Greater Manchester Integrated Care Partnership

NHS
Greater Manchester and Eastern Cheshire
Strategic Clinical Networks

Induction of labour (IOL) Guideline

Final
April 2022

LMNS
Greater Manchester and Eastern Cheshire
Local Maternity and Neonatal System

Document Control

Ownership

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Process

V1.0	Document approved and ratified by GMEC SCN Maternity Steering Group.	14/12/2018
V1.1	Revision commenced. Edits by K Bancroft. Circulated to Maternity Steering Group for comments 16/12/21	16/12/2021
V1.2	Comments considered and version updated.	24/2/2022
V2	**Ratified by Maternity Steering Group**	**8/4/2022**

Ratification process

Formal ratification	Formal ratification by the Greater Manchester and Eastern Cheshire SCN Maternity Steering Group	
Circulation	Issue Date: Circulated by	April 2022 Sarah.west20@nhs.net
Review	Review Date: Responsibility of:	April 2024 GMEC SCN

Contents

1 Introduction

Induction of labour (IOL) is an obstetric intervention and is the initiation of labour by artificial means. IOL can increase risks of intrapartum complications in some women and may place workload pressures on the delivery unit. Thus, it is only recommended when there is greater benefit to the health of the mother and/or baby than if the pregnancy continues. Treatment and care should take into account women's individual needs and preferences.
This guideline is to describe the management of the induction of labour (IOL) by dinoprostone vaginal tablets/gel (Prostin®), dinoprostone vaginal insert (Propess®), misoprostol (Angusta®) and cervical ripening balloon (CRB). Unless there are specific circumstances where it should not be used as a first line agent (e.g. previous caesarean section, severe asthma), prostaglandins should be used to induce labour. The preparation selected for use may depend on unit preference and experience.

2 Information and decision making

Preferences about mode of birth should be discussed with women early in their pregnancy. They should be made aware that options include:

- Expectant management
- Induction of labour
- Planned Caesarean Section

Women's preferences should be confirmed towards the end of pregnancy as these may change.

Women who are being offered IOL should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals.
Information should cover the following:

- The indication for IOL (risks/benefits of not being induced).
- Where, when and how induction can be carried out, including the need for vaginal examinations to assess the cervix before and during induction.
- That their choice of birth place will be limited as some recommended interventions are not available for home birth, midwife led units or when using a birthing pool.
- Arrangements for support and visiting times of birth partners.
- Risks and benefits of the recommended methods of induction of labour as outlined by this policy must be relayed prior to induction. Methods of pain relief should also be discussed. The woman should be signposted to further information resources as outlined in appendix 1.
- The alternative options if the woman chooses not to have IOL .i.e. expectant management or Caesarean Section. When a woman declines IOL an individual

management plan should be developed to address further management; this must be clearly documented in the maternal notes. She should be given advice regarding who to contact should she change her mind.

- An explanation that IOL may not be successful and the subsequent options that would be available to her at that point. It should be discussed that IOL can be a lengthy process and that waiting for artificial rupture of membranes once that is deemed the next step – may be >24 hours.

Ensure women have time to discuss this information with others if they wish to do so before making a decision. Direct women to sources of information, including written information leaflets (Appendix 1) and the NHS website.

Ensure women have the opportunity to ask questions and think about their options. Respect the woman's decision, even if healthcare professionals disagree with it and recognize that women can agree to proceed, delay, decline or stop an induction.

Contraindications to IOL:

- Previous classical Caesarean Section/hysterotomy.
- Previous myomectomy breeching uterine cavity.
- Breech presentation.
- Absent/reversed fetal umbilical artery Doppler.
- Transverse/oblique lie.
- Active genital primary herpes.
- Invasive cervical cancer.
- Severe pelvic structural abnormalities.
- Placenta/vasa praevia.

3 Induction of labour in specific circumstances

3.1 Prolonged pregnancy

Women with uncomplicated pregnancies should be given every opportunity to go into spontaneous labour.
Women with uncomplicated pregnancies should be recommended IOL from 41+0 weeks (NICE 2021) to avoid the risks of prolonged pregnancy which increase over time after 41+0 weeks gestation:

- Increased likelihood of Caesarean Section
- Increased likelihood of the baby needing admission to a neonatal intensive care unit
- increased likelihood of stillbirth and neonatal death

The exact timing should take into account the woman's preferences and local circumstances.

Women should be offered the alternatives of expectant management or Caesarean Section.

From 41+0, women who decline induction of labour should be offered increased antenatal monitoring consisting of x2 weekly CTG. An ultrasound scan for growth and liquor volume estimation and umbilical artery Doppler should be offered at the point of declining IOL. If undelivered a further scan should be offered one week later. The woman should be informed that monitoring only gives a snapshot of the current situation but provides information which may help them decide on an option for birth. There is no evidence that such monitoring can predict adverse outcomes reliably or prevent stillbirth.

Offer women who choose to await spontaneous labour the opportunity to discuss their decision at all subsequent reviews and advise them to contact their midwife of they change their minds before their next review.

Women from some minority ethnic backgrounds or who live in deprived areas have an increased risk of stillbirth and may benefit from closer monitoring and additional support.

3.2 Preterm pre-labour rupture of membranes

If a woman has preterm pre-labour rupture of membranes, IOL should be carried out after 34 weeks unless there are additional obstetric indications (for example, infection or fetal compromise) to do so prior to this gestation. Expectant management should be offered until 37 weeks gestation unless circumstances change and women should take into consideration risks to herself, to the baby and her individual circumstances. IOL in all circumstances is recommended once 37 weeks gestation is reached.

If a woman has preterm, pre-labour rupture of membranes after 34+0 weeks, and has a positive group B streptococcus test at any time in their current pregnancy, offer immediate induction of labour or Caesarean Section.

See GMEC SCN Management of Pre-Labour Rupture of Membranes (PPROM) under 37 weeks gestation guideline

3.3 Pre-labour rupture of membranes at term

Women with pre-labour rupture of membranes at term (at or over 37 weeks) should be offered a choice of IOL with vaginal prostaglandin (one dose only of prostaglandin tablet/ gel or Propess) or expectant management (of approximately 24 hours) if there are no other obstetric concerns. However, Propess should be used with caution in patients with ruptured membranes as the evidence is limited. Since the release of dinoprostone from the insert can be affected by the presence of amniotic fluid, special attention should be given to uterine activity and fetal condition. At term, IOL is recommended approximately 24 hours after pre-labour rupture of the membranes.

Respect the woman's decision if she chooses to wait for spontaneous labour for over 24 hours after pre-labour rupture of membranes at term.

If a woman has pre-labour rupture of membranes at or after 37+0 weeks, and has a positive group B streptococcus test at any time in their current pregnancy, offer immediate induction of labour or Caesarean Section.
See GMEC SCN Pre-Labour Spontaneous Rupture of Membranes (SROM) at Term (>37 weeks) Guideline

3.4 Previous Caesarean Section

See also guideline for Management of women wishing a vaginal birth after Caesarean Section (VBAC) and those with a scarred uterus.
If birth needs to be expedited in women who have had a previous Caesarean Section offer a choice of:

- Induction of labour
- Caesarean Section

Advise women who have had a previous Caesarean Section that:

- Induction of labour could lead to an increased risk of emergency Caesarean Section
- Induction of labour could lead to an increased risk of uterine rupture
- The methods used for induction of labour will be guided by the need to reduce these risks

If induction is necessary and agreed, women who have had a previous Caesarean Section should be offered:

- ARM as first line
- CRB second line (depending on local availability).

This decision must be discussed with a consultant obstetrician. A care plan should be made taking into account the women's circumstances and wishes. Women should be aware that it is the use of prostaglandin that increases their risk of uterine rupture; with an additional increase should intravenous oxytocin (IVO) be required.

3.5 Maternal request

Consider requests for induction of labour only after discussing the benefits and risks with the woman, taking into account the woman's circumstances and preferences (NICE 2021). This should be a consultant discussion. The discussion and subsequent plan must be documented in the maternal records.

3.6 Fetal growth restriction

Prostin®, Propess® or a cervical ripening balloon can be utilised in the IOL for fetal

growth restriction. If there are any regular contractions (2 in 10 minutes or more) during the IOL process continuous monitoring should be utilised. If there is evidence of fetal compromise IOL should not be performed (non-reassuring CTG, absent or reversed umbilical artery Doppler flow). Offer Caesarean Section instead (NICE 2021).
Refer to North West Regional guideline for the detection and management of Fetal Growth Restriction for timing of delivery.

3.7 Maternal Diabetes

The decision for IOL for women with maternal diabetes will be made by the woman in consultation with the consultant obstetrician, taking into account the woman's diabetic stability, hypoglycaemic agent usage, maternal and fetal well-being. See also local guidelines for the management of gestational diabetes and Management of antenatal, intrapartum and postnatal care for women with Pre-existing Diabetes.

3.8 Intrauterine death

Refer to North West Management of Stillbirth Guideline or North West Second Trimester Pregnancy Loss Guideline found /gmec-clinical-networks/our-networks/maternity/resources/

3.9 Suspected fetal macrosomia

Discuss the following with women with a suspected macrosomic fetus:

- Options for birth are expectant management, induction of labour or Caesarean Section
- There is uncertainty about the risks and benefits of induction of labour compared to expectant management but with induction of labour compared with expectant management, the risk of shoulder dystocia is reduced, the risk of 3rd/4th degree tears is increased but there is no difference in the risk of perinatal death, brachial plexus injuries or the need for Caesarean Section.

Discuss the options with the woman, taking into account her individual preferences and circumstances and respect her decision

3.10 Precipitate labour, pelvic girdle pain, polyhydramnios

Women with a history of precipitate labour, polyhydramnios or pelvic girdle pain should not routinely be offered induction of labour. However, should a woman be requesting IOL, each case should be considered individually with a review by a consultant obstetrician.

3.11 Reduced fetal movements

Refer to regional guidelines on reduced fetal movements for indications and timing of IOL (GMEC Reduced Fetal Movements Guideline)

3.12 Advanced maternal age

The overall incidence of stillbirth is still low in women age ≥40years (2:1000 at 39-40 weeks) but it is increased compared to women ≤35 years (1:1000). Thus IOL in these women should be offered after 39+0 weeks following careful counselling of the risks and benefits of IOL including the risk of failed IOL.

3.13 Breech Presentation

Induction of labour is not generally recommended if a woman's baby is presenting by the breech. Planned Caesarean Section is recommended. Consider induction of labour for breech presentations if:

- Birth needs to be expedited
- External cephalic version is unsuccessful, contraindicated or declined
- A woman chooses not to have a planned Caesarean Section

Discuss the benefits and risks associated with induction of labour

4 Process (including booking) for Induction of labour (IOL)

4.1 Booking Arrangements for IOL

See Appendix 2.

4.2 Gestation at Which Induction of Labour Should Take Place

Ensure the estimated date of delivery (EDD) has been checked and that a reliable EDD is in place (i.e. a first scan at <16 weeks gestation). If there is not a reliable EDD, timing of IOL should always involve discussion with a consultant.
The gestation at which IOL should take place is dependent on the following risk factors:

- Women with identified risk factors: the decision to induce labour for women who are high risk must be discussed with a consultant, including the agreed timing.
- Low risk women: a midwife should offer IOL for low risk women whose pregnancy is post mature at 41+0 weeks gestation. All prostaglandins and misoprostol must be prescribed by a doctor.

4.3 Deciding the Appropriate Place for Induction of Labour

If a member of staff is uncertain as to the planned location of the IOL, they should ask the woman's consultant, ward cover consultant or the consultant on call.

Table 1: Location of IOL

Bolton FT	All inductions are performed on ward M2 except those outlined in Section 5
Saint Mary's Hospital Oxford Road Campus	All inductions should be performed on the IOL bay on Ward 65 except those outlined in Section 5 below
Saint Mary's Hospital at Wythenshawe	All inductions should be performed on ward C3 except those outlined in in Section 5 below
Saint Mary's at North Manchester	All inductions should be performed on the Antenatal ward except those outlined in Section 5 below
Royal Oldham Hospital, NCA	All inductions should be performed on the Ante-natal ward except those outlined in Section 5 below
Stepping Hill Hospital, Stockport FT	All inductions are performed on the Delivery suite
Royal Albert Edward Infirmary, WWL FT	All inductions are performed in the Induction Bay on Delivery Suite.
Macclesfield DGH, East Cheshire HT	
Tameside Hospital, T&G Integrated Care FT	

5 Indications for IOL that require a Delivery Unit location

- Any conditions that require additional maternal monitoring e.g. severe pre-eclampsia, significant APH, sepsis
- Any IOL in a patient with a care plan – either fetal or maternal medicine - where it is specified that the location for IOL should be delivery unit.
- Gestation <35 weeks
- Fetal death in utero

6 Methods of Induction of Labour

These can be divided into:

- Membrane sweep
- Pharmacological
- Cervical ripening balloon (CRB)
- Amniotomy and intravenous oxytocin

6.1 Membrane sweep

Membrane sweeping involves the examining finger passing through the cervix to rotate against the wall of the uterus, to separate the chorionic membrane from the decidua. If the cervix will not admit a finger, massaging around the cervix in the vaginal fornices may achieve a similar effect.

At the 38 week antenatal visit, all women should be offered information about the risks associated with pregnancies that last longer than 41 weeks and their options. Part of that discussion should involve an explanation of a membrane sweep. Explain that it makes spontaneous labour more likely, that it is not associated with an increase in maternal or neonatal infection, that it is associated with increased levels of discomfort when compared to a routine examination and that it may be associated with a small amount of bleeding.

A membrane sweep should then be offered at antenatal visits after 39+0 weeks and verbal consent obtained if the woman agrees.

If a vaginal examination is carried out at term to assess the cervix, the opportunity should be taken to offer the woman a membrane sweep.

Additional membrane sweeping may be offered if labour does not start spontaneously following the first sweep.

Details of whether a membrane sweep was declined, performed or not technically feasible must be recorded in the maternal records.

Healthcare professionals should always check for signs of a low lying placental site, including ultrasound reports, before membrane sweeping and before IOL (NICE, 2008).

6.2 Pharmacological methods

The preferred method of induction when the Bishop score is 6 or less involves the use of vaginal prostaglandin (PGE2). This can either be administered as a repeated dose vaginal tablet or dinoprostone gel (will be referred to as Prostin® in this guideline) or as a slow release pessary over 24 hours (dinoprostone vaginal insert –

will be referred to in this guideline as Propess®). Oral misoprostol (will be referred to as Angusta® in this guideline) is an alternative pharmacological method of induction when the Bishop score is less than 6.

What is Prostin®?

Prostin® is dinoprostone vaginal tablet/gel that can be inserted into the vagina every six hours to a maximum of three doses.

What is Propess®?

Propess® is a slow release prostaglandin (dinoprostone, prostaglandin E2) delivery system. It is inserted vaginally into the posterior fornix and remains in situ for up to 24 hours as shown in appendix 3.

What is Angusta®?

Angusta® is a low dose (25 micrograms) oral misoprostol tablet. It can be used for induction of labour after 37weeks gestation when the Bishop score is 6 or less, either 25micrograms 2 hourly or 50 micrograms 4 hourly. Maximum dose is 200micrograms in 24 hours.

Guide to using Prostin®/Propess®/ Angusta®

Any maternal or fetal parameters which do not follow the standard IOL guidelines may affect the location, decision or method to induce and must be discussed with the woman's own consultant or designated substitute consultant.

Administration

Doctors and midwives who have received the appropriate training can administer dinoprostone vaginal tablets/gel (Prostin®), see below, dinoprostone vaginal insert (Propess®) – see appendix 3 or oral misoprostol tablets (Angusta®).

A midwife can give Propess® and Prostin® after 37 weeks gestation. Any midwife who has only received the theoretical training can administer Prostin® or Propess® under either the supervision of a midwife trained in induction procedures or an ST3 or above. A midwife can give oral Angusta®.

Prostin® vaginal tablets

- Prostin® vaginal tablets are given every 6 hours at a dose of 3mg each (irrespective of parity) up to a maximum of three doses. Once an ARM is possible that is the preferred step rather than more prostaglandin.

Prostin® Gel

- Prostin® vaginal gel is given every 6 hours to a maximum of 3 doses. Once an

ARM is possible that is the preferred step rather than more prostaglandin. The dosage regime for gel is different in primiparous and multiparous women due to the different initial dose:

- Primiparous: 2mg Prostin®, 1mg Prostin®, 1mg Prostin® at six hourly intervals
- Multiparous: 1mg Prostin®, 1mg Prostin®, 1mg Prostin® at six hourly intervals

General Guidance of Prostaglandin Administration (Tablets/Gel)

- Tightening / Contracting - "Prostin pains" are a common side effect of prostaglandin administration.
- Oral analgesia and TENS can be employed after maternal and fetal assessment. If additional pain relief is required a medical review should take place.
- The presence of regular, painful contractions/uterine activity is a relative contraindication to administration of Prostin® vaginal gel/tablet. If at point of assessment for Prostin® administration there are regular painful contractions discuss with an obstetrician (ST3 or above) whether delayed administration of Prostin® and reassessment in 2 hours or an ARM may be more appropriate.
- If there is no longer regular painful uterine activity and an ARM cannot be performed Prostin® may be administered if indicated as above.
- If regular painful uterine activity persists, assessment of cervical change must be made to diagnose onset of labour and/or to assess the need and favourability for an ARM. If in doubt, discuss with obstetric staff.
- The decision regarding a third dose of Prostin®, if the woman is still not suitable for ARM, must be discussed with the Registrar and/or consultant as to the appropriateness of administration of the third Prostin® vaginal gel/tablet.
- If ARM is possible, transfer to the Delivery Unit should be arranged as soon as possible.
- If the obstetric registrar is busy when an IOL patient requires their assistance, responsibility should be escalated to the consultant responsible for the delivery unit (will often be the same as the on call consultant) who will attend or organise an appropriate member of staff to attend and report back to the consultant. At MFT – Oxford Road site there is also an additional consultant on the wards Monday-Friday 08:30-16:30 (excluding bank holidays).

Propess®

See appendix 3 for guidance on administration of Propess ®

Angusta®

See appendix 4 for guidance on administration of Angusta®

Prior to Administration of Prostin®/ Propess®/ Angusta® with SROM

- Confirm timing of SROM and evidence (e.g. liquor seen on speculum examination) and confirm the gestational age. Follow steps for maternal and fetal

risk assessment during IOL.

If on admission the patient is contracting regularly (2 in 10 minutes or more) and is ≥3cm dilated and/or fully effaced cervix, DO NOT administer Prostin®, Propess® or Angusta®. The delivery unit coordinator must be informed and the patient transferred to Delivery Unit for intravenous oxytocin.

6.3 Cervical Ripening Balloon (CRB)

The cervical ripening balloon (CRB) is a silicone double balloon catheter. It encourages gradual cervical dilatation by gentle and constant pressure on the cervix. It can be used for induction of labour at term when the Bishop score is 6 or less and if pharmacological methods are not suitable (see below) or the woman chooses a mechanical method. For instructions on use refer to appendix 5.

It is indicated in non-labouring women at term with a singleton pregnancy, longitudinal lie, cephalic presentation, intact membranes, with an indication for induction of labour and no contraindications (see below).

The indications to use a CRB are:

- Women with one previous CS where ARM is not possible

Women with a FDIU where Prostin®/ Angusta® has failed or multiple previous CS

- Women where Propess®/ Prostin®/ Angusta® has failed
- Women who are para 4 or more

Table 3 - The contraindications for a CRB are:

- Severe IUGR.
- Polyhydramnios.
- Previous cervical tear.
- Presenting part above pelvic inlet
- Pelvic structural abnormality.
- Multiple pregnancies.
- Prelabour rupture of membranes.
- Any contraindication to labour induction.
- Severe maternal hypertension.
- Unstable maternal cardiac disease.

Use of Propess®, Prostin® or Angusta® is excluded when a CRB is in situ.

6.4 Amniotomy (ARM) and Intravenous Oxytocin (IVO)

ARM and IVO can be used to initiate the induction process in women with a Bishop score of more than 6 or sustain the process after other interventions. Women should be advised that they can proceed with an amniotomy and can then choose whether or not to have an oxytocin infusion, or can delay starting this, but this may mean labour takes longer and there may be an increased risk of neonatal infection. In the

event of a high presenting part the plan of care should be discussed with an ST3 or above or consultant obstetrician prior to ARM due to the increased risk of cord prolapse.

IV oxytocin may be used as first line as follows:

- Women with SROM and evidence of chorioamnionitis.
- Women with SROM, with a cervix Bishop score above 6 and not contracting regularly
- Women with Group B Streptococcus with pre-labour SROM.

See also local guidelines for the use of intravenous oxytocin in the induction and augmentation of labour.

6.5 Outpatient IOL

Sites offering outpatient IOL management for low risk women are below (please see local guideline)

- Saint Mary's Hospital at Oxford Road
- Saint Mary's at Wythenshawe
- Saint Mary's at North Manchester
- Stepping Hill Hospital, Stockport FT - these women are seen on ADU/ Triage to initiate the IOL process and then if no concerns are identified, discharged home to await events. If active labour does not occur, they are then admitted to Delivery suite for further assessment and care planning
- Royal Albert Edward Infirmary, WWL FT

Note this is not offered/available at Bolton FT or Tameside Hospital.

7 Risk Assessment prior to commencing IOL process

7.1 Initial Assessment

- Confirm indication for IOL.
- Confirm gestational age against the first ultrasound scan.
- Check appropriate location to commence IOL as per Table 1.
- For women under the care of a specialist clinic: confirm individual care plan.
- Assess whether a neonatal cot is required and if so inform the Newborn Intensive Care Unit (NICU) about the patient – see appendix 7.
- Ensure no contraindication to induction of labour with Propess®, Prostin®,

Angusta® or CRB.

- Complete the admission paperwork.
- Maternal observations (MOEWS – modified obstetric early warning score) should be performed on admission and should be documented.. See local guideline for MOEWS
- For low risk women MOEWS should be repeated once daily as a minimum.
- For high risk women a MOEWS should be recorded at admission and thereafter to be repeated four-six hourly unless otherwise clinically indicated as per guideline for MOEWS.
- If there is a change in the woman's clinical condition e.g. contractions/tightenings or maternal observations during the induction prior to the establishment of labour a CTG must also be commenced. An obstetrician should be informed if the CTG or observations are abnormal.

7.2 Prior to Administration of PROSTIN®, PROPESS® or ANGUSTA® With Intact Membranes

- Check all the woman's medication is prescribed on the prescription chart in addition to Prostin®/Propess®/ Angusta®/and analgesia: if not bleep the junior doctor on call for the wards.
- Discuss the process of induction with the woman and confirm verbal consent. Check the placental site on last ultrasound scan and perform a VTE risk assessment.
- Ensure bladder has been emptied. Perform an abdominal palpation to confirm the fetal lie and presentation are longitudinal and cephalic and assess the level and stability of the fetal head.
- Carry out an ultrasound scan if there are any concerns about the fetal lie or presentation.
- Confirm the woman has had no regular, painful uterine activity (2 in 10 minutes or more) or history of spontaneous rupture of membranes.

Perform a pre Prostin®/Propess®/ Angusta® CTG (minimum 30 minutes) before undertaking a vaginal examination and administration of Prostin®/ Propess®/ Angusta®

- Obtain verbal consent for vaginal examination. With each administration of Prostin®, Propess® or Angusta® a Bishop score should be assessed as shown in Table 3.The score should be recorded on paper or the electronic notes depending on the individual unit.

7.3 Bishop score of cervical favourability

Table 2:

CERVICAL SCORING	0	1	2	3
Dilation (cm)	<1	1-2	2-4	>4

Length (cm)	>4	2-4	1-2	<1
Consistency	Firm	Average		Soft
Position	Posterior	Mid		Ant
Station	S -3	S-2	S-1/0	Below spines

If at any point in the induction process a woman experiences abdominal pains, tightenings or contractions, assessment of uterine activity should be made. If palpable uterine activity is occurring, pains are considered severe or there are other concerns, a CTG should be commenced to assess fetal wellbeing for twenty minutes, or until reassuring. If not reassuring seek review from an obstetrician.

8 Fetal observations during Induction of Labour

Perform either computerised or standard 30 minute CTG (unit discretion) which must be classified as normal (all 4 features reassuring) prior to the administration of Prostin®/ Propess®/ Angusta® or a CRB. Either use a CTG classification sticker or classify on K2.

If the midwife is unsure with regard to the CTG findings, obtain a second opinion from a senior midwife or obstetrician (ST3 or above). If there is any doubt as to whether to proceed with the IOL, contact the obstetric registrar or Consultant.

Following the administration of Prostin®/ Propess®/ Angusta® or a CRB the CTG must remain in progress for a minimum of 30 minutes before being discontinued and should only be discontinued if normal (all 4 features reassuring). If a midwife is unsure, obtain a second opinion from a registrar (ST3 or above) or consultant. The women should remain semi-recumbent during this time.

When repeated doses of Prostin®/Propess®/ Angusta® are required a CTG must be done for 20 minutes before the prescribed medication is administered. Following administration the CTG must remain in progress for a total of 30 minutes before being discontinued and should only be discontinued if normal (all 4 features reassuring), there is no evidence of regular uterine activity (2 contractions in 10 minutes or more) and provided there are no other clinical concerns. Any concerns regarding the CTG should escalate as previously described.

A CTG should be commenced if there is a change in the woman's clinical condition or maternal observations (MOEWS) during IOL prior to the establishment of labour.
If regular painful uterine activity (2 contractions in 10 minutes or more) a CTG must also be commenced to assess fetal well-being.

As a routine the FH should be auscultated 4 to 6 hourly, except if the woman is asleep overnight and there are no prior concerns. A CTG should be repeated at a minimum of 12-14 hourly intervals during the IOL process in the absence of particular clinical scenarios that

mandate such e.g. administration of prostaglandin, ante-partum haemorrhage. If there have been no prior concerns and the patient is asleep overnight, this can be deferred and performed on her waking, but the interval from last CTG must be no more than 24 hours. If there is regular and painful uterine activity, increased analgesia requirements, reduced fetal movements or any clinical concerns CTG monitoring should be performed as soon as possible irrespective of the time of day/night and when the last CTG tracing occurred.

There should be a daily obstetric review whilst the woman is on the ante-natal ward to ascertain if there is any reason for fetal monitoring to be increased.

9 Pain relief

Explain that induced labour may be more painful than spontaneous labour and ensure women are aware of the available pain relief options in different settings.

During induction of labour, provide appropriate pain relief, which can include simple analgesia, labour in water and epidural analgesia.

10 Labour Following Prostin®, Propress® or Angusta® for Post Maturity

Provided that post maturity was the only indication for IOL, if a woman labours following the insertion of Prostin®, Propess® or Angusta® and is otherwise low risk, consideration can be made to continue labour on the Midwifery Led Unit. See local Care in Labour guideline.

Once contractions begin and fetal well-being has been confirmed by a normal CTG (this must be performed prior to admission to the midwifery led unit if that is the planned place of transfer), unless there are indications for continuous electronic fetal monitoring, intermittent auscultation of the fetal heart may be an acceptable option for continuing to monitor fetal wellbeing.

11 Transfer to Delivery Unit for Artificial Rupture of Membranes

On transfer to the Delivery Unit:

- Once the hand over is complete, the assigned midwife should artificially rupture the

patient's membranes' as soon as possible after transfer, if SROM has not already occurred

- If an ARM is performed, intravenous oxytocin may be started immediately (if there are no regular contractions present and particularly in a primiparous woman) or it may be appropriate to allow 2-4 hours to see if labour establishes (more usually in a multiparous woman). This can be addressed on an individual basis, after discussion taking into accounts the woman's preference. Discussion should take place with the on-call obstetric consultant regarding a plan for intravenous oxytocin ® in women with a previous caesarean section. In multiparous women if they are in established labour the decision to commence intravenous oxytocin should also be discussed with a consultant (for further guidance see local intravenous oxytocin guidelines).

12 Potential complications of IOL

Women should be made aware that an induced labour may be more painful than a spontaneous labour, their hospital stay may be longer than with a spontaneous labour and that there may be a need for an assisted vaginal birth with the associated risk of a 3rd/4th degree tear. Also that pharmacological methods of induction can cause uterine hyperstimulation (see hyperstimulation rates Appendix 6), mechanical methods are less likely to do so .

12.1 Uterine hyperstimulation:

- Tachysystole is defined as >5 contractions in 10 minutes for at least 20 minutes.
- Hypertonic uterine contraction is defined as painful sustained uterine contraction for >90 seconds.
- Hyper stimulation = tachysystole or hypertonic uterine contraction PLUS evidence of fetal compromise (i.e. a suspicious or pathological fetal heart rate pattern).
- If tachysystole or hypertonic uterine contraction is suspected, commence a CTG immediately.

12.2 Management of hyperstimulation:

- Commence continuous CTG
- Summon help (emergency buzzer if necessary) - senior midwife and obstetrician (ST3 and above) and arrange transfer to the Delivery Unit.
- If Propess® in situ, remove immediately if CTG pathological. If the CTG is suspicious consideration should be given to removal of Propess®. Do not administer any further doses of other medicines being used to induce labour
- In the context of an abnormal CTG, tocolysis is necessary.
- Tocolysis is given as terbutaline 250mcg subcutaneous injection.
- Hyperstimulation caused by Angusta® may be more difficult to reverse than that caused by prostaglandin.
- Transfer to Delivery unit for closer monitoring and Consultant led decision

regarding ongoing IOL/delivery pathway.

12.3 Cord prolapse:

To avoid cord prolapse

- Before induction, assess by abdominal palpation the level and stability of the fetal head.
- During the preliminary vaginal examination, umbilical cord presentation should be excluded and the fetal head should not be displaced.

12.4 Placenta Praevia, low lying placenta, antepartum haemorrhage:

Check there is no evidence of a low lying placenta on previous scans before any vaginal examination.

12.5 Uterine Rupture:

If uterine rupture is suspected during induced labour, carry out an immediate Caesarean Section

13 When IOL fails

:
If induction fails ie if ARM is not possible after initial induction method, the maternal and fetal condition and the pregnancy in general should be fully reassessed including a CTG. An individual patient management plan must be developed following discussion with the woman and the obstetric team (ST3 and above). There should be Consultant Obstetrician input into the plan and this should be documented in the maternal records.

The subsequent management options include:

13.1 Failed Prostin® vaginal tablets or gel

If after 3 doses of Prostin® vaginal tablets or gel, and when 6 hours has elapsed after the final dose, the cervix remains unfavourable and ARM is not possible, the options are:-

(a) A rest day (this can be at home after consultant assessment) and then re-assessment
(b) Expectant management.
(c) Use of 1 further dose of Prostin® vaginal tablets/gel – Consultant decision only.
(d) Use of CRB
(e) Elective Caesarean Section (aim to achieve within 24 hours of decision).

13.2 Failed induction with Propess®

If after 24 hours Propess®, the cervix remains unfavourable and ARM is not possible, the options are:-

(a) A rest day (this can be at home after consultant assessment) and then re-assessment
(b) Expectant management.
(c) Use of second Propess.
(d) Use of Prostin® vaginal tablet/gel (up to 2 doses) to commence immediately using the normal regime: 3mg 6 hours apart.
(e) CRB
(f) Elective Caesarean Section (aim to achieve within 24 hours).

13.3 Failed induction with Angusta®

If after 24 hours of Angusta® and maximum dose of 200micrograms, the cervix remains unfavourable and ARM is not possible, the options are:-

(g) A rest day (this can be at home after consultant assessment) and then re-assessment
(h) Expectant management.
(i) CRB
(j) Elective Caesarean Section (aim to achieve within 24 hours).

14 Operational aspects of IOL Patients

14.1 Medical Review on IOL bay/ward

The IOL bay/rooms should be visited at least once in 24hrs by an Obstetrician (ST3 and above) but ideally Consultant grade– ward round consultant or consultant on call. The aim of this visit is to prioritise all women waiting to commence IOL, to review verbally with the IOL midwife all the current patients and planned admissions to the IOL bay/ward, to review any women where the midwives have concerns and to prioritise the women awaiting ARM or IV oxytocin.

14.2 Management of ARM List

For logistical management of women awaiting transfer to DU at each site see Appendix 7.

14.3 Delay in continuation of IOL process

When a woman has started on an IOL pathway, a decision to delay or suspend IOL should only be taken by the consultant obstetrician on call and midwifery matron on call after discussion with the woman. Further treatment should not be withheld due to service and capacity issues other than in exceptional circumstances.

14.4 Delay in facilitation of ARM

If planned transfers to delivery unit are affected by availability of beds, the following protocol should be followed:

- Any women in the IOL bay/rooms waiting for a bed on the delivery unit should be reviewed to see if they require transfer or an assessment as to whether they can wait at home. This decision must be made by a consultant obstetrician and should only be considered for women who only require once daily MOEWS and CTG. Whilst waiting they should be seen and maternal and fetal wellbeing confirmed daily in the antenatal assessment unit/ IOL area.
- The consultant on call / senior obstetrician should assess and prioritise the outstanding ARM list (those awaiting transfer to DU). The priority list must be reviewed at least daily.
- Fetal and maternal surveillance in this time period should be individualised and planned by senior obstetrician/ Consultant.
- For MFT Oxford Road site - Women undergoing induction of labour for indications not requiring tertiary care and for whom transfer to delivery unit is likely to take longer than clinically appropriate due to restricted capacity (for most women this may be up to 48 hours), should have a discussion with the Consultant Obstetrician regarding the choice to transfer to an alternative maternity provider. This discussion and the outcome must be documented in the woman's hospital records'.

15 How will we know this guideline is being used effectively?

There should be an annual audit of the GMEC Induction of Labour Guideline to evaluate compliance. This should be augmented by an annual survey of women's views about the information they receive. The audit should be undertaken on a minimum of 2 weeks cases or 20 case notes, whichever is the smaller number. The audit findings should be reported to the local governance meeting .

1. The audit standards are:

a) Documentation to include:- reason for IOL, gestation recommended, alternatives discussed, method offered, complications, information leaflet given/ signposted complications, information leaflet given/ signposted
b) Timing of interventions consistent with guidance
c) Delays in progress of IOL
d) Maternal monitoring consistent with guidance
e) Fetal monitoring consistent with guidance

2. Process measures are:

a) Proportion of women whose IOL does not proceed within guidance
b) Proportion of women whose indication for IOL is outside guidance

3. Outcome measures are:

a) Method of delivery
b) Neonatal outcome

16 Equality Impact Assessment

IMPACT	Age	Disability	Sex (gender)	Gender reassignment	Race	Religion or belief	Sexual orientation	Marital status	Pregnancy and maternity
Do different groups have different needs, experiences, issues and priorities in relation to the proposed policy?									
Is there potential for or evidence that the proposed policy will not promote equality of opportunity for all and promote good relations between different groups?									
Is there potential for or evidence that the proposed policy will affect different population groups differently (including possibly discriminating against certain groups)?									
Is there public concern (including media, academic, voluntary or sector specific interest) in potential discrimination against a particular population group or groups?									

Appendix 1 - Signposting patients to information

Each unit inserts own instructions here

Appendix 2 – Procedure for booking a bed for induction either on induction of labour (IOL) bay or delivery unit

Each unit inserts own instructions here

Appendix 3 - Propess® insertion

- Remove Propess® from the freezer. It should not be left at room temperature for more than 20 minutes prior to insertion.
- Prior to insertion, ensure no contraindications to induction of labour; perform maternal observations and a pre- Propess® CTG of minimum 20minute duration.
- Provided the CTG is normal and cervical assessment demonstrates Bishops score<6 (Table 2) proceed with insertion of Propess®.
- Holding the Propess® between middle and index fingers, place pessary high into the posterior vaginal fornix as shown in pictures below. Hibitane cream should be avoided.
- Using the examining fingers, adjust the position of the pessary so that it lies horizontally in the posterior fornix behind the cervix.
- Gently withdraw fingers from the vagina, leaving the Propess®.
- The string can be trimmed to reduce chances of the pessary being inadvertently pulled out, but must be left long enough for easy intentional removal.

It is reasonable to request that women inform the midwife if any of the following occurs, prompt detection remains the responsibility of the midwife:

- Regular (2:10) painful contractions or tightenings.
- Rupture of membranes.
- Vaginal bleeding.
- Propess® falls out.
- Although it is possible to bathe/shower and use the toilet with Propess® in situ, women must be discouraged from pulling the string as this can lead to inadvertent removal.
- The Propess® should remain in situ for up to 24 hours. After this time the midwife

should remove the Propess® and assess suitability for ARM.

If Propess® falls out of the vagina:

- If it does not touch contaminated surfaces, the same Propess® can be re-inserted. In all other circumstances a new Propess® should be inserted.
- After re-insertion, a CTG should be performed for a minimum of 20 minutes and only discontinued if deemed normal.
- If a new Propess® is required, the time that the initial Propess® and the 2nd Propess® are insitu must not amount to >24 hours (combined insertion times).

Regular contractions (>2 in 10 minutes) with Propess® in situ

- Commence CTG.
- Assess cervix and if >3cm dilated arrange transfer to Delivery unit with Propess® in situ.
- If< 3cm, Propess® can remain in situ but if reassessed 4 hours later and adequate first stage progress has not been made, Propess® should be removed and 30 minutes later ARM performed and syntocinon commenced.

SROM with Propess® in situ:

- Commence CTG for minimum of 40 minutes and only discontinue if deemed normal.
- Perform vaginal and abdominal examination to determine contraction frequency and cervical dilatation.
- Propess® can be left in situ if not regularly contracting and cervical dilatation <3cm.
- If labouring (cervix >3cm dilated and regular contractions) Propess® can be left in situ and arrangements made for transfer to delivery unit.
-

Tightening, Contracting or requiring additional analgesia:

- Commence CTG for minimum of 40 minutes and only discontinue is deemed normal.
- Perform a VE.
- If labour is established (regular uterine contractions and cervical dilatation >3cm) Propess® can remain in situ, transfer to Delivery unit and consideration given to ARM if required.
- If labour is not established, Propess® should be left in situ and vaginal examination carried out 4 hours later (sooner if clinically indicated).
- In the presence of a uterine scar, assess for scar pain, bleeding and maternal wellbeing and summon medical review as appropriate.

Propess® removal.

- Propess® must be removed 24 hours after insertion (sooner if clinically indicated as above). To remove Propess®, apply gentle traction on the string. Document time and date of removal in woman's notes and on the prescription chart.
- An ARM can be performed immediately after Propess® removal, Oxytocin can be commenced a minimum of 30 minutes after Propess® removal.
- Refer to guideline for Oxytocin in induction and augmentation of labour.

- If a patient suffers from nausea, vomiting, diarrhoea, fever, hypotension, vaginal irritation or oedema it may be a reaction to the Propess and it should be removed and an obstetrician called to assess the woman.

Appendix 4 – Angusta Summary of product characteristics[i]

1. Name of the medicinal product
ANGUSTA25 micrograms tablets

2. Qualitative and quantitative composition
Each tablet contains 25 micrograms misoprostol.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form
Tablet

White, uncoated oval shaped tablets with the dimensions 7.5 x 4.5 mm with a score line on one side and plain on the other. The score line is not intended for breaking the tablet.

4. Clinical particulars
4.1 Therapeutic indications
Angusta is indicated for induction of labour.

4.2 Posology and method of administration
Posology

The recommended dosing regimen for Angusta is 25 micrograms orally every two hours or 50 micrograms orally every four hours according to hospital practice. The maximum dose is 200 micrograms over a period of 24 hours.

There may be a synergistic/additive effect of misoprostol and oxytocin. Plasma concentrations of misoprostol acid are negligible after 5 half-lives (3.75 hours), see section 5.2. It is recommended to wait 4 hours after the last dose of Angusta before administration of oxytocin (see sections 4.3, 4.4 and 4.5).

Due to the lack of clinical data, the use of Angusta is recommended from 37th week of pregnancy when the cervix is unfavourable (Bishop score <7).

Special populations

A lower dose and/or prolonged dosing intervals should be considered in pregnant women with renal or hepatic impairment (see section 5.2).

Paediatric population

The safety and efficacy of Angusta in pregnant women aged less than 18 years has not been established in clinical trials. No data are available.

Method of administration

- Angusta should only be administered by trained obstetric personnel in a hospital setting where facilities for continuous fetal and uterine monitoring is available.
- The cervix should be assessed carefully before Angusta is administered.
- Angusta should be taken orally with a glass of water.

4.3 Contraindications
Angusta is contraindicated:
- When there is hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- When labour has started
- When there is suspicion or evidence of foetal compromise prior to induction (e.g., failed non-stress or stress test, meconium staining or diagnosis or history of non-reassuring foetal status)
- When oxytocic drugs and/or other labour induction agents are being given (see section 4.2, 4.4, 4.5 and 5.2)

- When there is suspicion or evidence of uterine scar resulting from previous uterine or cervical surgery, e.g. caesarean delivery
- When there is uterine abnormality (e.g. bicornuate uterus) preventing vaginal delivery
- When there is placenta praevia or unexplained vaginal bleeding after 24 weeks gestation with this pregnancy
- When there is foetal malpresentation, contraindicating vaginal delivery
- In patients with kidney failure (GFR <15 ml/min/1.73 m^2).

4.4 Special warnings and precautions for use

Angusta should only be administered by trained obstetric personnel in a hospital setting where facilities for continuous fetal and uterine monitoring is available and the cervix should be assessed carefully before product use.

Angusta can cause excessive uterine stimulation.

If uterine contractions are prolonged or excessive, or there is a clinical concern for the mother or baby, additional Angusta tablets should not be administered. If excessive uterine contractions continue, treatment according to local guidelines should be started.

In women with pre-eclampsia, evidence or suspicion of foetal compromise should be ruled out (refer to section 4.3). There are no or limited clinical data with misoprostol in pregnant women with severe pre-eclampsia marked by Haemolytic anaemia; Elevated Liver enzymes; Low Platelet count (HELLP) syndrome, other end organ affliction or CNS findings other than mild headache.

Chorioamnionitis may necessitate fast delivery. Decisions regarding antibiotic treatment, induced labour or caesarean section will be at the physician's discretion.

There are no or limited clinical data with misoprostol in women whose membranes have been ruptured for more than 48 hours prior to administration of misoprostol.

There may be synergistic/additive effects of misoprostol and oxytocin. Concomitant administration of oxytocin is contraindicated. See section 4.3. Angusta is eliminated after 4 hours. See section 5.2. It is recommended to wait 4 hours after last dose of Angusta before administration of oxytocin (see sections 4.2 and 4.5).

There are no or limited clinical data with misoprostol in multiple pregnancies. There are no or limited clinical data with misoprostol in grand multiparity.

There are no or limited clinical data with misoprostol before week 37 of gestation (see section 4.6).

Angusta should be used only when induction of labour is clinically indicated.

There are no or limited clinical data with misoprostol in pregnant women with Bishop score (mBS) >6.

An increased risk of post-partum disseminated intravascular coagulation has been described in patients whose labour has been induced by any physiological or pharmacological method.

A lower dose and/or prolonged dosing intervals should be considered in pregnant women with renal or hepatic impairment (see section 5.2).

This medicinal product contains 0.874 mg sodium per tablet that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed with Angusta.

Concurrent use of oxytocic drugs or other labour induction agents is contraindicated due to the potential of increased uterotonic effects (see sections 4.2, 4.3, 4.4 and 5.2).

4.6 Fertility, pregnancy and lactation

Pregnancy

Angusta has been studied in pregnant women ≥37 weeks of gestation.

Angusta should only be used prior to 37 weeks of gestation if medically indicated (see section 4.4).

Angusta is used for labour induction at a low misoprostol dosage for a short period of time at the very end of pregnancy. When used at that time of pregnancy, there is no risk of foetal malformations. Angusta should not be used at any other time during pregnancy: a threefold increased risk of foetal

malformations (including Moebius syndrome, amniotic band syndrome and central nervous system anomalies) has been reported in pregnancies exposed to misoprostol in first trimester.

Breast-feeding

No studies have been performed to investigate the amount of misoprostol acid in colostrum or breast milk following the use of Angusta.

Misoprostol has been detected in human milk following oral administration of misoprostol in tablet form.

Pharmacokinetic trials reveal that oral misoprostol (at dose levels of 600 µg and 200 µg) is excreted into breast milk with drug levels that rise and fall very quickly. The maximum concentration of misoprostol acid in expressed breast milk was achieved within 1 hour after dosing and was 7.6 pg/ml (% CV 37%) and 20.9 pg/ml (% CV 62%) after single 200 mcg and 600 mcg misoprostol administration, respectively. Negligible amounts of misoprostol acid remain in maternal plasma after 5 half-lives (3.75 hours), and even lower concentrations will remain in breast milk. Breast-feeding can start 4 hours after the last dose of Angusta is administered.

Fertility

Studies of fertility and embryo development in rats have shown that misoprostol may have an impact on implantation and resorption. This is, however, considered of no relevance for the indicated use of Angusta in late pregnancy.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

The undesirable effects listed in the table below have been reported in 41 trials where a total of 3,152 women were exposed to oral misoprostol at doses of 20-25 µg every 2 hours or 50 µg every 4 hours. In addition, adverse events reported in a compassionate use program, where approximately 29,000 women have been exposed to Angusta for induction of labour are also listed.

System Organ Class	**Very common (≥ 1/10)**	**Common (≥ 1/100 to < 1/10)**	**Uncommon (≥ 1/1,000 to < 1/100)**	**Not known (cannot be estimated from the available data) [1)]**
Nervous system disorders				Dizziness Convulsion neonatal*
Respiratory, thoracic and mediastinal disorders				Neonatal asphyxia* Cyanosis neonatal*
Gastrointestinal disorders	*With 50 µg, 4-hourly:* Nausea[2)] Vomiting[3)]	Diarrhoea *With 25 µg, 2-hourly:* Nausea[2)] Vomiting[3)]		
Skin and subcutaneous tissue disorders				Rash pruritic
Pregnancy, puerperium and perinatal conditions	Meconium stain *With 25 µg, 2-hourly:* Postpartum haemorrhage[5)]	Uterine hyperstimulation[4)] *With 50 µg, 4-hourly:* Postpartum haemorrhage[5)]		Foetal acidosis* Premature separation of placenta Uterine rupture
General disorders and administration site conditions		Chills Pyrexia		
Investigations		*With 50 µg, 4-hourly:* Apgar score low*[6)] Foetal heart rate abnormal*[7)]	*With 25 µg, 2-hourly:* Apgar score low*[6)] Foetal heart rate abnormal*[7)]	

* Neonatal adverse reaction

1) ADRs which were reported from the compassionate use programme including birth hospitals in Denmark, Norway and Finland, where approximately 29,000 women have been exposed to Angusta for induction of labour.

2) Nausea was common with 25 µg every 2 hours and very common with 50 µg every 4 hours.

3) Vomiting was common with 25 µg every 2 hours and very common with 50 µg every 4 hours.

4) Uterine hyperstimulation was reported both with and without foetal heart rate changes.

5) Postpartum haemorrhage was very common with 25 µg every 2 hours and common with 50 µg every 4 hours.

6) Apgar score low was uncommon with 25 µg every 2 hours and common with 50 µg every 4 hours.

7) Foetal heart rate abnormal was reported in connection with uterine hyperstimulation.

Uterine hyperstimulation with foetal heart rate changes was uncommon with 25 µg every 2 hours and common with 50 µg every 4 hours.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple Store.

4.9 Overdose

There is no information on overdose with Angusta.

In case of overdose symptoms (e.g. excessive uterine stimulation causing prolonged or excessive contractions), dosing with Angusta should be arrested and treatment according to local guidelines should be started. The potential consequences of uterine hyperstimulation include foetal heart rate disorders and asphyxia in which case caesarean section should be considered.

Appendix 5 – Cervical Ripening Balloon (CRB) Instructions

Prior to use:

1. Confirm term, singleton, longitudinal lie, cephalic presentation, intact membranes.
2. A CTG should be performed for 30 minutes before CRB insertion.
3. An abdominal palpation should be performed to ensure the fetus is cephalic and the head is engaged.
4. A VE should be performed to determine if ARM is possible and to calculate the Bishop's score by an appropriately trained member of staff who should insert the CRB, if ARM is not possible.

Insertion of balloon:

1. Perform vaginal examination.
2. Hold the CRB with the left hand and insert into cervix by siding along the fingers of your right hand and advance until both balloons have entered the cervical canal.
3. Inflate the uterine balloon with 40ml normal saline through the red Check-Flo valve (U).
4. Once inflated, pull back until the uterine balloon is against the internal cervical os.
5. When the vaginal balloon is visible outside the external cervical os, inflate with 20ml normal saline through the green Check-Flo valve (V).
6. Once the balloons are situated on each side of the cervix, add more fluid in 20ml increments until each balloon contains 80ml (maximum).

Alternatively, If the cervix is very posterior or unfavourable, balloon insertion may be difficult:

1. Place the patient in lithotomy position.
2. Insert a speculum to visualise the cervix.
3. Grasp the catheter with sponge holders and insert the device into the cervix (4-7) as above.

After insertion:

1. A post-procedure CTG should be performed for 30 minutes.
2. If reassuring, discontinue, encourage the woman to mobilise.

Removal (after 12 hours):

1. Perform a CTG 11½ hours following insertion for at least 30 minutes.
2. The midwife should deflate the balloons (removing 80ml from both the uterine and vaginal balloons) and remove 12hrs after insertion.
3. Perform a VE to assess suitability for ARM.
4. If suitable for ARM, transfer to Delivery Unit for ARM and/or oxytocin.
5. If unsuitable for ARM, the patient should be reviewed by the consultant on call or a ST3 doctor or above.

Issues following CRB insertion:

- If the balloon falls out, this would imply that the cervix has dilated. Perform a VE to confirm ARM is possible, and transfer to the delivery unit when possible.
- If SROM occurs, deflate both the balloons and remove the catheter. Do a VE to assess the cervix. Transfer to the delivery unit if in labour. If does not labour spontaneously, transfer to the delivery unit 6 hrs after SROM for syntocinon.
- If bleeding (significant bleeding, not just a show) occurs, the woman should be reviewed by a doctor. A CTG should be commenced and consideration should be given to deflating both the balloons and removing the catheter.
- If the woman is in significant constant discomfort (i.e. not contractions) following the balloon insertion, consideration can be given to deflating the balloons slightly. It is important to document the amount removed from the balloons when they are removed.

If ARM is not possible following CRB and having been assessed by a ST3 or above (and discussed with a consultant), the following options should be discussed with the woman:

- Rest period of 12 hours, and then repeat attempt at CRB.
- Rest period of 12 hours, and then insert a maximum of 2 doses of Prostin (minimum 6 hours apart) or 1 Propess. The increased risk of uterine rupture with the use of prostaglandin in women with a previous Caesarean section should be re-discussed when this option is given.
- Elective Caesarean section (this should be done within the next 24 hours).

CRB insertion not possible

- If the CRB cannot be inserted either digitally or by using a speculum, the options include:
  - Repeat examination and attempt by consultant on call if initial attempt by ST5 doctor or above.
  - Use of Propess®. See Appendix 3.

Appendix 6 - Risks of hyperstimulation associated with IOL

Appendix C: Risks of hyperstimulation associated with different pharmacological methods of inducing labour

Table 9: Risks of hyperstimulation with dinoprostone and misoprostol

Preparation (dose or type)	Risk of hyperstimulation with fetal heart rate changes compared to placebo in women with a Bishop score of 6 or less (OR, 95% Credible Interval)
Oral misoprostol (under 50 micrograms)	1.54 (0.32 to 7.60)
Titrated oral (low dose) misoprostol	1.96 (0.65 to 8.12)
Vaginal dinoprostone tablet	2.22 (0.59 to 6.03)
Oral misoprostol (50 micrograms or more)	3.09 (1.10 to 9.19)
Vaginal dinoprostone gel	3.45 (1.24 to 10.53)
Vaginal misoprostol (under 50 micrograms)	4.12 (1.57 to 11.60)
Vaginal dinoprostone pessary (slow release)	4.98 (1.82, 15.01)
Vaginal misoprostol (50 micrograms or more)	5.92 (2.26, 16.81)
Buccal/sublingual misoprostol	7.07 (2.22, 24.45)

Source: https://www.nice.org.uk/guidance/ng207/resources/appendices-a-b-and-c-pdf-14105621715397[ii]

Appendix 7 – Management of women awaiting transfer to DU for ARM

Each unit inserts own instructions here

Appendix 8 – How to contact the neonatal unit

Each unit inserts own instructions here.

References

[i] Norgine.it/press_release/norgine-b-v-completes-important-regulatory-milestone-for-angusta-misoprostol-in-europe-for-oral-induction-of-labour/ DK_H_2584_001_FinalSPC.pdf (cts-mrp.eu)/https://www.medicines.org.uk/emc/product/12147/smpc accessed 8/12/21

[ii] https://www.nice.org.uk/guidance/ng207/resources/inducing-labour-pdf-66143719773637