomaly
- Repeat abortion procedure (medical or surgical)
- Unwanted pregnancy

- Patient satisfaction

Evidence to decision

Benefits and harms

Research evidence

Primary literature search conducted using search terms “abortion” OR “termination of pregnancy” AND “ongoing pregnancy” OR “failed” OR “incomplete”

Two studies were identified that report on the outcome of a second dose of medical management of sub-population of women in other randomised controlled trials who have ongoing pregnancy after first medical abortion dosage. No studies for management of ongoing pregnancy after surgical management were identified.

Additional considerations

Fewer than 0.005% of patients who use mifepristone choose to continue their pregnancy[74]. A systematic review by Grossman et al 2015 investigated management of pregnancy if a woman changes her mind about an abortion after taking medications to induce an abortion. This review identified a single observational study on “abortion reversal” (administration of high dose of progesterone following the initial dose of mifepristone) (n = 7), and 13 studies for continuing pregnancy after mifepristone alone. The authors concluded that the evidence is insufficient to determine whether treatment with progesterone after mifepristone results in a higher proportion of continuing pregnancies compared to expectant management.

A larger case series of 754 women who underwent “abortion reversal” was published by Delgado et al in 2018[75]. The study was of poor quality, lacked ethical approval, and was at high risk for selection bias. Although the authors conclude that the reversal of the effects of mifepristone using progesterone is safe and effective, this procedure is not supported by RCT evidence and remains experimental. A randomized clinical trial was attempted to evaluate safety and efficacy of MAB reversal by Creinin et al 2020, but was ceased prematurely owing to safety concerns following 3 instances of severe maternal haemorrhage[76].

Summary

No randomised controlled trials were identified comparing management options of ongoing pregnancy following abortion.

Two observational studies were identified that report on the outcome of a second dose of medical management of sub-population of women in other randomised controlled trials who have ongoing pregnancy after first medical abortion dosage. No studies for management of ongoing pregnancy after surgical management were identified.

One study (Chen et al 2015) reports on 3 RCTs containing mifepristone and buccal misoprostol protocols for abortion less than 9 weeks pregnant. In these RCTs participants returned at 1 week for follow-up. Participants with a persistent

gestation sac and cardiac activity seen on ultrasound were recommended to undergo uterine suction curettage. Participants with a persistent gestational sac but no cardiac activity were given the option of expectant management or a second dose of buccal misoprostol. The proportion of participants who received a second dose of misoprostol who subsequently had a complete abortion was between 91-100% in all four studies. If a complete abortion was not achieved after the second misoprostol dose surgical management was performed.

Reeves et al 2008 reported on the outcome of repeat medical management in a sub-population of women in two RCTs of medical abortion less than 9 weeks. Both RCTs used a protocol of mifepristone 200 mg orally followed by misoprostol 800 mcg vaginally and compared varying time differences between mifepristone and misoprostol doses. Participants with a persistent gestational sac regardless of cardiac activity were offered a repeat misoprostol dose at 1 week follow-up. Of 68 women receiving a repeat misoprostol dose 62% had a complete abortion following that dose. There was a significant difference in the proportion of women having complete abortion following the second dose of misoprostol between women who had a fetal pole on ultrasound (42%) compared to no fetal pole (74%, p-value 0.01), but there was no significant difference in the proportion of complete abortion after second misoprostol dose between women with fetal cardiac activity (36%) and no fetal cardiac activity (54%, p-value 0.45).

The studies differed in route of misoprostol administration (buccal and vaginal routes) and in the protocols used for inclusion. The participants receiving vaginal misoprostol may or may not have had cardiac activity, whereas the participants receiving buccal misoprostol did not have cardiac activity (those with cardiac activity had surgical management). Both routes used the same dose of misoprostol (800 mcg).

Certainty of the evidence

Observational data only of ongoing pregnancies from RCTs. GRADE assessment was not performed for this evidence.

Values and preferences

Acceptability and patient preference outcomes were not reported in the observational evidence identified.

Resources

Economic evaluation was not part of the scope of this guideline.

PICO (16.2)

Population: Woman who has undergone an abortion who has an ongoing pregnancy (failed abortion)
Intervention: Additional investigations and management
Comparator: Standard abortion care

Summary

No randomised controlled trials were identified comparing management options of ongoing pregnancy following abortion.

Two observational studies were identified that reported on the outcome of a second dose of medical management in a sub-population of women from other randomised controlled trials who have ongoing pregnancy after first dosage medical abortion. Neither study provided direct evidence as they did not use the intervention and comparator prespecified in the PICO.

Clinical Question 17a: Feticide

For a woman undergoing an abortion is pretreatment induced fetal death (feticide) safer, more effective, and more acceptable than usual abortion care?

P – Woman undergoing an abortion (medical or surgical) for which pretreatment induced fetal death (feticide) is offered (any gestation)

I – Pretreatment induced fetal death (feticide) in addition to usual abortion treatment (medical or surgical)

C – Usual care (no feticide or placebo)

O – Adverse events:

- live birth
- failure to induce fetal death
- sepsis
- maternal cardiac complications

- Time to expulsion in medical abortion
- Patient satisfaction
- Accessibility of abortion services

Evidence to decision

Benefits and harms

Research evidence

Evidence drawn from the SOGC Clinical Practice Guideline No. 360 - Induced abortion: surgical abortion and second trimester medical methods 2018.

Additional primary search conducted 9th September 2022 using search term: “induced fetal death” OR “inducted fetal demise” OR “feticide” OR “fetal asystole AND termination of pregnancy OR abortion”.

16 articles were retrieved for full text review. 1 RCT was included in the evidence considering the use of feticide vs placebo

Summary

No randomized controlled trials comparing feticide with placebo or standard care were identified for women undergoing medical abortion at any gestation.

A single randomised controlled trial (Jackson et al 2001) for women having D&E between 20 and 23 weeks pregnant was identified comparing feticide using digoxin 1 mg intraamniotic to placebo. Digoxin was effective in inducing fetal death in 92% of cases in which it was used.

- Little or no difference was reported in the proportion of women with complications (a composite of cervical laceration, endometritis requiring readmission, retained products of conception, or blood loss >500 mL) between women receiving digoxin vs placebo.
- Women who had received intraamniotic digoxin for feticide had longer procedure times (15.4 minutes digoxin group vs 14.7 minutes placebo group), higher blood loss (129 mL digoxin group vs 116 mL placebo group), and higher total intraoperative intravenous pain medication (6.2 mL digoxin group vs 5.9 mL placebo group). The clinical impact of these differences is, however, likely to be minimal.

Observational studies considering the use of feticide vs no feticide prior to abortion have a high potential for selection bias. Feticide efficacy may be related to gestational age which varies substantially between cohorts, and the use of feticide may have been preferred when practitioners were expecting a more difficult procedure, impacting the procedure time

and complication rates reported. Results from observational studies reporting the impact of feticide on abortion procedure duration (D&E) and abortion medication to delivery interval (medical abortion) are conflicting.

Certainty of the evidence

Quality of evidence assessed as moderate using GRADE.

Values and preferences

Participants in the Jackson et al 2001 trial demonstrated a strong preference for fetal death before abortion if they were in the same situation in the future (92%), with no difference between the active and placebo groups. However, these participants may not represent the views of all women as they had already demonstrated a willingness to have feticide by digoxin by agreeing to participate in the trial.
A prospective cohort study (Lohr 2018) surveyed 291 women about the acceptability of having feticide with intracardiac potassium chloride or not, prior to D&E from 18-24 weeks pregnant. Most women in both groups found their procedure (feticide plus Dilapan insertion vs Dilapan insertion alone) very acceptable or acceptable (79% KCl vs 87% no-KCl, p-value 0.2), with no significant difference between the groups.

Resources

Cost effectiveness analysis is outside of scope.

Equity

Women from rural and remote areas would have to travel a day earlier to a centre able to offer feticide.

Acceptability

Graham et al. 2009 conducted interviews with 12 parents (men and women) who had experienced an abortion beyond 20 weeks for fetal anomaly and 23 health professionals with experience of feticide provision in the NHS. Two key themes from the study provide data on how perceptions of feticide were described by those involved in late abortion: (1) feticide is recognised and described as a legitimate clinical procedure and (2) the practice of feticide is conceptualised as difficult but necessary.

Feasibility

Would likely require additional staff training to administer feticide.

PICO (17.1)

Population: woman undergoing an abortion (medical or surgical) for which pretreatment induced fetal death (feticide) is offered (any gestation)
Intervention: Pretreatment induced fetal death (feticide) in addition to usual abortion treatment (medical or surgical)
Comparator: Usual care (no feticide or placebo)

Outcome Timeframe	Study results and measurements	Absolute effect estimates		Certainty of the evidence (Quality of evidence)	Plain language summary
		Usual care (no feticide or placebo)	Feticide		
Total complications - digoxin 1 mg intraamniotic vs placebo [RCT] Jackson 2001	Relative risk: **0.41** (95% CI 0.08 - 2.05) Based on data from 126 participants in 1 study	**78** per 1000	**32** per 1000 Difference: **46 fewer per 1000** (95% CI 72 fewer - 82 more)	**Moderate** Due to serious imprecision[1]	We are uncertain whether feticide using digoxin 1 mg intraamniotic improves or worsen total complication rates among women having abortion compared to placebo due to a wide confidence interval
Mean procedure time - digoxin 1 mg intraamniotic vs placebo [RCT] Jackson 2001	Measured by: Minutes Scale: Lower better Based on data from 126 participants in 1 study	**14.7** Mean	**15.4** Mean Difference: **MD 0.70 higher** (95% CI 1.95 lower - 3.35 higher)	**Moderate** Due to serious imprecision[1]	Feticide using digoxin 1 mg intraamniotic probably has little or no clinically important difference on mean procedure time (for abortion) compared to placebo
Total intraoperative intravenous pain medication - digoxin 1 mg intraamniotic vs placebo [RCT] Jackson 2001	Measured by: mL Scale: Lower better Based on data from 126 participants in 1 study	**5.9** Mean	**6.2** Mean Difference: **MD 0.30 higher** (95% CI 0.43 lower - 1.03 higher)	**Moderate** Due to serious imprecision[1]	Feticide using digoxin 1 mg intraamniotic probably has little or no clinically important difference on need for additional IV pain relief (during abortion - all had PCB + conscious sedation with fentanyl and midazolam) compared to placebo
Pain of intraamniotic injection - digoxin 1mf intraamniotic vs placebo [RCT] Jackson 2001	Measured by: 6-point pain scale Scale: Lower better Based on data from 126 participants in 1 study	Median **2**	Median **2**	**Moderate** Due to serious imprecision[1]	Feticide using digoxin 1 mg intraamniotic probably has little or no clinically important difference on median pain score (during intraamniotic injection) compared to placebo
Estimated blood loss - digoxin 1 mg intraamniotic vs placebo [RCT] Jackson 2001	Measured by: mL Scale: Lower better Based on data from 126 participants in 1 study	**116** Mean	**129** Mean Difference: **MD 13.0 higher** (95% CI 13.46 lower - 39.46 higher)	**Moderate** Due to serious imprecision[1]	We are uncertain whether feticide using digoxin 1 mg intraamniotic improves or worsen estimated blood loss among women having abortion compared to placebo due to a wide confidence interval

1. **Imprecision: serious.** Only data from one study.

Clinical Question 17b: Method of Feticide

For a woman undergoing an abortion what method of feticide is the safest, most effective, and most acceptable?

P – Woman undergoing an abortion (medical or surgical) for which pretreatment induced fetal death (feticide) is offered (any gestation)

I – Pretreatment induced fetal death (feticide) method A, in addition to usual abortion treatment (medical or surgical)

C – Pretreatment induced fetal death (feticide) method B, in addition to usual abortion treatment (medical or surgical)

O – Adverse events:

- live birth
- failure to induce fetal death
- sepsis
- maternal cardiac complications

- Time to expulsion in medical abortion
- Patient satisfaction
- Accessibility of abortion services

Benefits and harms

Research evidence

An additional search (19th May 2023) was undertaken to specifically consider potassium chloride use in feticide, as this agent is used in several hospital protocols supplied by the guideline development group to the research team.

Search terms: “potassium chloride” OR KCl AND feticide OR “induced fetal death” OR “Induced fetal demise” OR “abortion” OR “termination” - limited to humans and English language - 131 identified, 6 full texts reviewed. One systematic review and one RCT included in the evidence summary.

Additional considerations

In a study that performed close monitoring, including a 24-h Holter monitoring, serial serum digoxin levels, and coagulation parameters in women who were administered 1 mg of intraamniotic digoxin, maternal serum digoxin concentrations peaked at 12 hours after intraamniotic administration of digoxin 1 mg and these levels were not associated with clinically significant maternal health issues (Drey et al. 2000)

Summary

The most frequently studied methods of feticide involve chemical injections to induce demise pharmacologically. Studied agents include:

Digoxin

Two RCTs were identified (Nucatola 2010 and White 2016) and both compare intraamniotic and intrafetal digoxin to induce fetal death prior to mid-trimester D&E. A meta-analysis of these studies by Tufa et al 2020 found intraamniotic digoxin resulted in a lower efficacy (measured as fetal asystole at 24 hours after administration) than intracardiac digoxin (RR 0.88 95%CI 0.81 - 0.96). Overall both routes of digoxin administration demonstrated high efficacy (93.8% intracardiac; 82.7% intraamniotic). Little or no difference was reported by White (2016) in pre-procedure expulsion and any adverse event between routes. Adverse event rates were low overall (2-5%). No instances of adverse reactions to digoxin such as chorioamnionitis, haemorrhage requiring transfusion, or need for additional surgery were reported in either RCT.

Potassium chloride (KCl) vs lignocaine

Chen et al (2009) compared intracardiac potassium chloride with intracardiac administration of lignocaine 2% in an RCT of feticide techniques prior to medical abortion conducted in Taiwan. This study reported little or no difference in efficacy (measured as fetal asystole at 3 mins after feticide administration). No instances of adverse reactions to medications were reported in either group.

Saline cardiac tamponade

In the Chen et al (2009) study a rescue procedure of instilling 10-20 mL of saline into the fetal pericardium was performed in cases where fetal asystole was not achieved with the primary medication. This procedure was effective in 100% of cases. The efficacy of this technique has not been studied in an RCT setting.

Intracardiac potassium chloride vs intraamniotic digoxin

No RCT evidence comparing these techniques was identified.

A prospective cohort study (Akalin et al 2022) compared intraamniotic digoxin, intracardiac KCl, and funic KCl (into the umbilical vein) for abortion of pregnancies with fetal anomaly between 22 and 31 weeks of gestation. All participants received antibiotic prophylaxis with 2g Cephazolin. All feticide methods had high efficacy rates. Success rates in achieving fetal asystole by 36 hours after the procedure were 93.0, 95.1, and 97.5% for intraamniotic digoxin, intracardiac KCl, and funic KCl, respectively. Intraamniotic digoxin was associated with shorter procedure times (68.6s intraamniotic digoxin vs 296.6s intracardiac KCl and 273.6s funic KCl), lower procedural difficulty scores (1.75 intraamniotic digoxin vs 4.82 intracardiac KCl and 5.13 funic KCl), and lower patient pain scores (2.42 intraamniotic digoxin vs 4.56 intracardiac KCl and 4.36 funic KCl, on VAS 1-10) (p-value <0.001). No cases of cardiac arrhythmias or ECG changes were detected in any treatment group and maternal serum digoxin levels remained under the therapeutic limit. Of note, in this study it was unclear how the method of feticide was chosen, raising the rise of selection bias.

Certainty of the evidence

Overall quality GRADEd as moderate. Studies downgraded for risk of bias and imprecision

Values and preferences

No acceptability or patient satisfaction outcomes were reported.

Resources

Additional considerations

Currently there is a global shortage of digoxin.

Summary

Out of scope.

Equity

Concerns raised by the guideline development group with the ability for rural and remote women in particular to access maternal fetal medicine (MFM) services.
Digoxin administered by the intraamniotic route was considered by the guideline development group to be safe and effective and able to be offered more widely, lessening any impacts on equity. Delay in achieving asystole with intraamniotic digoxin compared to other methods and routes of administration, requires longer interaction with medical services/multiple visits to the hospital which may impact on women who have travelled to another centre to obtain this service. When feticide has failed to achieve asystole consideration is often given to repeating the method or using an alternative further increasing equity impacts for those who have travelled to another centre to receive feticide services.

Acceptability

Intracardiac KCl administration is effective immediately, so success of the procedure is immediately apparent. If the procedure fails this can be dealt with immediately without requiring repeated contacts with the woman. For women who have been referred to another centre for feticide, intracardiac KCl success can be determined immediately enabling a quicker return to their referring hospital for induction of labour or surgical services.

Feasibility

Additional considerations

Ensure access to MFM to perform procedure for indications other than fetal anomaly.

Summary

Feticide by intracardiac injection may require additional training and technical skill, possibly requiring service provision by MFM clinicians or specialist training in this procedure. Intraamniotic administrations required skill in amniocentesis only and therefore may be able to be provided by a wider pool of clinicians without advanced MFM training.

PICO (17.2)

Population: women undergoing an abortion (medical or surgical) for which pretreatment-induced fetal death (feticide) is offered (any gestation)
Intervention: Pretreatment-induced fetal death (feticide) method A, in addition to usual abortion treatment (medical or surgical)
Comparator: Pretreatment-induced fetal death (feticide) method B, in addition to usual abortion treatment (medical or surgical)

Outcome Timeframe	Study results and measurements	Absolute effect estimates		Certainty of the evidence (Quality of evidence)	Plain language summary
		Comparator (listed second in outcome title)	Intervention (listed first in outcome title)		
Effectiveness - fetal asystole prior to D&E - intraamniotic vs intrafetal digoxin [SR] Tufa 2020	Relative risk: **0.88** (95% CI 0.81 - 0.96) Based on data from 317 participants in 2 studies	**938** per 1000	**825** per 1000 Difference: **113 fewer per 1000** (95% CI 178 fewer - 38 fewer)	**Very low** Lack of blinding, imprecision, wide confidence intervals[1]	Intraamniotic digoxin may decrease effectiveness (fetal asystole at 24hrs) compared to intrafetal digoxin for feticide prior to D&E
Pre-D&E expulsion of the pregnancy - intraamniotic vs intrafetal digoxin [RCT] White 2016	Relative risk: **2.58** (95% CI 0.51 - 13.05) Based on data from 268 participants in 1 study	**15** per 1000	**39** per 1000 Difference: **24 more per 1000** (95% CI 7 fewer - 181 more)	**Low** Due to serious risk of bias, Due to serious imprecision[2]	We are uncertain whether feticide using intraamniotic digoxin increases or decreases pre-D&E expulsion of the pregnancy compared to feticide using intrafetal digoxin due to a very wide confidence interval
Any adverse event - intraamniotic vs	Relative risk: **2.4** (95% CI 0.64 - 9.1)	**22** per 1000	**53** per 1000	**Low**	We are uncertain whether feticide using intraamniotic

intrafetal digoxin [RCT] White 2016	Based on data from 268 participants in 1 study	Difference: **31 more per 1000** (95% CI 8 fewer - 178 more)		Due to serious risk of bias, Due to serious imprecision[2]	digoxin increases or decreases adverse event rates compared to feticide using intrafetal digoxin due to a very wide confidence interval
Effectiveness - fetal asystole 3 minutes after procedure - intracardiac KCl vs intracardiac lignocaine 2% [RCT] Chen 2009	Relative risk: **0.67** (95% CI 0.41 - 1.1) Based on data from 26 participants in 1 study	**857** per 1000 Difference: **283 fewer per 1000** (95% CI 506 fewer - 86 more)	**574** per 1000	**Low** Due to serious risk of bias, Due to serious imprecision[3]	Use of intracardiac KCl may decrease effectiveness (fetal asystole 3 minutes after procedure) compared to intracardiac lignocaine 2% when used for feticide prior to medical abortion

1. **Risk of Bias: serious.** Inadequate sequence generation/ generation of comparable groups, resulting in potential for selection bias, Inadequate/lack of blinding of participants and personnel, resulting in potential for performance bias, Inadequate/lack of blinding of outcome assessors, resulting in potential for detection bias; **Inconsistency: no serious.** The magnitude of statistical heterogeneity was high; **Imprecision: no serious.** Wide confidence intervals.
2. **Risk of Bias: serious. Imprecision: serious.** Wide confidence intervals.
3. **Risk of Bias: serious.** Lack of blinding; **Imprecision: serious.** Wide confidence intervals.

Appendix F: Disclaimer

Purpose

This clinical practice guideline has been developed provide general advice to practitioners about performing abortion and counselling women who are considering an abortion and should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any person. It is the responsibility of each practitioner to have regard to the particular circumstances of each case. Clinical management should be responsive to the needs of the individual person and the particular circumstances of each case.

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