TERMINATION OF PREGNANCY (TOP) (MEDICAL 2ND AND 3RD TRIMESTER) – CLINICAL PROTOCOL

This LOP is developed to guide clinical practice at the Royal Hospital for Women. Individual patient circumstances may mean that practice diverges from this LOP.

1. AIM
   • Medical termination of pregnancy during the second or third trimester
   • Medical induction of labour for fetal demise
   • Minimise medication side effects

2. PATIENT
   • Pregnant woman requiring a medical termination of pregnancy in the second or third trimester, or induction of labour after intrauterine fetal demise in the second or third trimester
   • The use of Mifepristone at Royal Hospital for Women (RHW) is restricted to greater than 12 weeks gestation, apart from a few specific situations such as:
     o Women requiring early pregnancy interruption in whom surgery is risky (e.g. significant maternal cardiac disease with an unplanned pregnancy or fetal anomaly) or surgical evacuation is potentially difficult (e.g. previous difficult or failed mechanical dilatation or Asherman’s syndrome)
     o When there is a fetal anomaly or fetal demise occurs in the first trimester and medical termination is preferred for histopathological examination of the placenta or fetus

3. STAFF
   • Registered Midwives
   • Student Midwives
   • Registered Nurses
   • Medical Staff
   • Social Workers

4. EQUIPMENT
   • Nil

5. CLINICAL PRACTICE
   • Counsel the woman appropriately
   • Notify the Social Work Department of the woman’s admission and the reason for termination. The Social Worker must see the woman prior to the commencement of the procedure. (Most women having terminations are seen by the Social Worker prior to admission)
   • Accurate gestational assessment is essential
   • Approval for termination of pregnancy must be sought from Termination Review Committee if gestation is 20 weeks or greater
   • Give all women the information sheet for women: Mifepristone / Misoprostol Induction of Labour (Attachment A)
   • Obtain consent for termination of pregnancy (including potential for evacuation of retained products of conception) on generic consent form and consent for use of Mifepristone at the end of patient information leaflet
   • Select a method from the following:
     o Mifepristone and Misoprostol
     o Misoprostol alone
     o Gemeprost alone
TERMINATION OF PREGNANCY (TOP) (MEDICAL 2ND AND 3RD TRIMESTER) –
CLINICAL PROTOCOL  cont’d

ON ADMISSION
- Allocate woman a single room for her stay and ensure privacy is maintained
- Perform nursing and medical admission
- Take a blood sample for group and hold (gain intravenous access only if additional risk factors)

CARE OF THE WOMAN
Monitoring
- Record BP, pulse and respiratory rate fourth hourly
- Record dates and times of medications, amount of vaginal loss, passage of products of conception and cervical assessment at each administration of vaginal medication.

Further Care
- Administer medication vaginally or orally according to table
- Advise patient to remain in bed for 30 mins following vaginal medication
- Patient may get out of bed and take light refreshment up until the commencement of contractions
- Once labour is established, the woman should remain in bed and be nil by mouth
- Ensure adequate analgesia e.g. oral Paracetamol / Opiates or Morphine. Epidural is not contra-indicated in these circumstances
- Ativan 1 mg orally 6 hourly prn can be considered for anxiety
- After membrane rupture continue with dosing regimen or consider Syntocinon
- If IV Oxytocin is required, standard hospital protocol should be followed
- Nausea, vomiting and pain are common reactions, inform RMO of hypotension, tachycardia, palpitations or dyspnoea

Third Stage of Labour for All Women
- When the fetus is expelled, clamp and cut the cord
- Administer 10 units of Syntocinon IM to the mother after delivery of the fetus
- Arrange surgical removal of the placenta if placental separation and delivery has not occurred within three hours of delivery or there is heavy bleeding before this time
- Examine fetus, placenta and membranes
- If patient is Rh negative ensure Anti-D is given

Following Delivery
- Offer mother the opportunity to see and hold her fetus for as long as she deems appropriate
- Record BP, pulse and fundal height 15 minutely for the first hour then 4th hourly
- Save specimens for karyotyping (cord, placenta, connective tissue) in normal saline (never in formalin)
- All paperwork is to be completed as necessary and consent for autopsy signed
- A baby that shows signs of life, regardless of gestation is to be registered as a birth

Discharge Planning
- This may include :
  - Breast care and the use of Dostinex (usually beyond 16 weeks)
  - Pain relief
  - Vaginal bleeding
  - Social Work support
MEDICATION REGIMENS

1. **Mifepristone (RU486) and Misoprostol (Cytotec) Regimen**
   - Prescribe 200 mg of Mifepristone orally by a medical officer authorised by the Therapeutic Goods Administration (TGA). Under exceptional circumstances the woman may have to stay in hospital.
   - Instruct the woman to take Mifepristone orally, preferably 36 – 48 hours before planned admission for Misoprostol administration.
   - Give another dose after 30 – 60 minutes if the dose is vomited.
   - Organise return admission 24 – 48 hours after Mifepristone. Give written information as to when and where to return to hospital as per patient information sheet.

### Dosage and administration of Misoprostol when used after Mifepristone

<table>
<thead>
<tr>
<th>Misoprostol</th>
<th>&lt;13 weeks gestation*</th>
<th>13 – 20 weeks gestation*</th>
<th>21 – 28 weeks gestation*</th>
<th>29 – 34 weeks gestation</th>
<th>&gt; 34 weeks gestation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial dose</td>
<td>800 micrograms (mcg) PV</td>
<td>800 mcg PV</td>
<td>400 mcg PV</td>
<td>100 mcg PV</td>
<td>100 mcg PV</td>
</tr>
<tr>
<td>Subsequent dose</td>
<td>400 mcg PER VAGINA every three hours to a maximum of TWO doses</td>
<td>400 mcg PER ORAL or PER VAGINA every three hours to a maximum of FOUR doses</td>
<td>400 mcg PER ORAL or PER VAGINA every three hours to a maximum of FOUR doses</td>
<td>200 mcg PER VAGINA every FOUR hours to a maximum of FOUR doses</td>
<td>100 mcg PER VAGINA every FOUR hours to a maximum of FOUR doses</td>
</tr>
</tbody>
</table>

* Women with a previous scar consider halving the dose of Misoprostol, especially in the presence of a fetal death < 28 weeks gestation.

### Contraindications
- Severe asthma requiring oral corticosteroids
- Chronic or acute adrenal or hepatic failure
- Bleeding disorders or on concurrent anticoagulation therapy
- Known allergy to mifepristone or Prostaglandin
- Suspected ectopic pregnancy
- Inherited porphyria
- Any contraindication to a vaginal delivery

### Side effects
- Nausea and vomiting 15 – 20%
- Headache 15 – 20%
- Occasional pelvic cramping before admission
- Pelvic infection (rare), or systemic infection
TERMINATION OF PREGNANCY (TOP) (MEDICAL 2ND AND 3RD TRIMESTER) – CLINICAL PROTOCOL  cont’d

2. **Where Mifepristone is not used**
   - Inform the woman of likely longer induction to delivery interval and need to remain as an in-patient and document
   - Administer vaginally one of the following options :

<table>
<thead>
<tr>
<th>Medication</th>
<th>12 – 28 weeks</th>
<th>29 – 34 weeks</th>
<th>&gt; 34 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Misoprostol</td>
<td>400mcg PV, 3 hourly maximum of 5 doses</td>
<td>100mcg Initially PV, then 200mcg 3 hourly PV to a maximum of 5 doses</td>
<td>100mcg PV 4 hourly to a maximum of 5 doses</td>
</tr>
<tr>
<td>Gemeprost</td>
<td>1 Milligram (mg) PV 3 hourly to maximum of 5 doses</td>
<td>Use with caution</td>
<td>Not recommended</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>Prostin</td>
<td>Not recommended</td>
<td>2 mg initial dose PV followed by 2 mg 6 hourly</td>
<td>According to Bishop’s score</td>
</tr>
</tbody>
</table>

If not delivered after any of the regimens above :
- Rest woman overnight and recommence regimen the following day
- In addition, a repeat dose of mifepristone can be given after two days of Misoprostol treatment
- Alternative regimens include high dose Syntocinon, extra-amniotic PGF2a, or Gemeprost

6. DOCUMENTATION
   - Medication Chart
   - Integrated Clinical Notes
   - ObstetriX Database
   - Birth Registration papers

7. EDUCATIONAL NOTES
   - Misoprostol is 300 times cheaper than Gemeprost (30 cents versus $92), generally has fewer side effects and can be stored at room temperature for several years
   - Mifepristone is the only anti-progesterone that is internationally approved for the induction of abortion. Mifepristone binds to progesterone receptors to reverse their inhibition of cervical softening and dilation and uterine contraction. More importantly, it sensitizes the myometrium to prostaglandins and 5. The maximum effect of Mifepristone is achieved when Prostaglandins are administered 36 – 48 hours after Mifepristone dose. Mifepristone pre-treatment prior to administration of Prostaglandin analogues can be given to prime the uterus. It has been shown to have the following benefits:
     - increase abortion rate within 24 hours
     - reduce curettage rate for retained products
     - reduce induction to abortion interval
• There is a 0.2% rate of abortion after Mifepristone administration prior to treatment with Prostaglandins\(^3\). In women given Mifepristone pre–treatment, 97% will abort within five doses of Prostaglandins\(^3\). Abortion rate and induction–to–abortion interval for 200mg and 600mg doses of Mifepristone have been found to be the same\(^6\). Common side effects of the Prostaglandins Misoprostol and Gemeprost, are:
  o 50% of women get a fever
  o 20 – 25% suffer from nausea, vomiting, dizziness, diarrhoea or headache\(^1\)

• The safety and efficacy of Mifepristone used in conjunction with a Prostaglandin analogue usually Misoprostol, is well established, as the best available regimen for medical termination of pregnancy. The TGA has given authorised prescriber status to listed medical practitioners at RHW to prescribe Mifepristone for this purpose. In addition, authorisation has been obtained from the Research Ethics Committee to use Mifepristone for the indications above

• Gemeprost is the only synthetic PGE1 analogue licensed for mid–trimester termination of pregnancy

(TOP). Misoprostol is a synthetic PGE1 analogue only licensed for the prevention and treatment of peptic ulcer disease, however it is commonly used for cervical priming, medical abortion and induction of labour

• Misoprostol is not approved for use in pregnancy by the Australian TGA. Use is “off label” in obstetrics and gynaecology, although it has been used extensively both within Australia and worldwide for this purpose. The woman should be informed of this

• There is no evidence that Gemeprost is more fetotoxic than any other prostaglandin analogue

8. RELATED POLICIES / PROCEDURES / CLINICAL PRACTICE LOP

• Termination of Pregnancy (Medical and Surgical 1\(^{st}\), 2\(^{nd}\) and 3\(^{rd}\) trimester) – Admission
• Termination of Pregnancy; Framework
• Stillbirths and Fetal Deaths – Diagnosis and Delivery
• Stillbirths, Fetal, Neonatal and Infant Deaths – Documentation and Transport
• Stillbirths, Fetal, Neonatal and Infant Deaths – Post Delivery Care and Creation of Memorabilia

9. REFERENCES