Queensland Clinical Guidelines

Translating evidence into best clinical practice

Maternity and Neonatal **Clinical Guideline**

Therapeutic termination of pregnancy

Queensland Government

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The guideline is not a substitute for clinical judgement, knowledge and expertise, or medical advice. Variation from the guideline, taking into account individual circumstances, may be appropriate.

This guideline does not address all elements of standard practice and accepts that individual clinicians are responsible for:

- Providing care within the context of locally available resources, expertise, and scope of practice
- Supporting consumer rights and informed decision making including the right to decline intervention or ongoing management
- Advising consumers of their choices in an environment that is culturally appropriate and which enables comfortable and confidential discussion. This includes the use of interpreter services where necessary
- Ensuring informed consent is obtained prior to delivering care
- Meeting all legislative requirements and professional standards
- Applying standard precautions, and additional precautions as necessary, when delivering care
- Documenting all care in accordance with mandatory and local requirements

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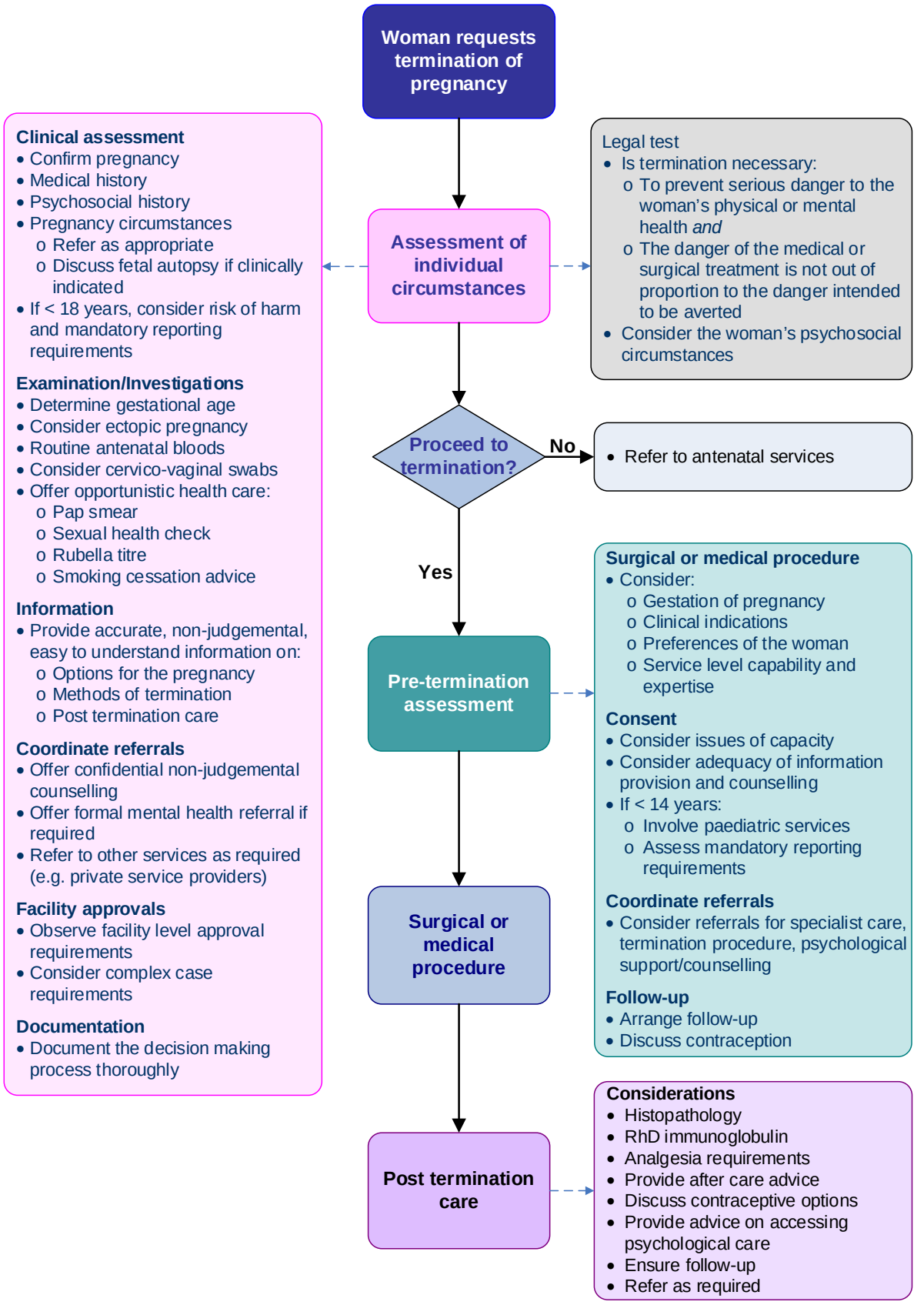
Flow Chart: Summary of therapeutic termination of pregnancy



Abbreviations: **<**: less than

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Abbreviations

ARTG	Australian Register of Therapeutic Goods
βhCG	Beta human chorionic gonadotropin
BP	Blood pressure
GP	General Practitioner
HHS	Hospital and Health Services
LAM	List of Approved Medicines (Queensland Health)
TGA	Therapeutic Goods Administration

Definition of Terms

Complex case	A complex case may be one in which: In the judgement of the treating health professional(s), there are circumstances that complicate the decision making process and/or care and management of a woman requesting termination of pregnancy. This may include (but is not automatically a requirement of or limited to) issues related to a woman's: • Medical, social or economic circumstances • Capacity to consent • Mental health • Age • Gestation of pregnancy at which termination of pregnancy is requested
Live birth[1]	The complete expulsion or extraction from its mother of a baby, irrespective of the duration of the pregnancy, which after such separation, breathes or shows any other evidence of life, such as beating of the heart, pulsation of the umbilical cord or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached. Each product of such a birth is considered live born.
Obstetrician	Local facilities may as required, differentiate the roles and responsibilities assigned in this document to an "Obstetrician" according to their specific practitioner group requirements; for example to Gynaecologists, General Practitioner Obstetricians, Specialist Obstetricians, Consultants, Senior Registrars and Obstetric Fellows.
Routes of Misoprostol administration[2]	Oral: pills are swallowed immediately Buccal: pills are placed between the cheek and gums and swallowed after 30 minutes Sublingual: pills are placed under the tongue and swallowed after 30 minutes Vaginal: pills are placed in the vagina fornices (deepest portions of the vagina) and the woman is instructed to lie down for 30 minutes
Young person	In this document a *young person* refers to a person less than 18 years of age

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1 Introduction

Therapeutic termination of pregnancy as used in this document refers to the deliberate ending of a pregnancy[3] where necessary to preserve the woman from a serious danger to her life or physical or mental health. The purpose of this guideline is to assist health professionals to provide care to women requesting therapeutic termination of pregnancy.

1.1 Queensland law

In Queensland, it is unlawful to administer a drug or to perform a surgical or other medical procedure intending to terminate a pregnancy unless such conduct is authorised, excused, or justified by law. It is also a crime for a woman to allow a termination of pregnancy to be carried out. Specifically, Section 224 of the *Criminal Code Act 1899*[4] (the Code) provides that:

> *any person who, with intent to procure the miscarriage of a woman, whether she is or is not with child, unlawfully administers to her or causes her to take any poison or other noxious thing, or uses any force of any kind, or uses any other means whatever, is guilty of a crime, and is liable to imprisonment for 14 years.*

Section 225 provides that:

> *any woman who, with intent to procure her own miscarriage, whether she is or is not with child, unlawfully administers to herself any poison or other noxious thing, or uses any force of any kind, or uses any other means whatever, or permits any such thing or means to be administered or used to her, is guilty of a crime, and is liable to imprisonment for 7 years.*

A defence to a charge under Section 224 can be found in Section 282 of the Code, which provides that criminal responsibility will not attach if a surgical operation or medical treatment (where the intention is to adversely affect the unborn child) is provided:

- In good faith and
- With reasonable care and skill and
- It is to preserve the mother's life and
- Performing the operation or providing the medical treatment is reasonable, having regard to the patient's state at the time and to all the circumstances of the case

1.1.1 Case law decisions

The Code itself does not consider the meaning of "unlawful" or describe conduct that would be considered "unlawful" however a Victorian common law decision *(R v Davidson)*[3] provided that a termination of pregnancy is lawful on therapeutic grounds if the practitioner honestly believes on reasonable grounds that the act done was:

- Necessary to preserve the woman from a serious danger to her life or physical or mental health (not being merely the normal dangers of pregnancy and childbirth) and
- In the circumstances, not out of proportion to the danger to be averted

In this case, Justice Menhennitt ruled that the Crown would have to prove beyond reasonable doubt:

- That the accused performed an unlawful abortion and
- That the accused did not honestly believe on reasonable grounds that the abortion was necessary to preserve the woman from serious danger to her life or her physical or mental health and
- That the abortion was not proportionate to the danger presented by the pregnancy

This decision was extended by Justice Levine in *R v Wald*[5] in New South Wales to include socioeconomic reasons that may form the reasonable grounds upon which a practitioner could honestly and reasonably believe there would result a serious danger to the woman's physical or mental health.

Davidson's case[3] was accepted into Queensland law in *R v Bayliss & Cullen*[6]. The Judge stated that in order for a termination to be lawful, the doctor must honestly and reasonably believe that the continuation of the pregnancy would result in a serious danger to the woman's physical or mental health. These reasonable grounds can stem from social, economic or medical bases. Justice Macguire also stated:

> *It may be that an honest belief be held that the woman's mental health was in serious danger at the very time when she was interviewed by a doctor, or that her mental health, although not then in serious danger, could reasonably be expected to be seriously endangered at some time during the currency of the pregnancy, if uninterrupted.*

Justice Macguire opined that in his view, the phrase 'for the preservation of the mother's life' in the context of abortion law in Queensland has a more or less judicially settled meaning based on these prior judicial interpretations.

In a later Queensland civil court decision[7], Justice de Jersey held that Section 282 would stand as such a defence, and also that a relevant serious risk to the mother could arise not only during the term of the pregnancy but even after the birth of the child. This view has been approved and applied by Justice Kirby[8] who further noted that, in light of growing recognition of postnatal depression and other 'serious economic and social pressures', the dangers of pregnancy have to be evaluated as they apply to each woman.

One legal academic has noted that in a criminal context, the standard of proof required (beyond reasonable doubt) coupled with the Crown having to prove that a doctor did not hold an honest belief makes Section 224 of the Criminal Code an extremely difficult conviction for the Crown to achieve.[9]

1.1.2 Lawful direction of a health professional

Section 282 of the Code particularly identifies that if the administration by a health professional of a substance to a patient would be lawful, the health professional may lawfully direct or advise another person to administer the substance to the patient or procure or supply the substance for that purpose.

And further that:
It is lawful for a person acting under the lawful direction or advice, or in the reasonable belief that the advice or direction was lawful, to administer the substance, or supply or procure the substance, in accordance with the direction or advice.

NOTE: The legal commentary above should not be relied upon as legal advice for any particular patient circumstance. Health professionals may seek legal advice if necessary through the Hospital and Health Services (HHS) usual arrangements after first consulting with the Executive Director of Medical Services or equivalent

2 Indemnity

Queensland Health provides indemnity to health care practitioners as outlined in the relevant Human Resource Policies.[10,11] All staff should familiarise themselves with the terms of the Human Resource policy relevant to their employment.

If a medical practitioner is notified that he/she is being investigated by the Australian Health Practitioner Regulation Agency or the Queensland Police Service, Queensland Health will appoint and instruct solicitors to provide legal representation for and legal assistance to a medical practitioner who is being investigated, or has been charged with a criminal offence pursuant to the terms of the policy.[11]

3 Clinical standards

Where service level capabilities, as defined in the Clinical Services Capability Framework[12], are insufficient to provide termination of pregnancy services, establish referral and transfer systems with other service level facilities[2] in accordance with the Clinical Services Capability Framework.[12]

Table 1. Clinical standards

Aspect	Good Practice Point
Access	• Women requesting termination of pregnancy require assessment by a medical officer (who is not a conscientious objector) • Where termination of pregnancy is considered lawful [refer to Section 4 Individual case considerations] but the service is not locally available, support women to access the service as would occur for any specialist procedure as per local HHS policy for consultation and referral • Provide documented information to consumers, external service providers and support agencies within the local HHS on the choices available within the service, and on routes of access to these services • Facilitate access to termination of pregnancy services as early as possible in the pregnancy to reduce the likelihood of associated health risks[2] • Ideally, offer an assessment appointment within 5 days of referral[13] • Provide dedicated clinic time for the assessment appointment[13] separate from antenatal clinics where feasible • Ideally, provide termination of pregnancy within 2 weeks of the decision to proceed being agreed[13]
Referral	• Document referral pathways within the HHS (e.g. between departments within a facility, between facilities and between a facility and external agencies and GPs) • Consider engagement with statewide external service providers and agencies in the development of referral pathways and mechanisms • Provide documented referral pathways to external service providers, agencies and GPs • Inform health care professionals in contact with women seeking termination of pregnancy (e.g. in emergency departments, GPs) about the referral pathways • Where the woman considers but does not proceed to termination of pregnancy, provide information and access to appropriate referral pathways (e.g. access to a social worker, referral for antenatal care)
Care setting	• A multidisciplinary and coordinated approach is required so as to avoid unnecessary delay in the provision of care • The most appropriate care setting for termination of pregnancy is dependent on the: o Method of termination of pregnancy chosen o Gestation of the pregnancy[2] o Preferences of the woman and her care provider o The service capabilities of the facility[12] • Ensure there are local arrangements for the safe and sensitive handling, storage and disposal of fetal tissue[14]
Workforce	• Health care professionals may decline to provide termination of pregnancy care on the basis of conscientious objection: o Where there is conscientious objection to involvement with termination of pregnancy care[2,15], health care professionals have a professional responsibility to ensure appropriate transfer of care occurs within a reasonable time frame for the circumstances • Educate providers and referrers about the service, the pathways, any service limitations and their professional responsibilities • For health professionals involved in the provision of termination of pregnancy services: o Provide ongoing training and education[2] o Offer counselling and debriefing support

3.1 Birth registration

Table 2. Registration requirements

Gestation/Birth weight	Signs of life	Requirement
Less than 20 weeks **AND** less than 400 grams	Not live born	• Birth registration not required • Death certificate not required • Burial/cremation not required
Less than 20 weeks **AND** less than 400 grams	Live born	• Birth registration required • Death certificate required • Burial/cremation required
Greater than 20 weeks **OR** more than 400 grams	Not live born Live born	

3.2 Facility level approval

The purpose of facility level approvals is to establish and document a considered process for the woman and to provide reassurance and support to the health practitioner. Each facility should determine the local approval structure and mechanisms appropriate to its service. While not a legal requirement, it is strongly recommended that the treating obstetrician observe such requirements. Suggested approval mechanisms are outlined in Sections 3.2.1–3.5.2.

3.2.1 All cases

- Two medical specialists, one of whom must be a specialist obstetrician, consider the circumstances of each individual case
  - Ideally, one specialist should be the practitioner performing or overseeing the procedure
  - The speciality of the second medical practitioner should be relevant to the circumstances of the individual case
- Consider local facility approval requirements. This may include notification to/approval from the Executive Director of Medical Services or equivalent (e.g. Medical Superintendent)

3.2.2 Complex cases

Where there are complex issues present [refer to Definition of terms], a case review is recommended to consider the complexities specific to the individual case.

- In addition to the treating obstetrician, include a minimum of one other health professional in the case review *as appropriate for the individual case*
  - Other health professionals *may* include (but are not limited to) a social worker, psychiatrist, obstetrician, general practitioner, maternal fetal medicine specialist or paediatrician,
  - Other members of the case review *may* include (but are not limited to) a lawyer, ethicist, religious officer or sexual assault worker
- The case review members consider all the circumstances and provide an opinion to the treating obstetrician and the Executive Director of Medical Services (or equivalent) on whether or not the criteria for termination of pregnancy under Section 282 are met. [refer to Section 1.1 Queensland law]

4 Individual case considerations

The decision to provide a termination of pregnancy is made in partnership with the woman (and her family, where appropriate) and her health care professional. It is led by the woman's health needs and concerns.

4.1 Legal test for each case

All health professionals involved in termination of pregnancy should be familiar with the legal requirements of the Criminal Code[4] as it pertains to termination of pregnancy.[15]

Consider each woman's circumstances on an individual basis.

- The legal test that ought to be applied in each individual case is:
  - Whether a termination of the pregnancy is necessary to preserve the woman involved from a serious danger to her life or her physical or mental health **and**
  - That in the circumstances, the danger of the medical treatment or surgical operation is not out of proportion to the danger intended to be averted
- Assess the legal test in light of the woman's:
  - Social and
  - Economic and
  - Medical circumstances
- An abnormal fetus with high likelihood for disability or death is not of itself a basis for termination being lawfully performed. Therefore this issue should be explored as to how it affects the woman
  - It may be important to have documented advice from a paediatrician regarding the prognosis for the fetus if the pregnancy were to continue.

4.2 Consent

Where termination of pregnancy has been agreed, informed written consent must be obtained prior to commencement.[16] The process of gaining consent includes:

- Assessment of capacity (whether an adult or young person) [refer to Sections 4.2.1–4.2.3]
- Discussion of the available methods of termination of pregnancy
- Discussion of the risks and complications of each method of termination of pregnancy [refer to Appendix A Complications of termination of pregnancy]

4.2.1 Capacity to consent

The legal test for capacity in adults is found in Schedule 3 of the Powers of Attorney Act 1998 (Qld), namely that the person:

- Understands the nature and effect of decisions about the matter
- Freely and voluntarily makes decisions about the matter and
- Communicates the decisions in some way

4.2.2 Adults who lack capacity

If an adult does not have the capacity to consent, the Queensland Civil and Administrative Tribunal may consent for an adult to undergo a termination of pregnancy "only if the Tribunal is satisfied the termination is necessary to preserve the adult from serious danger to her life of physical or mental health". Termination of a pregnancy of an adult is considered to be "special health care" under the Guardianship and Administration Act 2000 (Qld) and is not a matter for which a legal guardian or substitute decision maker can provide consent.

4.2.3 Young person

A young person is generally considered to be one who has not yet attained the age of 18 years.

- A *Gillick* competent young person can give consent to medical procedures as would an autonomous adult.
- A young person is considered *Gillick* competent when she achieves a sufficient understanding and intelligence to enable her to understand fully what medical treatment is proposed[17]
- The law leaves the decision about whether a young person is *Gillick* competent to the individual practitioner
  - Documentation should evidence that the young person has sufficient understanding to comprehend in general terms:
    - The nature of their clinical condition
    - The nature and purpose of the proposed treatment
    - The effects of the treatment including side-effects
    - Consequences of non-treatment
    - Other treatment options including continuing with the pregnancy
    - Possible repercussions of the proposed treatment
- Consider other elements of informed consent when obtaining consent from a *Gillick* competent young person (e.g. the ability to freely and voluntarily make decisions without coercion) [refer to Section 4.2.1 Capacity to consent]
- When considering what is in the best interests of the young person, the doctor should encourage the young person to involve her parents/guardians in decision making and consultation. This step should be regarded as important and routine in the context of termination of pregnancy decisions, although it will not always be agreed to by the young person. The law requires that when a competent young person refuses to include her parents/guardians in consultation, this must be respected and her confidentiality not breached
- Where termination of pregnancy is being sought for a young person deemed not *Gillick* competent, particular consideration must be given to the individual circumstances of each case. While a parent or legal guardian generally would have legal authority to consent to most treatment on behalf of a young person deemed not *Gillick* competent, termination of pregnancy requires a court's sanction to authorise the treatment as in Queensland, a young person's parents are not able to consent to a termination of pregnancy. This is a decision that must be made by the Court acting in the best interests of the young person. These cases should be escalated to the Executive Director of Medical Services or equivalent (e.g. Medical Superintendent) for urgent attention
- Report any reasonable suspicions of child abuse and neglect to Child Safety Services in the Department of Communities, Child Safety and Disability Services[18-20]
- Involve paediatric and mental health services for assessment of *Gillick* competency, psychosocial assessment and family court matters *where clinically indicated*

4.2.4 Young person less than fourteen years

Individual HHS's should determine their individual capability to provide termination of pregnancy services for young people less than 14 years.

Where the young person is less than 14 years refer to Section 4.2.3 Young person and:

- Involve social worker support
- Provide pre-termination of pregnancy psychological counselling from an appropriately qualified health care professional [refer to Section 5 Psychological support]
  - Include documented evidence of the pre-termination of pregnancy counselling in the medical record
- Report any reasonable suspicions of child abuse and neglect to Child Safety Services in the Department of Communities, Child Safety and Disability Services[18-20]
  - Sexual activity in a young person under 14 years is a mandatory report to the Department of Communities' Child Safety Services for Queensland Health employees[21]
- Involve paediatric and mental health services for assessment of *Gillick* competency, psychosocial assessment and family court matters

4.3 Documentation of decisions

When both doctors reasonably believe that the termination of pregnancy meets the requirements of the legal test then this should be documented by both doctors.

- Documentation should evidence:
  - Clinical opinion relevant to the circumstances that will form the basis of serious danger to the woman's life or her physical or mental health
  - Clinical opinion as regards the proportionality test, namely the reasons why the option of termination of the pregnancy will, on balance, avert the serious risk that has been identified
  - A detailed and well documented informed decision making process[16] [refer to Section 4.2 Consent]
  - Individual clinical assessment of the woman [refer to Section 4 Individual case considerations and Section 5 Psychological support]
- Document facility level approvals [refer to Section 3.2 Facility level approval]
- Document all decisions including what was done to meet the duty of care if the termination of pregnancy is not provided [refer to Table 1. Clinical standards]

5 Psychological support

Involve social worker support in the care of women requesting and accessing termination of pregnancy services.

Table 3. Information and counselling

Aspect	Good practice points
Information	• Support the decision making process by providing accurate, impartial and easy to understand information[2] including[22,23]: o Options to continue the pregnancy and parent the child o Options to continue the pregnancy and place the child for foster care/adoption o Information about methods of termination of pregnancy[23] o Post-termination of pregnancy considerations including contraceptive options and counselling support o Discuss birth registration requirements
Counselling	• Offer confidential, nonjudgemental support and counselling[2,15,24] • Counselling should be provided by someone (e.g. social worker, psychologist, counsellor) who: o Is appropriately qualified and/or trained[2] o Is familiar with the issues surrounding termination of pregnancy o Has no vested interest in the pregnancy outcome[22] • Where feasible, offer counselling 'close to home' to aid the establishment of longer term counselling support • Consider the requirement for formal mental health referral especially if there is a history of mental illness[25]

Table 4. Mental health considerations

Considerations	
Evidence	• There are significant limitations in the evidence examining the relationships between unwanted pregnancy, termination of pregnancy, birth and mental health[26] • For the majority of mental health outcomes, there is no statistically significant association between pregnancy resolution and mental health problems[26] • An unwanted pregnancy may lead to an increased risk of mental health problems, or other factors may lead to both an increased risk of unwanted pregnancy and an increased risk of mental health problems[26] • When a woman has an unwanted pregnancy, rates of mental health problems will be largely unaffected whether she has a termination or goes on to give birth[26] • Women with a past history of mental health problems are at increased risk of further problems after an unintended pregnancy[13]
Recommendation	• Offer referral to a mental health service where there is a pre-existing mental health problem[26] • Consider the need for support and care for all women who request a termination of pregnancy, because the risk of mental health problems increases whatever the pregnancy outcome[26] • Involve social worker support where feasible

6 Pre-termination assessment

Pre-termination assessment including counselling and psychosocial support services [refer to Section 5 Psychological support] should be offered 'close to home' where feasible. Components of the pre-termination clinical assessment are outlined in Table 5.

Table 5. Assessment prior to termination of pregnancy

Aspect	Good practice points
Circumstances of pregnancy	• Obtain a full picture of the circumstances leading to the request for termination of pregnancy[14] o Offer referral to other services as appropriate – especially where risk factors are identified (e.g. young women, women with physical or intellectual disabilities, mental illness, rape or sexual assault, domestic violence, fertility issues and cultural beliefs/values[2,14]) • Offer fetal autopsy if clinically indicated (e.g. if there is fetal abnormality) o Usual consent processes and counselling are required [refer to Queensland Clinical Guideline: Stillbirth care[27]]
Medical history	• Date of last menstrual period[2] • Gynaecological, obstetric, and sexual health history[2] • Past and current medical history[2,24,28]
Clinical exam and investigations	• Physical exam as indicated by medical history and symptoms including: o Vital signs: temperature, blood pressure (BP), pulse[28] • Confirm the diagnosis of pregnancy[28] and location by ultrasound, urinary or serum βhCG assay[22,24] • Determine gestational age[2,24,28] as this may impact on choice of termination method o Consider ultrasound to confirm gestation[23] and obtain in all cases of second trimester procedures[22] • Consider ectopic pregnancy and evaluate further if clinically indicated[23,28] • Consider cervico-vaginal swabs to allow treatment of bacterial infections prior to termination of pregnancy[29] o If bacterial vaginosis suspected/confirmed treat with Metronidazole before the termination[22] • Routine antenatal screening o Haemoglobin[22,23] o Blood group and Rh status to identify Rh negative women for administration of RhD immunogloblulin[22,24,28]
Opportunistic health care	• Consider opportunistic health screening or advice. For example: o Pap smear[2,22] o Sexual health check o Rubella titre o Smoking cessation advice[24]
Referral coordination	• Consider the requirement for timely referral and coordination with other facilities/disciplines/agencies.[14,29] For example: o Specialist medical assessment (e.g. cardiologist, clinical genetics services, tertiary imaging) o Psychosocial counselling/support o Mental health support/treatment o Termination of pregnancy procedure • Arrange a follow-up appointment to facilitate[24,28]: o Assessment of physical recovery o Confirmation of procedure success[28] o Discussion of ongoing contraception[30] o Consideration of emotional issues and counselling as necessary
Contraception	• Promote and facilitate commencement of contraception at the time of termination of pregnancy or immediately after[2,24]: o Intrauterine devices may be inserted immediately post-termination if clinically appropriate[31]

6.1 Other pre-termination considerations

Table 6. Pre-termination considerations

Aspect	Good practice points
Method of termination	• A pregnancy may be terminated using a medical or surgical approach or a combination of the two[24] • The choice of method may be dependent on local clinician expertise and service capabilities as well as availability of pharmacological agents[24] and the woman's preference • There is limited evidence that examines the acceptability and side effects of medical compared to surgical first trimester termination of pregnancy[32] • Prostaglandins used alone seem to be less effective and more painful compared to surgical first trimester termination of pregnancy[32] • Complications and risks should be discussed in a way the woman can understand and should emphasise the overall safety of the procedure[13]
Selective/non-selective reduction	• If selective reduction or non-selective reduction in multiple pregnancy is required, consider individual circumstances on a case by case basis confirming with the principles outlined in preceding Sections
Feticide	• Usually for gestations greater than 22 weeks • Refer the woman to the closest Level 6 facility with the capability to provide this service[12] • If feticide is clinically indicated this should normally be undertaken by injection of intracardiac potassium under ultrasound guidance • Post feticide, a woman may be transferred to another facility for birth if this is considered clinically safe and there is a robust referral process and comprehensive documentation
Live birth	• Consider the potential for a live birth and discuss with the woman if appropriate: o Ensure there are local procedures for the management of live birth o Offer counselling and support services if live birth occurs.

7 Medical termination

Medical termination of pregnancy is one where drugs are used to induce the termination.[24] It may be considered at all gestations of pregnancy. Mifepristone (RU486) in combination with other agents is frequently cited in international literature as the preferred regimen for medical termination of pregnancy.[2,14,23,28,33,34]. However, Misoprostol alone is also common, especially in settings in which Mifepristone is not available.[35] Gemeprost may also be used for second trimester terminations[2] at the discretion of the treating obstetrician.

Where local protocols are not well established or do not exist, suggested protocols are provided in:

- Appendix B Mifepristone and Misoprostol protocol
- Appendix C Misoprostol alone protocol
- Appendix D 2nd trimester Misoprostol protocol for increased risk of uterine rupture

Refer to the Australian product information for complete drug information.

7.1 Precautions for medical termination

Medical methods of abortion have been shown to be safe and effective[2,33] Uterine rupture is a rare complication associated with later gestational age and prior uterine surgery.[2,36-38] Although causality has not been established, serious infections and bleeding occur very rarely following use of Mifepristone for medical termination of pregnancy.[39] Bacterial infection may present without fever or abdominal pain.

Table 7. Contraindications and cautions for medical termination

Aspect	Good practice points
Contraindications	• Known hypersensitivity or allergy to prostaglandins or any component of the product[35] • Suspected or confirmed ectopic pregnancy[35] • Gestational trophoblastic disease[35] • Intrauterine device (must be removed prior to termination)[35] • Obstructive cervical lesions (e.g. fibroids)[40] • High suspicion of placenta accreta • High risk of uterine rupture[35] (consider individual circumstances[41]–may still be suitable in women with history of caesarean section or multiple pregnancies or who have uterine abnormalities[42])
Cautions	• Cardiovascular disease – monitor cardiovascular status closely as prostaglandins may cause transient BP changes[43] • If membranes are ruptured consider IV Oxytocin (Syntocinon) due to the increased risk of infection

7.2 Outpatient care

The most appropriate setting for medical termination of pregnancy requires consideration of the local service capabilities and the individual circumstances of the woman including geographic distances to be travelled should emergency care be required. Involve social worker support where appropriate. Women cared for on an outpatient basis should:

- Be less than 9 weeks gestation
- Be accompanied by a support person, who has been adequately informed about what to expect, until the termination of pregnancy is complete[34]
- Have immediate access to transport and telephone
- Be able to communicate by telephone (e.g. have an interpreter available if required)
- Have the capacity to understand and follow instructions
- Be able to access a healthcare facility
- Have follow-up arrangements in place

7.3 Mifepristone

Table 8. Mifepristone considerations

DRUG	*MIFEPRISTONE[39] (Antiprogesterone and antiglucocorticoid)
Indications	• Termination of first or second trimester pregnancy with Misoprostol
Contraindications[39]	• Refer to Table 7 for cautions and contraindications to medical termination of pregnancy • Contraindicated in: o Adrenal failure/insufficiency o Severe hepatic failure o Some gynaecological conditions (e.g. serious pelvic infection[41]) o Some haematological conditions (e.g. inherited porphyria) o Concurrent anticoagulants o Potential for serious Cytochrome P450 (CYP) drug interactions
Precautions[39]	• Renal or hepatic impairment (dosage adjustment recommended) • Severe anaemia, haemostatic disorders or hypocoagulability • May reduce efficacy of long term corticosteroids for 3–4 days after use[43]
Approval for use	• In August 2012 Marie Stopes International Australia successfully applied to register Mifepristone with the Therapeutic Goods Administration (TGA) and is the sponsor of the medicine • Mifepristone 200 mg tablet is included on the Australian Register of Therapeutic Goods (ARTG) and is indicated in females of childbearing age for[44]: o Medical termination of a developing intrauterine pregnancy in sequential combination with a prostaglandin analogue up to 49 days of gestation o Preparation for the action of registered prostaglandin analogues that are indicated for the termination of pregnancy for medical reasons beyond the first trimester • Access and distribution is controlled by the sponsor and is limited to sponsor recognised practitioners and pharmacies • Refer to the sponsor for practitioner recognition requirements
Presentation	• Tablet 200 milligrams (mg)
Dosage	• The effect of Mifepristone is not decreased by lowering the dose from previously recommended 600 mg to 200 mg when combined with at least 400 micrograms of Misoprostol[33] • Refer to Appendix B or C for suggested protocol
Administration	• Oral
Efficacy	• A combination regimen with a prostaglandin analogue is more effective than use of either medication as a single analogue agent[33] • The failure rate of first trimester medical termination with Mifepristone and Misoprostol is slightly higher (2–7%) than that for surgical termination[45]
Adverse effects	• Side effects are dose dependent[46] and are frequently reported in combination with Misoprostol use. They most commonly include: o Nausea, vomiting diarrhoea[23,33] o Headache, dizziness, fatigue[23,45] o Thermoregulatory[23,30] (hot flushes, low grade temperature) • Abdominal pain and cramps[40] • Prolonged vaginal bleeding[45] • Adrenal insufficiency, bacterial infection, hypokalemia and QT interval prolongation have been reported[39]

*Caution: refer to the Australian product information for complete drug information

7.4 Misoprostol

Table 9. Misoprostol considerations

DRUG	*MISOPROSTOL (Prostaglandin E1 analogue)
Indications	• To ripen the cervix before surgical termination of first or second trimester pregnancy[43] • Termination of second trimester pregnancy[43] • Medical termination of first or second trimester pregnancy with Mifepristone[43]
Precautions	• Refer to Table 7 for cautions and contraindications to medical termination of pregnancy • Asthma, Chronic Obstructive Pulmonary Disease – prostaglandins may cause bronchospasm[43] • Predisposition to diarrhoea (e.g. inflammatory bowel disease)[43] • Epilepsy[45]
Approval for use	• In August 2012 *Marie Stopes International Australia* successfully applied to register Misoprostol with the TGA • Misoprostol is included on the ARTG and is indicated for females of childbearing age for medical termination of a developing intrauterine pregnancy in sequential combination with a Mifepristone 200 mg tablet up to 49 days of gestation[44] • Queensland Health approves the use of Misoprostol for obstetric/gynaecologic indications when[47]: o Prescribed by a specialist for the therapeutic termination of a pregnancy (or the management of missed abortion) o Informed consent that includes awareness of the TGA status of the drug has been obtained
Presentation	• Tablet 200 micrograms[47]
Dosage	• The optimal dosing regimen is uncertain.[22,30,33,36,48] Dose and dosing interval should be selected so as to generate sufficient and sustained uterine activity while minimising adverse effects[35] • The sensitivity of the uterus to prostaglandins increases with gestational age therefore decreasing amounts of Misoprostol may be required with increasing gestational age.[35,46] Adjust dose based on clinical experience and judgement • Refer to Table 10 and Table 11 for cervical priming regimens • Refer to Appendix B, C or D for relevant termination of pregnancy protocols
Administration	• Oral • Buccal/sublingual • Vaginal (oral tablets are administered intravaginally)
Efficacy	• Vaginal Misoprostol is more effective than oral Misoprostol with fewer side effects[23,49] • Sublingual or buccal Misoprostol are similarly effective to vaginal Misoprostol however they have higher rates of side effects[33] • Misoprostol is as effective as other preparations in effecting vaginal birth within 24 hours[5,48,49] • In comparison to other prostaglandin preparations (Gemeprost, Prostaglandin E_2 and Prostaglandin F_2 alpha), Misoprostol, is more cost effective, more stable at room temperature and has fewer side effects[36,41,48]
Adverse effects	• Adverse effects increase with gestational age[50] • Side effects are dose dependent[46] and most commonly include: o Nausea, vomiting diarrhoea[23,33] o Headache[23] o Thermoregulatory[23,30] (hot flushes, low grade temperature) o Abdominal pain and cramps[40]

*Caution: refer to the Australian product information for complete drug information

8 Surgical termination

Surgical curettage is generally suitable for gestations of pregnancy up to 14 weeks. If the pregnancy is between 14 and 16 weeks gestation, the procedure should only be performed by experienced practitioners[2]. The procedure may be preceded by cervical priming.[2,24]

8.1 Cervical priming

- Cervical preparation decreases the length of the termination procedure.[51] It may also[22,51]:
  - Reduce complications of uterine perforation and cervical injury
  - Make the procedure easier to perform
  - Make the procedure more comfortable for the woman
- Routine cervical preparation is recommended[2,36]:
  - For women less than 18 years of age
  - For nulliparous women
  - After 12–14 weeks of gestation (although may be considered at any gestational age)[2,15]
- Cervical priming can be accomplished using[2,22,28,51]:
  - Osmotic dilators (e.g. Laminaria–not included in the Queensland Health List of Approved Medicines (LAM))
  - Pharmacological agents:
    - Refer to Table 10. Misoprostol alone for cervical priming or
    - Refer to Table 11. Mifepristone and Misoprostol for cervical priming prior to surgical termination
    - Gemeprost may also be used at the discretion of the treating obstetrician[2]

8.1.1 Misoprostol alone regimen

Table 10. Misoprostol alone for cervical priming prior to surgical termination

***MISOPROSTOL alone regimen**	
Precautions	• Refer to Table 7. Contraindications and cautions for medical termination of pregnancy • Refer to Table 9. Misoprostol considerations
Dosage	**3–4 hours prior to surgery[2,13]** • 400 micrograms[51] inserted into the posterior fornix of the vagina **OR** **2–3 hours prior to surgery[2,13,51]** • 400 micrograms oral, sublingual or buccal

*Caution: refer to the Australian product information for complete drug information

8.1.2 Mifepristone and Misoprostol regimen

Table 11. Mifepristone and Misoprostol for cervical priming prior to surgical termination

***MIFEPRISTONE and MISOPROSTOL regimen**	
Precautions	• Refer to Table 7. Contraindications and cautions for medical termination of pregnancy • Refer to Table 8. Mifepristone considerations • Refer to Table 9. Misoprostol considerations
Day 1: Pre-dose care	• May occur as an outpatient • Baseline maternal observations (temperature, Blood Pressure (BP) and pulse) o If BP greater than 140/90 on two consecutive readings 15 minutes apart then withhold Mifepristone and seek obstetrician review
Day 1: Dosage (24–36 hours prior to procedure)	• Mifepristone 200 mg oral[39,40]
Day 1: Post-dose care	• Check BP 15 minutes after Mifepristone administration • Observe for 1 hour post Mifepristone administration in case of nausea and vomiting
Day 2 (Day of procedure)	• If less than 14 weeks gestation: o Misoprostol 400 micrograms, oral, sublingual or buccal 2 hours prior to procedure • If greater than 14 weeks gestation: o Misoprostol 400 micrograms, oral, sublingual or buccal, 4 hours prior to the procedure and then again 2 hours prior to procedure

*Caution: refer to the Australian product information for complete drug information

Adapted from Royal Brisbane and Women's Hospital Work Unit Guideline: *Administration of Mifepristone and Misoprostol in medical induction of labour at less than 28 weeks gestation where a live birth is not the expected outcome*

8.2 Considerations for surgical curettage

Table 12. Considerations for surgical termination

Aspect	Good practice points
Indications	• Generally for gestations up to 14 weeks
Prophylactic antibiotics	• Perioperative prophylactic antibiotics are recommended[2,22,28]
Anaesthesia	• The method chosen may depend on service capabilities and the woman's choice[24] • The procedure may be performed with or without oral or intravenous tranquilliser.[24] Generally analgesics, local anaesthesia and/or mild sedation are sufficient[2]
Oxytocic agents	• May decrease the risks of haemorrhage but not routinely recommended for vacuum aspiration[2,13]
Ultrasound	• May be used to check completeness • Routine use not required[13] at less than 12 weeks
Examination of tissue	• Examination of the products of conception by the surgeon may assist with recognition of gestational trophoblast and exclude ectopic pregnancy[2,24] • Histopathology if clinically indicated
Effectiveness of procedure	• Highly effective but failure does occur[24] • Continuing pregnancy rate reported to be 2.3 per 1000 women[24]
Side effects	• Pain: analgesia is usually required (e.g. Non-steroidal antiinflammatory drugs)[2] • Bleeding: expected duration 5–18 days[24] • Nausea: usually related to prostaglandins or anaesthetic drugs[24]
Risks and complications	• Serious complications are rare[24] • Risk rises with[28,36]: o Operator inexperience o Gestational age • Refer to Appendix A for specific risks and complications

9 Post-termination care

Most serious complications are detectable in the immediate post-procedure period.[28] Appropriate and accessible follow-up care is essential.[28]

Table 13. Post-termination care considerations

Aspect	Good practice points
Histopathology	• Consider histopathological examination of tissue obtained during termination procedures if clinically indicated
Rh prophylaxis	• Recommend RhD immunoglobulin to all non-sensitised RhD negative women within 72 hours following termination of pregnancy[28] • Less than 13 weeks gestation 250 IU RhD immunoglobulin via intramuscular injection[2,52] • 13 or greater weeks gestation 625 IU RhD immunoglobulin via intramuscular injection[2,52]
Analgesia	• Individually determine analgesia requirements after surgical termination or during and after medical termination as requirements vary[36] • Offer medication for pain management[2] • Clinical surveillance is required as pain may be indicative of uterine perforation or clot retention[2]
Post-procedural care	• Provide routine post-procedural care including assessment of vital signs, consciousness and observation of vaginal loss[2]
Discharge	• Determine timing of discharge on an individual basis • Consider routine discharge criteria (e.g. vital signs stable, recovery from effects of sedation/anaesthesia)
Aftercare advice	• Refer to Appendix E: Aftercare advice • Provide written information regarding possible symptoms and emergency care [2,35] • Document the provision of aftercare advice[28]
Follow-up	• Refer to Section 5 Psychological support • Promote continuity of care to facilitate the development of longer term support opportunities • Offer or advise the woman to obtain a follow-up appointment[30] within 6–8 weeks of the procedure. This may be within the termination service or with the referring service • Schedule an appointment for provision of pathology results (where appropriate), especially where there was histopathology/autopsy for fetal abnormality • Provide a letter that gives sufficient information about the procedure to allow another practitioner elsewhere to deal with any complications[13] • Offer referral for further counselling, especially where risk factors for long-term post-termination distress are evident (e.g. ambivalence before the termination, lack of a supportive partner, a psychiatric history or membership of a religious or cultural group that considers termination of pregnancy wrong)[13] • Provide information on accessing support agencies/organisations appropriate to individual circumstances (e.g. General Practitioner, grief counselling or support groups) • Offer information and assistance as appropriate regarding birth registration and funeral arrangements • Offer referral to medical specialists as clinically appropriate (e.g. clinical genetics services)

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Appendix A: Complications of termination of pregnancy

Complication	Comments
Retained products of conception	• Uncommon following surgical termination • Requirement for surgical evacuation of retained products increased following medical termination
Infection	• Risk reduced if: o Prophylactic antibiotics are given[13] o Lower genital tract infection has been excluded by bacteriological screening[13]
Cervical trauma	• Rates vary. Risk of damage to the external cervical os at the time of surgical termination is no greater than 1 in 100[13] • Decreased risk with: o Experienced clinician[13] o Use of preoperative cervical priming[22] o Earlier gestations[13]
Haemorrhage	• May be more common following medical termination of pregnancy (bleeding may persist up to 45 days) but evidence is not conclusive[13] • Risk is lower at earlier gestations o Less than 13 weeks: 0.88 in 1000 terminations[13] o Greater than 20 weeks: 4 in 1000 terminations[13]
Uterine perforation	• Risk at the time of surgical termination is 1–4 in 1000[13] • Decreased risk of uterine perforation associated with: o Experienced clinician[13] o Use of pre-operative cervical priming[22] o Earlier gestations[13]
Uterine rupture	• Uterine rupture has been rarely reported in association with mid-trimester medical terminations[37] • More frequently associated with later gestational ages and previous uterine scar[2,13] • Risk is less than 1 in 1000 terminations[13]
Maternal mortality	• Estimated at 0.6 per 100,000 terminations[53] • First trimester procedures are safer than second trimester procedures o 0.1–0.4 deaths per 100 000 first trimester[53] o 1.7–8.9 deaths per 100 000 second trimester procedures[53] • Suction curettage has the lowest rate of any surgical pregnancy termination method[53]
Psychological sequelae	• Emotional responses following termination of pregnancy are complex and may change over time[54] • Risk factors for post-termination of pregnancy psychological problems may include: previous or concurrent psychiatric illness, coercion, increasing length of gestation, ambivalence and lack of social support, poor relationships with others or religious affiliation[54] • Adverse psychological sequelae are no more likely following termination than following continuation of the pregnancy[13]
Failure to achieve termination of the pregnancy	• All methods of first trimester termination of pregnancy carry a small risk of failure to terminate[13] o Surgical method – approximately 2.3 in 1000[13] o Medical method – risk increases with gestation[13] • More likely following early rather than late termination of pregnancy • Failed termination of pregnancy while uncommon may lead to fetal anomalies if the pregnancy persists[33,46]
Future pregnancies	• Conflicting results have been reported about the risk of low-birth weight, premature delivery or spontaneous miscarriage in subsequent pregnancies for women who have had a prior termination of pregnancy[13,55] • There are no proven associations between termination of pregnancy and subsequent ectopic pregnancy, placenta praevia or infertility[13]

Appendix B: Mifepristone and Misoprostol protocol

Adapted from World Health Organization (2012). "Safe abortion: technical and policy guidance for health systems."

Caution: refer to the Australian product information for complete drug information	
Day 1: Protocol – all gestations	
Pre-dose care	• Provide written information to the woman regarding the process of medical termination to be followed • Take baseline maternal observations (temperature, BP and pulse) o If BP greater than 140/90 on two consecutive readings 15 minutes apart then withhold Mifepristone and seek medical review • Confirm review appointment arranged if indicated
Dose	• Mifepristone 200 mg oral • Check BP 15 minutes after Mifepristone administration • Observe for 1 hour post Mifepristone administration in case of nausea and vomiting **If gestation less than 9 weeks and outpatient care planned** (as per local criteria) • Supply Misoprostol 800 micrograms to be taken buccal or sublingual on Day 2 • Supply a script for analgesia and anti-emetics
Day 2: Follow protocol according to gestational age	
Less than 9 weeks (< 63 days)	• 24–48 hours after Mifepristone o Misoprostol 800 micrograms buccal or sublingual • If fetus undelivered, consider additional Misoprostol dose or surgical procedure • Administer Anti D to Rh negative women • Day 3: Perform ultrasound scan to ensure termination successful
9–12 weeks (63–90 days)	• 36–48 hours after Mifepristone* o Misoprostol 800 micrograms vaginal o Followed by Misoprostol 400 micrograms vaginal or sublingual every three hours up to a maximum of four further doses • If fetus undelivered, consider additional Misoprostol dose or surgical procedure • Administer RhD immunoglobulin to Rh negative women • Day 3: Perform ultrasound scan to ensure termination successful
13 weeks to 24 weeks (91–174 days)	• 36–48 hours after Mifepristone* • Misoprostol 800 micrograms vaginal OR Misoprostol 400 micrograms oral • Followed by Misoprostol 400 micrograms vaginal or sublingual every three hours up to a maximum of four further doses
Greater than 24 weeks	• For pregnancies greater than 24 weeks reduce the dose of Misoprostol due to increased sensitivity of the uterus to prostaglandins • Consider individual circumstances • Seek expert advice from a higher level service as required

*Misoprostol may be given 24 hours after Mifepristone if required

Appendix C: Misoprostol alone protocol

Where Mifepristone is not available the following Misoprostol alone protocols are recommended. Adapted from World Health Organization (2012). *Safe abortion: technical and policy guidance for health systems.*

Caution: refer to the Australian product information for complete drug information	
Pre-care (all gestations)	• Provide written information to the woman regarding the process of medical termination to be followed • Confirm review appointment arranged as indicated • Ensure Queensland Health prescribing requirements met [refer to the List of Approved Medicines} • Baseline observations: temperature, BP, pulse, vaginal loss, pain level prior to commencement • If there is a risk of uterine rupture refer to Appendix D: 2nd trimester Misoprostol protocol for increased risk of uterine rupture
Protocol for gestations 12–24 weeks (84–174 days)	
Care requirements	• IV access is recommended • Consider cervical priming especially in nulliparous women • Observations o Following initial dose of Misoprostol – (½ hourly for one hour) ▪ BP, pulse, vaginal loss, contractions, assess pain o Following each subsequent dose of Misoprostol (one set) ▪ Temperature, BP, pulse, vaginal loss, contractions, assess pain • Offer analgesia • Offer antiemetics if required • Vaginal examination as clinically indicated • Bed rest for 30 minutes after each dose but may mobilise freely at other times • If the placenta is not spontaneously delivered within 60 minutes of the fetus (or earlier if excessive bleeding occurs) consider operative removal
Dose	• Misoprostol 400 micrograms vaginal or sublingual • May be repeated every three hours up to a maximum of four further doses
Protocol for gestations greater than 24 weeks (> 175 days)	
Gestations greater than 24 weeks	• Reduce the dose of Misoprostol due to increased sensitivity of the uterus to prostaglandins • Consider individual circumstances • Seek expert advice from a higher level service as required

Appendix D: 2nd trimester Misoprostol protocol in cases with increased risk of uterine rupture

Aspect	Good practice points
Pre-care	• Ensure Queensland Health prescribing requirements met [refer to the List of Approved Medications (LAM)] • Baseline observations: temperature, BP, pulse, vaginal loss, pain level prior to commencement • IV access is recommended • Consider cervical priming especially in nulliparous women
Observations	• Following initial dose – (½ hourly for one hour) o BP, pulse, vaginal loss, contractions, assess pain • Following each subsequent dose of Misoprostol o Temperature, BP, pulse, vaginal loss, contractions, assess pain
Care requirements	• Offer analgesia • Offer antiemetics if required • Vaginal examination as clinically indicated • Bed rest for 30 minutes after each dose but may mobilise freely at other times • If the placenta is not spontaneously delivered within 60 minutes of the fetus (or earlier if excessive bleeding occurs) consider operative removal
Caution: refer to Australian pharmacopeia for complete drug information	
Dosing for previous uterine surgery	**Initial dose:** • Misoprostol 200 micrograms inserted into the posterior fornix of the vagina **Subsequent doses:** • If undelivered at 4 hours after initial dose, then Misoprostol 200 micrograms inserted into the posterior fornix of the vagina every 4 hours for 4 doses • If undelivered at 24 hours after initial dose, then commence Misoprostol 400 micrograms inserted into the posterior fornix of the vagina every 6 hours for a maximum of 4 doses • If undelivered at 48 hours after initial dose, then review by an obstetrician is indicated. Options may include: o Continue with Misoprostol 400 micrograms 6 hourly **or** o Rest day then recommence **or** o IV Oxytocin is most effective if some effacement and dilation has occurred o Surgical delivery

*Adapted from Royal Brisbane and Women's Hospital Work Unit Guideline: *Administration of Mifepristone and Misoprostol in medical induction of labour at less than 28 weeks gestation where a live birth is not the expected outcome*

Appendix E: Aftercare advice

Aspect	Good practice points
Vaginal bleeding	• Use sanitary pads rather than tampons to limit the risk of infection • Bleeding may occur with or without clots • Bleeding may last for up to 2 weeks after a surgical termination and up to six weeks after a medical termination • Bleeding should decrease over the weeks • If bleeding is continuous and heavy (e.g. more than one pad soaked per hour for more than three hours) seek urgent medical attention
Pain	• Over the counter pain medicines (analgesia) such as Ibuprofen can be used • Hot packs or hot water bottles may provide relief for abdominal cramps
Infection	• If there are signs of infection seek medical attention • Signs of infection include fever, lethargy, offensive vaginal discharge, excessive pain
Ectopic pregnancy	• There may be a possibility of ectopic pregnancy – especially if the pregnancy site was not confirmed by ultrasound scan before the procedure • If there is increasing pain and/or a reoccurrence of vaginal bleeding seek medical assistance
Breast discomfort	• Can persist for two weeks (especially after mid trimester terminations) • Lactation can occur (at later gestations) • Advise physiological management of breast discomfort (not stimulating, firm supportive bra, cold packs, analgesics) • Consider pharmacological lactation suppression with caution [56]
Sexual intercourse	• Sexual intercourse should be avoided while still bleeding to limit the risk of infection
Future fertility	• Fertility can return immediately so contraception should be initiated immediately if having sexual intercourse • Urine pregnancy tests are not reliable until at least 4–6 weeks post-termination because human chorionic gonadotropin levels may still be discernible and distort test results
Menstruation	• May commence within 3 weeks of termination but in some cases can take up to 9 weeks • If menstruation has not commenced within 4–6 weeks post-termination, perform a pregnancy test

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Working Party Members

The multidisciplinary working party for the guideline *Therapeutic termination of pregnancy* included representatives from the following professions and disciplines:

- Obstetrics
- Midwifery
- Mental Health
- Allied Health
- Pharmacology
- Maternal Fetal Medicine
- Law
- Medical Health Administration
- Consumer
- Ethicist

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