BACKGROUND/RATIONALE

This guideline has been based on the Victorian Standard for Induction of Labour (IOL) with Prostaglandin E2 (PGE2) Vaginal Gel (Prostin) Clinical Practice Guideline prepared by the Maternity Newborn Clinical Network which has the objective of providing Maternity Service providers in Victoria with an agreed Standard of Care based on the best currently available evidence.

DESIRED OUTCOME/OBJECTIVE

- To use PGE2 Vaginal Gel (Prostin) to promote cervical ripening (softening and effacement) and to stimulate myometrial contractions where delivery is indicated but not urgent and increases the likelihood of a spontaneous vaginal birth.

DEFINITIONS

Augmentation: is an intervention that increases the rate of the progress of spontaneous labour.

Cervical ripening: is the process of IOL employed when the cervix is unfavourable in order to facilitate dilation as labour is established.

Induction of labour (IOL): is an intervention designed to artificially initiate cervical ripening and uterine contractions resulting in progressive effacement and dilation of the cervix and birth of the baby.

Prolonged pregnancy: is a pregnancy with a gestation of more than 41 complete weeks. Gestation should be based on the agreed estimated date of confinement (EDD). The EDD is based on the last known menstrual period (LNMP) and modified by the earliest dating scan, if outside the margin of error of the scan. A dating scan is recommended for all women <14 weeks gestation.

Standard primipara: is a woman, 20-34 years of age, who has given birth for the first time, free of obstetric and specific medical complications and pregnant with a singleton pregnancy at term (37 weeks 1 day-40 weeks 6 days gestation), with a non-small for gestational age (greater than tenth percentile) infant and a head first (cephalic) presentation.

Uterine hyperstimulation (tachysystole) may occur with or without FHR changes and is defined as:
  ➔ 4 or more contractions in 10 minutes over a 30 min period or
  ➔ Contractions lasting more than 2 minutes in duration or
  ➔ Contractions of normal duration occurring within 60 seconds of each other
Bishop Score: is a measure of cervical suitability for IOL. A favourable Bishop score is >7.

<table>
<thead>
<tr>
<th>Score</th>
<th>Dilation</th>
<th>Effacement</th>
<th>Station</th>
<th>Position</th>
<th>Consistency</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>closed</td>
<td>0-30%</td>
<td>-3</td>
<td>Posterior</td>
<td>Firm</td>
</tr>
<tr>
<td>1</td>
<td>1-2 cm</td>
<td>40-50%</td>
<td>-2</td>
<td>Mid-position</td>
<td>Moderately firm</td>
</tr>
<tr>
<td>2</td>
<td>3-4 cm</td>
<td>60-70%</td>
<td>-1.0</td>
<td>Anterior</td>
<td>Soft</td>
</tr>
<tr>
<td>3</td>
<td>5+</td>
<td>80+%</td>
<td>+1,+2</td>
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CONTRAINDICATIONS

Never proceed with PGE₂ IOL with the following:

- Bishop score ≥ 6
- Abnormal Cardiotocography (CTG) or known fetal compromise
- Persisting maternal temperature
- Vaginal bleeding
- Known hypersensitivity to PGE₂ or any constituents of the gel
- Contraindication to vaginal birth (e.g. placenta/vasa praevia, active genital herpes)
- Spontaneous labour
- Previous caesarean section
- Malpresentation

Relative contraindications (may be used with caution under lead obstetrician supervision):

- Multiparous women particularly grand multiparity (>5 previous births)
- Previous uterine hyperstimulation
- Ruptured membranes
- Mobile presenting part
- Asthma
- Cardiac disease
- Multiple pregnancy
- Epilepsy
- Glaucoma or raised intraocular pressure
- Unexplained vaginal discharge or abnormal uterine bleeding during the pregnancy

ISSUES TO CONSIDER

- Ensure the woman has had the opportunity to make an informed decision about her care and treatment after a full explanation of the benefits and risks associated with the procedure
- Bishop score must be ≤5 at the time of insertion
- PGE₂ vaginal gel (Prostin) must not be inserted into the cervical canal
- To reduce the risk of hyperstimulation (tachysystole):
  - Oxytocin (Syntocinon) should not be commenced within 6 hours of PGE₂ gel being inserted
  - Artificial rupture of membranes (ARM) should not be performed within 4 hours of insertion of PGE₂ vaginal gel
- Physiological management of the third stage is contraindicated when labour is induced
- Potential complications of PGE₂ administration include:
  - Uterine hyperstimulation (refer to CPG Management of Uterine Hyperstimulation (Tachysystole))
→ Abnormal CTG
→ Hypersensitivity reactions
→ Vaginal irritation
→ Gastrointestinal disturbances (nausea, vomiting and diarrhoea) (rare in 1% or cases)
→ Placental abruption
→ Amniotic fluid embolism
→ Post partum haemorrhage
→ Genital oedema

EQUIPMENT
Gloves
PGE$_2$ Vaginal Gel (1 or 2 mg)
CTG machine
Draw sheet to place over the woman
Plastic protective sheet for bed

PROCEDURE

<table>
<thead>
<tr>
<th>PROCESS STANDARDS:</th>
<th>KEYPOINTS:</th>
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<tbody>
<tr>
<td><strong>1. Assessment</strong></td>
<td></td>
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<tr>
<td>▪ Explain the procedure to the woman and ensure consent for IOL is documented (MR/360.02 Consent for Procedure Form recommended).</td>
<td>▪ Explain the anticipated outcome, benefits and risks of IOL with PGE$_2$ in a cultural and language appropriate manner and the support person is included in the process</td>
</tr>
<tr>
<td>▪ Document baseline maternal vital signs and record: o Maternal blood pressure o Pulse rate o Uterine activity over a 10 minute period (palpated) o Vaginal loss</td>
<td>▪ Notify medical officer if observations outside of normal parameters</td>
</tr>
<tr>
<td>▪ Perform abdominal palpation to confirm fetal lie and presentation – document findings</td>
<td>▪ Ensure cephalic presentation and engagement of the fetal head</td>
</tr>
<tr>
<td>▪ A normal CTG must be demonstrated within 6 hours (with no change in clinical situation) prior to insertion of PGE$_2$ gel.</td>
<td>▪ Establish fetal wellbeing prior to commencing induction</td>
</tr>
<tr>
<td>▪ Assess and document vaginal examination and Bishops Score</td>
<td>▪ To reassess indication and method of induction</td>
</tr>
<tr>
<td>▪ Assess uterine contractility</td>
<td>▪ Contraction frequency and duration should be reconciled with uterine activity recorded on the CTG.</td>
</tr>
<tr>
<td><strong>2. Documentation</strong></td>
<td>▪ Strength of contractions is a subjective assessment requiring manual palpation correlated with how the woman perceives her contractions</td>
</tr>
<tr>
<td>▪ The CTG report must be documented including the presence (frequency) or absence of uterine activity</td>
<td>▪ Fetal wellbeing should be assessed and reported</td>
</tr>
<tr>
<td>▪ The medical officer must write the order for the PGE$_2$ on the medication chart once only section.</td>
<td>▪ An abnormal CTG must be reported to the lead obstetrician prior to commencing IOL</td>
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</table>
### 3. Administration
- PGE₂ vaginal gel should be removed from the refrigerator no more than 30 mins prior to insertion
- Explain the procedure
- Ensure the woman has an empty bladder
- Ask the woman to lie flat with her feet on the bed in a modified lithotomy position.
- Ensure privacy and cover the woman with a sheet
- Wash hands and don sterile gloves
- A vaginal examination is performed and the posterior fornix of the vagina identified.
- The PGE₂ vaginal gel is inserted via the syringe into the posterior fornix of the vagina avoiding the cervical canal.
- The administering clinician must ensure the PGE₂ order is recorded and signed on the drug chart.

### Dosage

<table>
<thead>
<tr>
<th>Dose</th>
<th>Description</th>
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<tbody>
<tr>
<td>1&lt;sup&gt;st&lt;/sup&gt; dose</td>
<td>1mg nulliparous and multiparous</td>
</tr>
<tr>
<td>2&lt;sup&gt;nd&lt;/sup&gt; dose</td>
<td>1 or 2 mg nulliparous, 1 mg multiparous</td>
</tr>
<tr>
<td>3&lt;sup&gt;rd&lt;/sup&gt; dose</td>
<td>1 or 2 mg nulliparous, 1 mg multiparous</td>
</tr>
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*Note:* These dosages may be altered at the request of the prescribing medical practitioner depending on the Bishops Score.

### Method of assembly
1. Remove protective end cap (to serve as plunger rod).
2. Insert protective end cap into the syringe.
3. Administer syringe content.

![Method of assembly diagram]

### 4. Observations
- The woman should remain recumbent in lateral position for at least **30 minutes**
- Continuous CTG monitoring for at least **one hour** after insertion
- A midwife/medical officer must stay with the woman and observe the CTG for the **first 10 minutes**
- **50 minutes** after insertion the midwife must remain with the woman for a full set of observations including:
  - Maternal blood pressure
  - Pulse rate
  - Uterine activity over a 10 minute period (palpated)
  - Vaginal loss
  - CTG report
- The woman may ambulate as desired after 1 hour if the CTG monitoring is normal

- To retain gel and prevent supine hypotension
- For assessment of fetal wellbeing and monitoring for potential uterine hyperstimulation
- If the first 10 minutes is reassuring the midwife must review the woman and CTG intermittently (at least every 10 minutes)
- Any abnormalities (fetal heart rate, uterine activity) must be reported to the midwife in charge and the medical officer immediately

**In the presence of abnormal fetal heart rate patterns and uterine hyperstimulation initiate emergency management principles and consider tocolysis refer to CPG Management of Uterine Hyperstimulation (Tachysytol)**
5. **Subsequent observations**

- After the initial hour if no contractions are detected and fetal wellbeing is established:
  - Half hourly fetal heart rate (FHR) by intermittent auscultation using a Doppler ultrasound
  - Half hourly vaginal loss (ruptured membranes, liquor, bleeding)
  - Hourly maternal uterine activity over a 10 minute period
- After 3 hours, cease the frequent observations, if there are no contractions detected/or reported by the woman and no fetal concerns
- 6 hours after initial PGE₂ vaginal gel insertion, a vaginal examination should be performed to reassess the Bishop score

- Strength of contractions is a subjective assessment requiring manual palpation correlated with how the woman perceives her contractions
- At this time another dose of PGE₂ may be administered
- May not be appropriate over night depending on timing of dose and clinical situation

6. **Continuous CTG monitoring should be recommenced if:**

- FHR abnormalities are auscultated
- Labour is established
- Spontaneous rupture of membranes (SROM) occurs
- The woman reports uterine activity
- The woman continues to contract but not in active labour

- If the woman reports uterine activity the CTG may be subsequently discontinued if the trace is normal and she is not in labour. If this occurs intermittent monitoring 2 hourly is recommended
- Transfer to a birth room if SROM occurs
- Obstetric review is required if it is unclear if the woman is labouring.

### RELATED DOCUMENTS

**Internal**

- PRO/?? Induction of Labour (IOL) Booking Protocol
- CPG/?? Induction of labour with Prostaglandin E2 (PGE2) Vaginal Gel (Prostin)
- CPG/S001 Oxytocin (Syntocinon) –Induction and Augmentation of Labour
- PRO/S001 Oxytocin (Sytocionon) Infusion
- CPG/?? Management of Uterine Hyperstimulation (Tachysystole)
- PRO/T005 Tocolysis – Pretem Labour and Inhibition of Established Labour

**External**

REFERENCES


| Reg. Authority: | CEO, Executive Directors, Nursing, Medical, Allied health & Psychiatric Services Clinical Director of Women & Children’s Health |
| Review Responsibility: | Maternity Unit |
| Date Effective: | October 2010 |
| Date Revised: | ---- |
| Date for Review: | October 2013 |
| Original Author: | Maternity Unit Project Officer |
| Updated by: | ---- |