

**Achieving Sustainable Quality in
Maternity Services**

ASQUAM

**Guideline for
Induction of Labour**

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Date of Next Review:	February 2022
Ratified by:	Labour Ward Forum Sub-Group Obstetric Guideline Group
Reviewed by:	Induction of Labour Task Group

VERSION CONTROL SCHEDULE

Version	Date	Author	Comments
1	1997		
2	2001		
3	2003		
4	2005		
5	2011 – February	██████████ Consultant Obstetrician	
6	2011 – December	As above	
7	2013 – March	As above	
8	2013 – October	As above	
9	2014 – January	As above	Combined start/stop sticker added
10	2014 – July	As above	CTG stickers added
11	2015	██████████ Reviewed by ██████████ Consultant Obstetrician and ██████████ Senior Registrar	Amalgamation of the Induction of Labour Guideline and the ASQUAM Guideline for Outpatient Management of Induction of Labour.
12	2019	██████████ Consultant Obstetrician Induction of Labour Task Group ██████████ Midwife	Full review undertaken Summary of changes include: Outpatient for multiples – removal of specified distance. Inpatients to have prostins unless previous uterine surgery included. Frequency of fetal monitoring has been changed. Bishops score prior to booking induction to be completed. If contractions are >3 in 10 minutes remove Dinoprostone (Propess®) and transfer to MBC.

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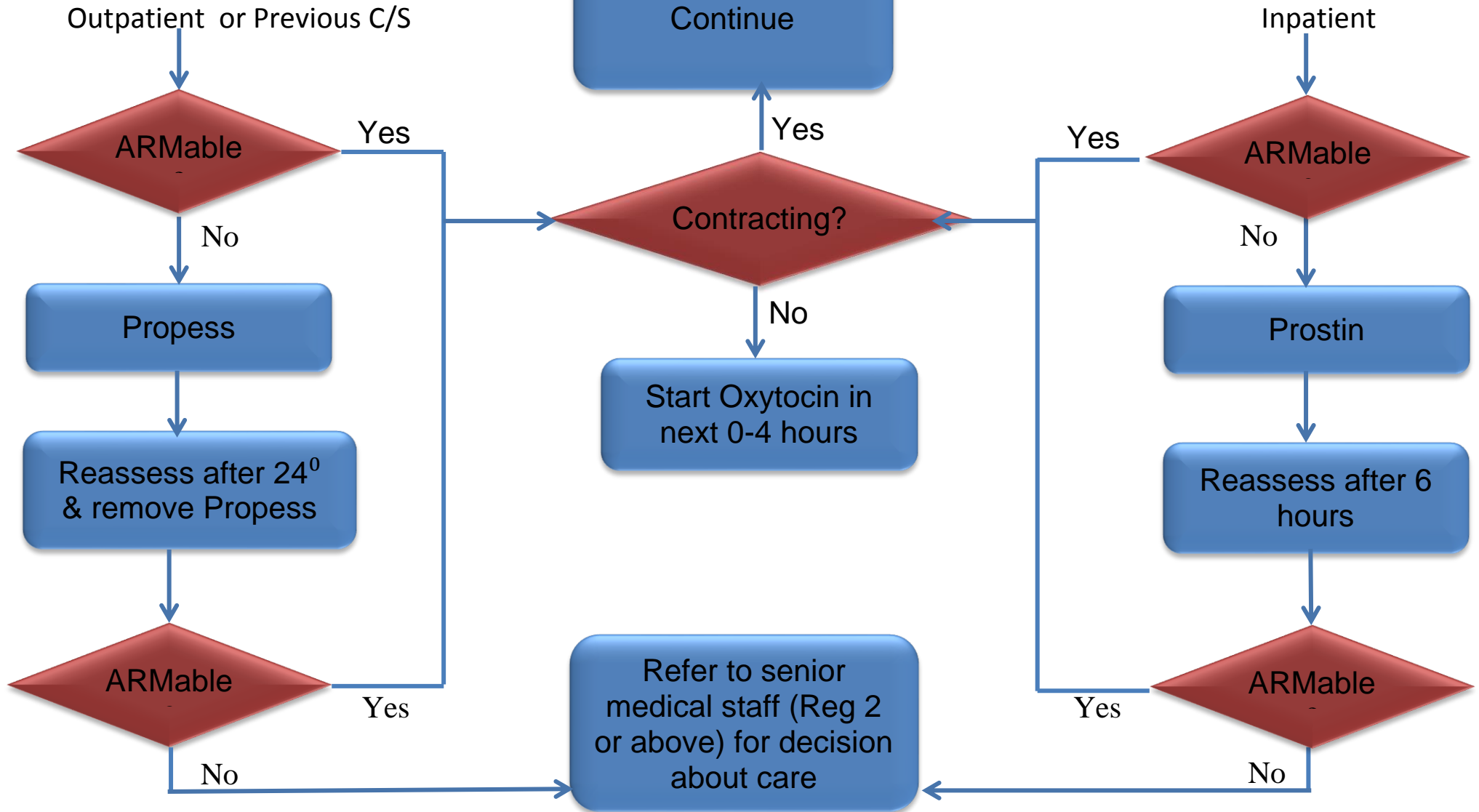
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Flowchart for Induction of Labour



1. PURPOSE OF THE GUIDELINE

The purpose of this guideline is to provide up-to-date information for medical and midwifery staff at the University Hospitals of North Midlands (UHNM), to ensure the provision of consistent, high quality evidence based care for women undergoing induction of labour.

2. BACKGROUND

Induction of labour (IOL) is defined as an intervention designed to artificially initiate uterine contractions leading to progressive dilatation and effacement of the cervix and the birth of the baby.

This includes both women with intact membranes and women with spontaneous rupture of membranes but who are not in labour.

IOL is a common procedure; approximately 25% of pregnant women will have their labour induced for a variety of reasons.

3. INDICATIONS AND CONTRA-INDICATIONS TO INDUCTION OF LABOUR

3.1 Indications for IOL

- When the intrauterine risks are such that the infant will be safer delivered.
- When the risk to the mother's health from continuation of the pregnancy outweighs the risk to the delivery of the fetus.

The process of induction of labour should only be considered when vaginal delivery is felt to be an appropriate route of delivery.

Obstetric Consultants should be involved with the decision to induce any women except for those that a midwife may book for women with post mature pregnancies from term plus 10 to 14 days and those women with pre-labour rupture of membranes at term. This will continue via a telephone booking to Ward 205 (672205).

Indications for recommendation for IOL are listed below but note that this list is not exhaustive.

- Pregnancy Induced Hypertension
- Pre-eclampsia
- Rhesus incompatibility
- Maternal diabetes mellitus
- Multiple pregnancies - monochorionic diamnionic (MCDA) twins at 36/40 gestation and dichorionic diamnionic (DCDA) twins at 37/40 gestation
- Obstetric Cholestasis
- Fetal growth restriction (please note NICE Guidance regarding fetal growth restriction: If there is severe fetal growth restriction with confirmed fetal compromise, induction of labour is not recommended (NICE 2008).
- Suspected fetal compromise
- Post dates (from term⁺¹⁰⁻¹⁴)
- Pre-labour spontaneous rupture of membranes
- Pre-term, pre-labour rupture of membranes.
- Severe pelvic girdle pain (PGP) requiring mobility aids.
- Maternal medical condition requiring delivery
- Maternal age >40

Induction of labour may also be considered for:

- Polyhydramnios
- Oligohydramnios
- Recurrent antepartum haemorrhage (APH)
- Previous still birth or neonatal death
- Prolonged latent phase of labour

Induction of labour should not routinely be offered for maternal request. Under exceptional circumstances, however, (for example, if the woman's partner is soon to be posted abroad with the armed forces), induction may be considered at or after 40 weeks (NICE 2008).

Social indications rarely constitute an adequate reason for induction but each case should be considered on its merits after adequate counselling of

the woman and has to be discussed with the individual's named Consultant.

NB: Please consider carefully the date for IOL where there are safeguarding concerns especially at weekend and bank holidays as there is limited access to Social Care during holiday periods.

For women who have been diagnosed with an intra-uterine death follow the ASQUAM guideline for Fetal Loss/Intrapartum Death.

3.2 Contra-indications to induction of labour

- The fetal lie is not longitudinal
- A tumour occupies the pelvis and obstructs the birth canal.
- Placenta praevia
- Previous classical caesarean section
- 2 or more lower segment caesarean sections

Decisions regarding optimal timing of delivery remain difficult and should always be taken by experienced staff and should be discussed with the woman's Consultant.

4. DISCUSSION AND DOCUMENTATION

In every case, to enable the woman to make an informed decision, discussions at 38 week antenatal visit, should be offered with information about the risks associated with pregnancies that last longer than 42 weeks, and their options. Discussion must include:

- the indication for induction
- the choice of methods used
- the potential risks and consequences for accepting or refusing the offer of induction.

The offer of increased antenatal monitoring consisting of at least twice-weekly cardiotocography (CTG) and ultrasound (US) estimation of maximum amniotic pool depth. Discussions must be documented and a plan of management must be outlined, and documented on K2 under 'management plan'. This discussion must also include an agreed

management plan if the induction process fails, e.g. delivery by caesarean section. An inpatient prescription chart should be completed by medical staff in antenatal clinic and remain with the woman to bring into hospital at her induction date. An assessment of the cervix and bishop score should be performed and documented (please see contents point 8). In the case of women requesting induction of labour who do not fall into a category for induction of labour, a referral to a Consultant Obstetrician must be made to discuss this.

5. MEMBRANE SWEEPING

Membrane sweeping is a relatively simple technique which can be undertaken by midwives and doctors. The aim is to separate the fetal membranes from the cervix, leading to a release of prostaglandins and subsequent onset of labour.

Where an earlier induction is not necessary, women should be offered a membrane sweep at 40 and 41 weeks for primigravidas and 41 weeks gestation for multigravidas.⁴

For those women booked for induction of labour earlier, based on their clinical condition, a management plan should be documented in the woman's K2 antenatal records for the Community Midwife to follow regarding membrane sweeping.

6. BISHOP'S SCORE

The Bishop's score is used to evaluate the degree of cervical ripeness and is easily assessed clinically. The cervical state is given a numerical value according to the modified Bishop's Score.

If the cervix is ripe (score >5) induction of labour is likely to be straightforward. A score of less than 5 does not preclude a successful induction, but the attempt is more likely to fail, have a longer latent phase and require a higher total dose of prostaglandins and Oxytocin.

Cervical state Score:	0	1	2	3
Dilation (cm)	Closed	1 – 2	3 – 4	5 +
Length of cervix (cm)	3	2	1	0
Station of vertex (cm above IS) – (cm above IS) +	-3	02	-1,0	+1,+2
Consistency	Firm	Medium	Soft	
Position of cervix	Posterior	Middle	Anterior	

7. BOOKING THE INDUCTION OF LABOUR

Once a decision has been made for induction, a cervical assessment should be performed and a sweep offered. The only exceptions to this should be where the decision is made a long time in advance, in the presence of ruptured membranes or where the woman declines examination. Cervical assessment will inform co-ordination of admission and the prescription of appropriate medication, which can be done at the time of decision making.

A booking form will be completed (Appendix 1) with the required information and a patient information leaflet will be given to the woman (available via Bounty app and intranet). At the end of each day, the forms will be collected and taken by antenatal clinic staff (or emailed when system is made available) to the induction lead midwife or core staff on Ward 205, they will allocate appropriate induction appointments and the women will be contacted the following day. County clinics will need to call Ward 205 where a booking form will be completed over the telephone.

For anybody requiring an urgent IOL, the Delivery Suite Co-ordinator and the Obstetric Consultant should be contacted directly.

All inductions of labour bookings are entered into a diary on the induction of labour area.

Women who are known to be favourable for Artificial Rupture of Membranes (ARM), or are being induced for pre-labour rupture of membranes will be contacted by the Delivery Suite Co-ordinator and notified of the time to attend.

Women being admitted to the Induction of labour ward will be contacted from 07.00 hours onwards.

Women should be asked to call the hospital if they have not been contacted to come in by 17:00 hours.

If the induction is postponed, ideally the Consultant should be informed. If the Consultant is unavailable or when the woman is waiting in the induction ward, the ongoing management plan should be made after informing the Delivery Suite Consultant/On Call Consultant.

8. METHODS OF INDUCTION OF LABOUR

Healthcare professionals should inform women that the available evidence does not support the following methods for induction of labour:

- herbal supplements
- acupuncture
- homeopathy
- castor oil
- hot baths
- enemas
- sexual intercourse.

The insertion of vaginal Dinoprostone (Propess®/Prostin®), amniotomy and the administration of intravenous infusion of Oxytocin (following amniotomy if indicated) are the main methods of induction of labour at UHNM at present. Mechanical methods of cervical ripening can also be considered with Consultant involvement where appropriate.

The cervical state has a profound influence on the outcome of induced labour and a policy of active cervical ripening prior to amniotomy produces dramatic results.

8.1 Dinoprostone (Propess®/Prostin®)

8.1.1 Preparations

- a. Dinoprostone (Propess®) 10 mg – for women having had a previous caesarean section (without rupture of membranes). Re-assess and remove after 24 hours.
- b. Offer Dinoprostone (Propess®) 10mg for post mature low risk multigravidas and primigravidas with no previous uterine surgery or no Spontaneous Rupture of Membranes (SROM) who wish outpatient management of induction of labour.
- c. Dinoprostone gel (Prostin®) 1 mg – for multigravidas women where the cervix is difficult to reach and/or BMI elevated over 40. Re-assess after 6 hours and repeat a 1mg dose if required.
- d. Dinoprostone tablets (Prostin®) 3 mg – for inpatient induction of labour and for women with ruptured membranes. Re-assess after 6 hours and repeat a 3mg dose if required.

8.1.2 Use with caution

The following situations should be discussed with a Consultant Obstetrician

- Previous caesarean section. The risk of uterine rupture when labour is induced with prostaglandins is 240 per 10,000.
- Previous uterine surgery
- Evidence of antepartum fetal compromise (significant fetal growth restriction, oligohydramnios, abnormal CTG, Doppler and Biophysical profile)
- Grand multipara (≥ 4)

8.1.3 Dinoprostone Pessary (Propess®) Insertion

- Remove Dinoprostone pessary from the freezer 20 minutes before administration.
- Insert Dinoprostone pessary high into the posterior fornix using aquagel NOT Hibitane.
- The pessary should lie transversely in the posterior fornix.

After Dinoprostone (Propess®) has been inserted the withdrawal tape may be cut, but ensure that there is sufficient tape outside the vagina to allow removal. No attempt should be made to tuck the end of the tape into the vagina

- The woman should be recumbent for 30 minutes after insertion
- Continue CTG for an hour.
- At 1 hour post-insertion check maternal observations, including: temperature, pulse and blood pressure, and note any adverse effects (nausea, vomiting, tachycardia, hypotension, fever, vaginal irritation, abdominal pain, vaginal bleeding, hypertonic uterine activity, abnormal CTG).

For women who have had a previous caesarean section, Dinoprostone pessary (Propess®) is administered only after the Consultant Obstetrician's approval; this discussion should be documented in the IOL management plan.

It may be possible for some women to go home following insertion of Dinoprostone pessary (see section 12).

8.1.4 Reasons to remove Dinoprostone Pessary (Propess®)

- Evidence of uterine tachysystole, hypertonus or hyperstimulation (see definitions below)
- Tachysystole = 5 contractions in 10 minutes with normal CTG

- Hypertonus = painful contraction lasting 90 seconds: normal CTG
- Hyperstimulation = 5 contractions in 10 minutes with an abnormal CTG
- Abnormal CTG
- Vaginal bleeding
- Achieved cervical ripening bs>7

8.1.5 Management of unsuccessful Dinoprostone induction

In cases of failed induction, the management plan must be made after discussion with the Consultant and the woman.

Options:

- a. Dinoprostone pessary (Propess®) can be left in for another 6 hours (total of 30 hours).
- b. Induction process can be restarted after a 24 hour rest period
- c. Deliver by Caesarean Section Category 3 if labour does not establish and the cervix remains unfavourable

8.2. Amniotomy (Artificial Rupture of Membranes)

8.2.1 Indications

- As part of induction of labour
- To augment established labour at term
- To allow attachment of fetal scalp electrode

8.2.2 Contraindications

- Unknown/uncertain gestation
- Lie not longitudinal
- Presenting part not determined
- High presenting part
- Vaginal bleeding and placenta praevia has not been excluded

8.2.3 Potential complications

- Cord prolapse
- Antepartum haemorrhage: Consider abruption, cervical trauma, vasa praevia, undiagnosed placenta praevia.

8.2.4 Following amniotomy

- Commence Oxytocin immediately in primigravida women undergoing induction of labour.
- Allow 2-4 hours following amniotomy in multiparous women to allow contractions to establish before commencing Oxytocin if required.
- Where used for augmentation of labour consider Oxytocin, where appropriate, if contractions/progress remains inadequate.

8.3 Oxytocin

Synthetic Oxytocin, is identical to the posterior pituitary polypeptide hormone. It selectively stimulates the contraction of the uterine smooth muscle.

Continuous monitoring of maternal and fetal condition is mandatory in these situations.

Until labour is established, maternal observations should include:

- Monitoring, recording and documenting of contractions, temperature, pulse and blood pressure 4 times in 24 hours (unless maternal condition indicates otherwise) observe for any signs of change in maternal condition and document any findings.

Fetal observations should include:

- Initial CTG of 20 minutes prior to commencement of Oxytocin unless any concerns have arisen with the fetal heart.
- Continuous CTG once Oxytocin commences.

8.3.1 Contra-indications

- Any condition where spontaneous labour or vaginal delivery inadvisable
- Hypertonic uterine inertia
- Mechanical obstruction to delivery
- Failed trial of labour
- Fetal distress
- Placenta praevia
- Severe pre-eclampsia toxaemia
- Severe cardiovascular disease

8.3.2 Precautions

- Abnormal presentation (NB breech)
- Multiple pregnancy
- High parity (i.e. ≥ 5)
- Previous caesarean section
- Action may be potentiated by prostaglandins, so it should not be started for 6 hours following the administration of vaginal prostaglandin

8.3.3 Side effects

Common/Very Common:

- Arrhythmia
- Headache
- Nausea
- Vomiting

Rare:

- Anaphylactoid reactions (with dyspnoea, hypotension, or shock);
- Disseminated intravascular coagulation;
- Hyponatraemia associated with high doses with large infusion volumes of electrolyte-free fluid;
- Rash;
- Uterine hyperstimulation (usually with excessive doses—may cause fetal distress, asphyxia, and death, or may lead to hypertonicity, tetanic contractions, soft-tissue damage or uterine rupture)
- Uterine spasm (may occur at low doses)

- Water intoxication associated with high doses with large infusion volumes of electrolyte-free fluid

Note: Oxytocin must not be infused through the same line as blood or plasma (Oxytocinase can inactivate Oxytocin).

8.3.4 Oxytocin regime for induction/augmentation

At UHNM a solution of Oxytocin should be prepared by two trained members of staff (i.e. midwife or medical staff). The authors of the guideline acknowledge the recommendations for dilutions and dose regimes for Oxytocin given in the NICE Guideline. Locally however, the decision at the Labour Ward forum (04-05-2010) and following discussion with Pharmacy, was to use the following Oxytocin low dose regimen for every patient:

5 international units Oxytocin (commonly referred to as Syntocinon® at UHNM) made up to 50 mls with 0.9% Sodium Chloride (1ml (5 international units) Oxytocin + 49 mls of 0.9% Sodium Chloride)

A drug additive label should be completed by both staff members to indicate the concentration prepared and attached to the syringe of 0.9% Sodium Chloride.

Rate commencing at:

1.5 mls/hr then after 30 minutes increasing to
3.0 mls/hr then after 30 minutes increasing to
4.5 mls/hr then after 30 minutes increasing to
6.0 mls/hr then after 30 minutes increasing to
a maximum of 9.0 mls/hr or until there are 4-5 contractions in 10 minutes.

If regular contractions are not established, request a medical review (obstetric registrar or consultant) and an individual plan of management should be clearly documented.

DO NOT INCREASE THE MAXIMUM RATE WITHOUT CONSULTING MEDICAL STAFF (OBSTETRIC REGISTRAR or CONSULTANT)

STOP THE INFUSION RATE IF:

- Prolonged deceleration of >3mins or bradycardia.

OTHER CTG CONCERNS SHOULD TRIGGER IMMEDIATE MEDICAL REVIEW AND DECISION RE: OXYTOCIN:

- Definite fetal distress
- Contractions last >60 seconds
- Uterus does not relax between contractions
- More than 5 contractions in 10 minutes.
- Coupling of contractions – this implies over stimulation

9. MONITORING OF FETAL HEART WITH PROSTOGLANDIN ADMINISTRATION FOR HIGH RISK WOMEN

Following administration of Propess®/Prostin® fetal wellbeing should be assessed initially by CTG for one hour, from there on with intermittent auscultation unless there are clear indications for continuous CTG.

Women with high risk pregnancies or complications require monitoring of observations and CTG until in labour. The frequency should be documented in K2 in the medical plan of care when the induction of labour is booked. It is reasonable not to wake a woman for monitoring overnight if she is asleep although the process should follow guidance if the woman is awake.

Continuous fetal monitoring is mandatory in the use of Oxytocin.

10. MANAGEMENT OF UTERINE HYPERSTIMULATION (TACHYSYSTOLE OR HYPERTONUS WITH ABNORMAL CTG)

- Continue CTG.
- Inform on-call registrar for medical review.
- IV Access

- Take bloods for FBC / Group & Save (but not via the cannula).
- Consider removing Propess® after medical review.
- Consider reducing or stopping Oxytocin after medical review.
- If hyperstimulation or non-reassuring CTG persists, administer 250 micrograms subcuticular (SC) Terbutaline, and involve the On-call Anaesthetist.
- If the cervix is unfavourable after removal of Dinoprostone (Propess®) and there is no fetal distress re-assess after 6 hours rest. If the cervix remains unfavourable discuss with Consultant in charge / On-call.

11. INDUCTION/AUGMENTATION OF PRELABOUR RUPTURE OF MEMBRANES AT TERM

- Consider vaginal examination to establish need for amniotomy and determine the Bishop's score.
- Avoid the use of Propess®
- Consider Prostin if Bishop's score <5 and no other contraindication (caesarean section / meconium liquor)
- Commence Oxytocin

12. OUTPATIENT INDUCTION OF LABOUR USING DINOPROSTONE (PROPESS®) AT UHNM

12.1 Criteria for outpatient Dinoprostone (Propess®) induction.

Women with a low risk pregnancy (either primiparous or multiparous) who are post mature may be encouraged to have an outpatient IOL. The woman must have access to a telephone and transport.

12.2 Exclusions

- Any women requiring regular CTG monitoring until in labour
- Previous uterine surgery
- Grand Multiparae >3
- Suspected fetal compromise including fetal growth restriction and oligohydramnios (Amniotic fluid index <5)
- Polyhydramnios (AFI >25cm)
- Fetal heart rate anomalies
- Bleeding at any time in pregnancy after 20 weeks gestation
- BS >5 (amniotomy more appropriate)
- Significant uterine activity
- Known hypersensitivity to prostaglandins
- Medical disorders e.g. active asthma, epilepsy, severe pre-eclampsia, Diabetes, hypertension, cardiac, renal and liver diseases and glaucoma

12.3 Additional information

If all is well the woman can go home with the information and instructions to return within 10-12 hours from insertion of Dinoprostone (Propress®).

The woman should be instructed to inform the IOL ward if:

- Her membranes rupture;
- Her contractions become distressful or regular (every 5 minutes or more frequent);
- She has bleeding;

- Fetal movements are reduced;
- Dinoprostone (Propess®) falls out or drops lower in the vagina;

Instruction on how to remove the Dinoprostone (Propess®) should be given before she goes home.

If there is spontaneous rupture of membranes with Dinoprostone (Propess®) in the vagina for low risk post mature inductions:

Advise woman to contact the induction of labour ward who will ask her to put on a pad so to check the colour of the liquor; additionally enquire whether there are normal fetal movements. Ask the woman to return for confirmation of SROM.

If confirmed SROM commence CTG for 30 minutes if reassuring discontinue CTG to aid mobilisation.

Assess contractions

If contractions are > 3 in 10 minutes remove Dinoprostone (Propess®) and transfer to MBC (if low risk post mature IOL with clear liquor and normal CTG) **exclusion** of term plus 14 going into term plus 15 as these ladies will require a CTG in labour.

If there are no contractions then arrange transfer to Delivery Suite for Oxytocin infusion-remove the Dinoprostone Propess.®

Infusion of Oxytocin should not be started until >30 minutes after removal of Dinoprostone (Propess).®

12.4 Re-admission to induction ward (within 10-12 hours of insertion of Dinoprostone [Propess®])

Observations should include:-

- Full antenatal examination should be performed and documented.
- Auscultation of fetal heart.
- Enquire about fetal movement pattern. A repeat CTG should only be performed if clinically indicated.

- The woman should be asked to report any abdominal pain, vaginal bleeding or SROM.
- The frequency of contractions and any vaginal loss should be documented.

If all is well the woman can go home for the night with instructions to return 23 hours following insertion of Propess®.

12.5 Admission 23 hours from propess insertion

- Conduct a full antenatal examination
- Commence CTG
- Perform a vaginal examination:
 - If BS \geq 5 - for amniotomy + Infusion of Oxytocin
 - If BS $<$ 5 see above
- Confirm and document on K2 that the Propess has been removed from the vagina.

13. PAIN RELIEF

Women being offered induction of labour should be informed that induced labour is likely to be more painful than spontaneous labour.

Women should be informed of the availability of pain relief options in different settings.

During induction of labour, healthcare professionals should provide women with the pain relief appropriate for them and their pain. This can range from simple analgesics to epidural analgesia.

Birth attendants (carers and healthcare professionals) should offer women support and analgesia as required, and should encourage women to use their own coping strategies for pain relief.

14. MULTIDISCIPLINARY MONITORING AND AUDIT

The need to monitor/audit the standards set out below will be considered alongside other Directorate requirements and prioritised accordingly. The Directorate Clinical Audit programme is drafted by the Directorate Clinical auditor, in liaison with clinical staff, and approved by the Directorate.

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements	Acting on recommendations and lead(s)	Change in practice and lessons to be shared
Guideline content	Guideline Co-ordinator	Guideline Review	Every three years	Labour Ward Forum Subgroup: Guideline Meeting	Required changes to practice will be identified and actioned with the release of the updated guideline.	Required changes to practice will be identified and actioned with the release of the updated guideline.
Clinical standards within guideline to include out patient induction and compliance of IOL booking form	Directorate Clinical Auditor	Clinical Audit	As required in relation to other Directorate priorities	Directorate Business, Performance and Clinical Governance Meeting	Required actions will be identified and completed in a specified timeframe as per the audit action plan.	Required changes to practice will be identified and actioned within a specific timeframe as per the audit action plan and, in addition, lessons will be shared with relevant stakeholders as per audit action plan.

15. REFERENCES

ASQUAM guideline for Fetal Loss/Intrapartum Death (2017)

National Institute for Health and Care Excellence (NICE) 2008.
Induction of Labour (NICE Clinical Guideline 70).

Appendix 1

Form for Induction of Labour

Unit number:

Name: Telephone number:

Past Obstetric History:

Previous uterine surgery:

Anaesthetic concerns

Significant Medical History.....

Neonatal Unit need to be informed of admission for IOL YES NO

Alerts (including Safeguarding alerts):

Indication for Induction of Labour:

Alternatives to IOL discussed:

Plan agreed by Consultant and Consultant's name (if not approved by Consultant IOL may not be arranged and lady return to ANC for consultant approval)

Consultant's name:	Date plan agreed:
--------------------	-------------------

Bishop's Score (must be completed or documented for date for VE/BS with CMW or at next ANC appointment)

Cervical Feature	Pelvic Score (Circle appropriate number)			
	0	1	2	3
Cervix position	Posterior	Centre	Anterior	-
Consistency	Firm	Medium	Soft	-
Length (cm)	3	2	1	0
Dilatation (cm)	0	1-2	3-4	5+
Station to spines (cm)	-3	-2	-1	0+
Total Score				

Gestation for IOL (eg. 37th week will be anything from 37-37⁺⁶/40, please specify if exact gestation required)

Gestation

Patient information leaflet given?

Directed to website for written advice?

Prescription chart completed including analgesia, prostaglandin and syntocinon infusion?

Document comprehensive IOL plan on K2 to include frequency of auscultation/CTG if different from guideline.