South Australian Perinatal Practice Guideline

Induction and Augmentation of Labour

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Note

This guideline provides advice of a general nature. This statewide guideline has been prepared to promote and facilitate standardisation and consistency of practice, using a multidisciplinary approach. The guideline is based on a review of published evidence and expert opinion.

Information in this statewide guideline is current at the time of publication.

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Health practitioners in the South Australian public health sector are expected to review specific details of each patient and professionally assess the applicability of the relevant guideline to that clinical situation.

If for good clinical reasons, a decision is made to depart from the guideline, the responsible clinician must document in the patient's medical record, the decision made, by whom, and detailed reasons for the departure from the guideline.

This statewide guideline does not address all the elements of clinical practice and assumes that the individual clinicians are responsible for discussing care with consumers in an environment that is culturally appropriate and which enables respectful confidential discussion. This includes:

- The use of interpreter services where necessary,
- Advising consumers of their choice and ensuring informed consent is obtained,
- Providing care within scope of practice, meeting all legislative requirements and maintaining standards of professional conduct, and
- Documenting all care in accordance with mandatory and local requirements

Note: The words woman/women/mother/she/her have been used throughout this guideline as most pregnant and birthing people identify with their birth sex. However, for the purpose of this guideline, these terms include people who do not identify as women or mothers, including those with a non-binary identity. All clinicians should ask the pregnant person what their preferred term is and ensure this is communicated to the healthcare team.

Explanation of the Aboriginal artwork

The Aboriginal artwork used symbolises the connection to country and the circle shape shows the strong relationships amongst families and the Aboriginal culture. The horse shoe shape design shown in front of the generic statement symbolises a woman and those enclosing a smaller horse shoe shape in this instance represents the unborn child. The artwork shown before the specific statements within the document symbolises a footprint and demonstrates the need to move forward toxether in unison.

Australian Aboriginal Culture is the oldest living culture in the world yet Aboriginal people continue to experience the poorest health outcomes when compared to non-Aboriginal Australians. In South Australia, Aboriginal women are 2-5 times more likely to die in childbirth and their babies are 2-3 times more likely to be of low birth weight. The accumulative effects of stress, low socio economic status, exposure to violence, historical trauma, culturally unsafe and discriminatory health services and health systems are all major contributors to the disparities in Aboriginal maternal and birthing outcomes. Despite these unacceptable statistics, the birth of an Aboriginal baby is a celebration of life and an important cultural event bringing family together in celebration, obligation and responsibility. The diversity between Aboriginal cultures, language and practices differ greatly and so it is imperative that perinatal services prepare to respectfully manage Aboriginal protocol and provide a culturally positive health care experience for Aboriginal people to ensure the best maternal, neonatal and child health outcomes.

Purpose and Scope of Perinatal Practice Guideline (PPG)

This guideline provides clinicians with information for the safe methods of induction and/or augmentation of labour. It includes information on indications, contraindications, precautions, best practice notes, dosage, administration and adverse effects.



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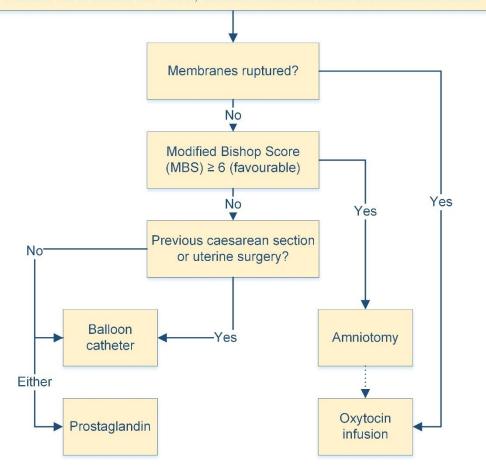
Flowchart

Antenatal Assessment for Induction of Labour (IOL)

- Review maternal history
- Confirm gestation
- Abdominal palpation (uterine size & fetal lie, presentation, position, engagement)
- Assess for indication(s) / contraindication(s) to IOL (including placental site)
- Undertake vaginal examination for cervical assessment and membrane sweeping
- Plan IOL following full discussion with woman re risks / benefits
- · Clearly document the indication for IOL in the woman's medical record

Assessment at time of Induction of Labour

- Review maternal history
- Confirm gestation
- Review and document indication for IOL
- Assess for contraindications to IOL (Incl placental site)
- Baseline maternal observations
- Abdominal palpation (uterine size & fetal lie, presentation, position, engagement)
- Undertake CTG for 20 minutes and ensure meets accepted criteria
- Discuss woman's understanding of IOL process and birth plan
- Obtain informed consent for VE and IOL
- Perform VE to assess the cervix, descent of the fetal head and membrane status



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Table 1: Modified Bishop Cervical Score System

CHARACTERISTIC	0	1	2	3	Score
Dilatation (cm)	< 1	1 - 2	3 - 4	> 4	
Length (cm)	> 3	2	1	< 1	
Consistency	firm	medium	soft	-	
Position of cervix	posterior	middle	anterior	-	
Station	-3	-2	-1 to 0	+1 to +2	
TOTAL					



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Summary of Practice Recommendations

- > IOL should be prioritised for medical indications.
- > Consideration of IOL for maternal request should not occur prior to 39 weeks.
- Individual local health networks/birthing sites should have their own processes for prioritising medical IOL.
- Consideration should be given to additional monitoring of maternal and fetal wellbeing wherever possible to avoid elective iatrogenic birth before 39 weeks.
- > The indication for IOL at any gestation should be clearly documented in the woman's medical record.
- > IOL for post-dates should be planned for 41 weeks (previously 40⁺¹⁰).
- > Women should understand their own individual risks and benefits with IOL and be actively involved in the decision-making. Inadvertent coercion for induction must be recognised and avoided.
- > Always perform a vaginal examination prior to 'booking' for IOL to determine most appropriate induction method.
- > During the vaginal examination to assess Modified Bishop Score (MBS), undertake 'sweeping of the membranes' with consent.
- > Outpatient management following cervical priming is appropriate in selected cases.
- > Synthetic oxytocin should be delayed for 6 hours following the last dose of vaginal prostaglandin gel or 30 minutes following removal of prostaglandin pessary.
- > Artificial rupture of membranes should be performed prior to commencement of synthetic oxytocin infusion.
- > Observe for uterine hyperstimulation following administration of prostaglandins or synthetic oxytocin.
- > Continuous cardiotocography (CTG) is required with synthetic oxytocin infusion.
- > Consider reducing or ceasing the synthetic oxytocin infusion once adequate contractions have been established.
- > Synthetic oxytocin should not be used to augment the latent phase of labour (i.e. prior to 5cm dilatation) when onset of labour has been spontaneous. See *Labour and Birth: Routine care in normal labour and birth* PPG at www.sahealth.sa.gov.au/perinatal for detail.
- > In an otherwise uncomplicated induction process, caesarean section should not be undertaken for 'failed IOL' in the latent phase of labour until after 15 (or 12-18) hours from commencement of synthetic oxytocin (after ARM).



Abbreviations

ARM	Artificial rupture of the membranes
BP	Blood pressure
CTG	Cardiotocography
cm	Centimetre(s)
e.g.	For example
FHR	Fetal heart rate
IOL	Induction of labour
IU	International units
IUGR	Intrauterine growth restriction
IV	Intravenous
MBS	Modified Bishop Score
mg	Milligram(s)
mL	Millilitre(s)
mU	Milliunit(s)
min	Minute(s)
PV	Per vaginam
PROM	Prelabour rupture of the membranes
PGE ₂	Prostaglandin E ₂
RANZCOG	Royal Australian and New Zealand College of Obstetrics and Gynaecology
ROM	Rupture of the membranes
SFH	Symphysio fundal height
SROM	Spontaneous rupture of the membranes
R	Registered trademark
VE	Vaginal examination

Definitions

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Augmentation of labour	Augmentation of labour is the process of stimulating the uterus to increase the frequency, duration and intensity of contractions after the onset of spontaneous labour ¹
Induction of labour	Induction of labour is the process of stimulating the onset of labour using artificial methods ²
Cervical ripening	Refers to the softening, thinning and dilatation of the cervix
Excessive uterine activity	Uterine hypertonus or tachysystole without fetal heart rate abnormalities ³
Uterine hyperstimulation	Uterine hypertonus or tachysystole with fetal heart rate abnormalities ³
Uterine hypertonus	Labour contractions lasting longer than 2 minutes in duration or contractions occurring within 60 seconds of each other ³
Tachysystole	More than 5 active labour contractions in 10 minutes ³
Failed IOL	Inability to achieve active phase of labour following artificial rupture of the membranes (ARM) and use of synthetic oxytocin infusion for a minimum of 15 hours ⁴



Background

Induction of labour (IOL) is recommended for women where the expected benefits outweigh both the risks of continuing the pregnancy for either the woman or fetus and the potential harms of the IOL process. Birth before 41 weeks is medically indicated in selected pregnancies (see indications), where there are established benefits / improvements in perinatal outcome.⁵ Importantly, the SWEPSIS trial⁶ demonstrated less stillbirth associated with IOL at 41 weeks compared to IOL at 42 weeks. This has prompted the World Health Organization (WHO) to change their recommendation for IOL for post-dates from 40⁺¹⁰ or 42 weeks to those pregnancies continuing beyond 41 weeks, but maintains that IOL prior to 41 weeks gestation should be reserved for medical indications.⁷

The latest Cochrane review⁸ relating to IOL in women with uncomplicated pregnancies versus expectant management after 37 weeks demonstrated a reduction in caesarean sections (16.7% versus 18.6%), NICU admissions (83 versus 95/1000), stillbirths (1 versus 2/1000) and overall perinatal deaths (0.4 versus 3 deaths/1000), along with less APGAR scores of 6 or below (10 versus 14/1000) in the IOL group. Minimal differences in rates of instrumental birth, postpartum haemorrhage, perineal trauma and breastfeeding at discharge were found. The review also found no differences for any of the main outcomes when comparing timing (< 40 versus 40-41 versus ≥ 41 weeks gestation), in subgroup analyses.

The ARRIVE trial⁹ compared IOL at 39 weeks with expectant management in nulliparous women without a medical indication for IOL. IOL at 39 weeks was associated with a lower rate of caesarean section (18.6% compared to 22.2%), with no significant difference in rates of death or serious injuries for babies or adverse maternal effects. A meta-analysis of 6 cohort studies of more than 650,000 women conducted in the United States by the ARRIVE trial research team comparing elective IOL at 39 weeks with expectant management in nulliparous women demonstrated lower rates of caesarean section and neonatal morbidity in the IOL group, although overall risks remained low in both groups.¹⁰

In contrast to the above work, and although a lower level of evidence, recent observational data from Victoria¹¹, a cohort study from SA¹² and a large retrospective study conducted in NSW¹³ using 16 years of birth and associated childhood data present different conclusions. IOL when compared with spontaneous labour in nulliparous women (particularly if no medical indication identified), was, in these studies, associated with increased rates of epidural use (71% vs 41.3%¹³; 50% vs 31%¹²), instrumental birth, caesarean section (30% vs 16.5%¹¹; 29.3% vs 13.8%¹³), episiotomy and postpartum haemorrhage; but less 3rd and 4th degree tears overall and less caesarean sections in the multiparous group (5.3 vs 6.2%¹³). Further, both the SA¹² and NSW¹³ studies reported increased adverse birth outcomes for neonates (but not neonatal death) in the IOL group and in NSW, increased childhood hospital admissions for infections up to 16 years in the IOL group. Whilst it is important to note that cohort and population based studies reflect association and not causation, the consistently similar outcomes between these studies and other longer-term population studies 14,15 argue against offering routine induction after 39 weeks gestation. There may also be generalisability issues when applying the results of the randomised controlled trials to a non-research setting, as between 70-86% of women invited to participate in the trials declined to take part. 13

It thus remains controversial whether or not there is definitive justification for offering nulliparous women IOL from 39 weeks without a medical indication.

Whilst the Cochrane review⁸ examined major outcomes, it did not consider maternal satisfaction. There are concerns that over-medicalisation of birth (including use of induction and augmentation of labour) may undermine a woman's autonomy, leading to more negative experiences of labour and birth. ¹⁶ IOL has been associated with less positive birth experiences for women when compared with spontaneous onset of labour. ¹⁷⁻¹⁹ Conversely, in the ARRIVE trial labour "agentry" scores were similar, although generalisability issues may be a confounding factor.

Avoiding early planned birth has important benefits for the baby (particularly neurological development). ^{20,21} Birth prior to 39 weeks gestation is associated with increased mortality and morbidity (both short and longer-term outcomes), with unfavourable developmental outcomes. ²⁰ Avoidance of birth prior to 39 weeks is now a recognised public health strategy and forms part of the Australian Government endorsed *Safer Baby Bundle*. ²¹ However, there are recognised medical indications for IOL prior to 39 weeks and discussion of an individual woman's and baby's risk should underpin shared decision-making.



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Methods

Induction of labour usually occurs in hospital, however some methods may be suitable for outpatient management, where women go home to wait for labour to commence or until additional IOL methods are required. A recent meta-analysis found no clear differences in outcomes between home and inpatient induction of labour, however women's satisfaction may be slightly higher in home settings. A

There are several methods used for IOL, including:

- > Cervical ripening Balloon catheter
- > Cervical ripening Prostaglandin
- > Amniotomy (artificial rupture of the membranes ARM)
- > Intravenous oxytocin

Sweeping of the membranes to promote spontaneous labour

Membrane sweeping is a mechanical technique whereby a clinician inserts one or two fingers into the cervix and using a continuous circular sweeping motion detaches the inferior pole of the membranes from the lower uterine segment. This produces hormones that encourage effacement and dilatation potentially promoting labour. When compared to expectant management, it reduces the incidence of formal induction of labour.²⁴

A Cochrane review compared sweeping of the membranes with expectant management: Sweeping was associated with a 40% reduction in formal IOL and also a 23% lower risk of not being in labour or not birthing within 48 hours. Another systematic review concluded that membrane sweeping is safe, effective and an inexpensive method of labour induction that can be done in the outpatient setting with minimal risks. Sweeping of the membranes did not result in increased maternal or fetal morbidity/mortality but was shown to decrease post-term pregnancy and the need for formal IOL methods. Pregnant women should be offered membrane sweeping from approximately 40 weeks' gestation to promote spontaneous labour.

Balloon Catheter

Meta-analyses examining cervical priming with balloon catheters found that balloon catheters had similar rates of complications when compared with vaginal prostaglandins and other methods of cervical priming. However, balloon catheters were also associated with a reduced risk of uterine hypercontractility and fetal heart rate changes that may lead to caesarean section and/or serious neonatal morbidity/ mortality.^{26,27}

Other studies²⁸ and meta-analyses^{22,29} specifically addressed outpatient management following insertion of balloon catheters for cervical priming and found similar rates of complications to inpatient management (equivalence in safety), with a possible added benefit of reduced caesarean sections with outpatient management. Furthermore, women have rated their overall experience and satisfaction with care more highly in outpatient management groups.^{30,31} The option of outpatient management following insertion of balloon catheters has been included in the PPG, however is reliant on local site implementation.

Prostaglandins

Prostaglandins promote cervical ripening and increase uterine activity. For women who have an unfavorable cervix (e.g. Bishop score < 6), rates of successful IOL are similar whether prostaglandins (E_2 or E_1) or transcervical balloon catheters are used for cervical ripening. Prostaglandins are contraindicated for cervical ripening or labour induction at term in women who have had a prior cesarean birth or other prior major uterine surgery as they are associated with higher rates of uterine rupture. Prostaglanding and increase uterine activity. For women who have an unfavorable cervix (e.g. Bishop score < 6), rates of successful IOL are similar whether prostaglanding are used for cervical ripening.

Amniotomy (artificial rupture of the membranes)

An older Cochrane review³³ found that there was limited evidence for amniotomy alone to induce labour. However, a retrospective descriptive study of over 3,500 births found that 90% of women went into labour within 24 hours following ARM alone: Approximately 10% of women required oxytocin for induction, with 90.5% of multiparous women and 63.4% of primiparous women having a spontaneous vaginal birth.³⁴



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Another randomised controlled trial in the Netherlands evaluated amniotomy in the woman's home versus hospital management and found that 85% of women went into labour within 12 hours (81% within 8 hours), with associated decreased rates of oxytocin and increased rates of normal vaginal birth, however length of ruptured membranes was increased.³⁵

Waiting for labour to commence rather than immediately commencing oxytocin may be an appropriate option for women who are GBS negative, similar to women who experience prelabour rupture of the membranes Women should be informed of the higher incidence of neonatal sepsis and need for prophylactic antibiotics if this option is chosen. Outpatient management following ARM may be possible in the future with a more established safety profile.

Synthetic oxytocin

Oxytocin is a hormone released from the posterior pituitary. Synthetic oxytocin is an effective drug used to stimulate rhythmic contractions in induction and augmentation of labour and to prevent or treat postpartum haemorrhage. However, it is associated with serious adverse effects such as uterine hyperactivity and hyperstimulation with associated fetal compromise and need for urgent birth. 4

Synthetic oxytocin can be associated with adverse perinatal outcomes and minimising its use is recommended to reduce harm to both the woman and her baby. A Cochrane review Reamined discontinuing the oxytocin infusion once women were in active labour. It found that ceasing the infusion probably resulted in less fetal heart rate abnormalities associated with uterine tachysystole, less intrapartum fetal monitoring and possibly fewer caesarean sections. Others Recommend actively titrating down the infusion rate to the lowest possible rate once adequate contractions are achieved.

Indications

Induction of labour (IOL) is medically indicated when the maternal and/or fetal risks of continuing the pregnancy outweigh the risks of IOL.⁴

Maternal:2,4

Refer to specific PPG for detailed information on when to consider IOL:

- > Diabetes Mellitus or Gestational Diabetes Mellitus (medicated and/or poor glycaemic control)
- > Maternal medical condition (e.g. Renal disease)
- > Severe intrahepatic cholestasis of pregnancy
- > Antepartum haemorrhage
- > Prelabour rupture of membranes (PROM)
- > Preterm prelabour rupture of the membranes (consider > 34 weeks gestation)
- > Hypertensive disorders of pregnancy (e.g. preeclampsia, eclampsia, HELLP syndrome)
- > Multiple pregnancy depending on gestation and chorionicity
- > Chorioamnionitis
- > BMI > 50 (IOL from 39 weeks)39

Fetal: 2,4

- > Pregnancy ≥ 41 weeks gestation (see *Prolonged Pregnancy* PPG available at www.sahealth.sa.gov.au/perinatal)
- > Suspected Fetal Compromise (including intrauterine growth restriction, decreased fetal movements, low AFI, fetal anomaly, oligohydramnios, isoimmunisation and abnormal fetal surveillance)
- > Fetal demise
- > Large for gestational age (estimated fetal weight ≥ 95th percentile)



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Maternal request for IOL without medical indication

Induction for maternal request is controversial. The ethical principle of maternal autonomy (fully informed choice) may conflict with the ethical principle of justice (fair distribution of scarce health resources) and non-maleficence (do no harm to the woman and her baby), as well as that of beneficence (doing good for the woman and her baby). Balancing these principles without being paternalistic or coercive is difficult and must be adapted to a woman and her family's particular circumstances, and the resources of the health system.

If the woman makes an informed decision for induction, then this decision should be respected, but IOL should not occur until 39 weeks gestation. Women should also be made aware that IOL for medical indications is prioritised and this may affect scheduling of the IOL.

Contraindications

As for vaginal birth

Informed decision-making

A recent Swiss population based study suggested that up to one in four pregnant women felt that they were being coerced into interventions during their pregnancy.⁴⁰ This perception is strongly associated with psychological harm, and must be avoided.

A qualitative systematic review with thematic synthesis on women's experiences of IOL found that women did not feel involved in decision-making, were not in control of their childbirth experience and were unprepared for many aspects of the process.⁴¹ The potential need for IOL (particularly in post-term pregnancy) should be discussed with women in advance.

All women should be provided with verbal and written information on the risks and benefits of IOL, tailored to their individual circumstances, including their preferences and values. This is particularly important if considering a woman's request for planned birth prior to 41 weeks without medical indication. There should thus be shared decision-making about whether and when IOL is the best course of action. The following general information, benefits and risks should be discussed with all women if IOL is proposed. It should be supported with written information that includes all details below.

General information:

- > Indication for IOL
- > Timing (urgent or planned in advance)
- > Proposed IOL method(s) and associated procedures
 - Regular vaginal examinations, including the likelihood of needing to be in lithotomy position for insertion of balloon catheter
 - Need for CTG following insertion of balloon catheter or prostaglandin
 - o Likelihood of IV oxytocin as part of IOL, which may affect a woman's movement
 - Requirement for continuous electronic fetal monitoring if medical indication for IOL or if oxytocin is required. This is likely to reduce a woman's movement in labour. Discuss options for telemetry if available
- > Options if:
 - IOL unsuccessful
 - IOL declined / expectant management preferred (plan for additional monitoring)
- > Options for pain management



Benefits associated with IOL:

- > Decreased risk of stillbirth for women with known risk factors (i.e. medical indication for IOL) and for all women after 41 weeks gestation. ^{6,8,9}
- > Depending on timing:^{9,10}
 - Reduction in caesarean section rate for nulliparous women if IOL at 39-39⁺⁴ weeks, with associated slightly shorter postnatal stay
 - Decreased risk of hypertension in late pregnancy⁶
 - Decreased risk of fetal macrosomia in late pregnancy
 - Risk reduction in relation to stillbirth:

	Risk of stillbirth per 10,000 births			
Gestation by week (e.g. weeks+0 - +6)	Meta-analysis of cohort studies including 15 million pregnancies ⁴²	South Australian Pregnancy Outcome Unit data 2008-2017 ⁴³		
38	1.6	3.3		
39	4.2	3.6		
40	6.9	6		
41	16.6	10.2		
42+	31.8	36.5		

Note: Risk of stillbirth is stated as per 10,000 births rather than per 1000 births as is usually quoted. This is to facilitate ease of discussion with women.

Risks associated with IOL:7,8,12,13,17-19

- > Increased time spent in all stages of labour, with more time spent in the labour ward
- > Increased perception of pain and associated increased rate of epidural use
- > Increased risk of uterine hyperstimulation and fetal heart rate abnormalities
- May alter instinctive newborn behaviour in first hour after birth, including reduced suckling, if exposed to epidural fentanyl and/or synthetic oxytocin⁴⁴
- > Increased rate of endometritis
- Increased risk of childhood hospital admissions for infection (particularly respiratory, ear, nose and throat)
- > Increased chance of being less satisfied with the labour and birth experience, particularly if a more 'natural' experience is desired
- > Increased rate of postnatal presentation/readmission for heavy vaginal bleeding (following active management of third stage)⁴⁵
- > Chance that IOL will not work which may result in repeating the IOL process or caesarean section
- > Possible impact on fetal brain development if request for IOL prior to 39 weeks. The 'Every Week Counts' brochure can be downloaded in 5 languages from here.21

Antenatal Assessment for IOL

Antenatal assessment (routine)

- > Review maternal history
- > Undertake antenatal check including:
 - Confirm gestation
 - Abdominal palpation to confirm uterine size and fetal lie, presentation, position, and engagement
 - Auscultate fetal heart and enquire re fetal movements
 - o Check BP
- > Assess for indication(s) / contraindication(s) to IOL (Note: Review ultrasound for placental position)
- > Document indication in SAPR and medical record



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^{*} These are in the same table for illustrative purposes only; the differences between them have not been tested for significance and so any difference must be interpreted with caution.

Vaginal examination (VE) for cervical assessment and membrane sweeping

Timing

- > Undertaken at approximately 40 weeks gestation in uncomplicated pregnancy
 - If the woman remains pregnant at the next antenatal visit, there is still benefit in repeating sweeping of the membranes
- > Undertaken at time of decision to proceed with IOL (or after administration and time for action of antenatal corticosteroids depending on gestation)

Cervical assessment

A Modified Bishop Score (MBS) (a scoring system to measure changes in the cervix) should be undertaken before booking IOL. A MBS < 6 is often referred to as an unripe cervix (unfavourable), whereas ≥ 6 is referred to as a ripe cervix (favourable).

Undertake VE with consent to determine most appropriate method of IOL based on the MBS (see <u>Table 1</u>). Generally, a MBS of < 6 indicates that the woman will require cervical priming.

Sweeping of the membranes

Favourable cervix

The cervix is soft and at least admits a finger through the internal os. The presenting part is in the pelvis. During VE the tip of an examining finger is introduced through the external and internal os' onto the membranes. Then, the inferior pole of the membranes is detached from the lower uterine segment by a circular movement of the examining finger.

Unfavourable cervix

The cervix is firm and closed. The presenting part is in the pelvis. During VE if the membranes cannot be reached, it is reasonable to attempt to digitally stretch the cervix until sweeping is possible. If the cervix is completely closed, perform cervical massage to stimulate the production of prostaglandins.

Post VE

- > Auscultate fetal heart for approximately 60 seconds
- > Record findings of VE and whether sweeping of the membranes was undertaken
- > Plan method of IOL based on MBS
- > Inform woman re likelihood of blood-stained 'show' and cramping/contractions
- > Discuss importance of monitoring fetal movements and when to contact her maternity care provider

Assessment at time of IOL

- > Review maternal history
- > Confirm gestation
- > Review and document indication for IOL
- > Assess for contraindications to IOL (Note: Review ultrasound for placental position)
- > Perform baseline maternal observations (e.g. temperature, pulse, SaO₂, respiratory rate and blood pressure)
- > Perform abdominal palpation to confirm uterine size and fetal lie, presentation, position, and engagement
- > Undertake CTG for 20 minutes and ensure meets accepted criteria as per *Fetal Surveillance* (cardiotocography) PPG available at www.sahealth.sa.gov.au/perinatal
- > Discuss woman's understanding of IOL process and birth plan
- > Obtain informed consent for VE and IOL
- > Perform VE to assess the cervix, descent of the fetal head and membrane status and commence IOL with agreed method



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Cervical ripening - Balloon catheter

Balloon catheters are used to ripen the cervix through applying pressure on the internal os of the cervix, thereby stretching the lower uterine segment and increasing local prostaglandin secretion.

Indications

- > Unfavourable cervix (MBS < 6)
- > May be considered with previous caesarean section
- > May be used following prostaglandin when there has been no/minimal effect on cervical ripening and ARM is not technically possible
- > May be preferred where a reduced risk of uterine hyperstimulation is desirable (e.g. IUGR, grand multipara, uterine scar)

Contraindications

- > Low lying placenta
- > Placenta praevia/Vasa praevia
- > HIV infection
- > Active herpes lesions
- > Malpresentation (transverse or oblique lie, footling breech)
- > High presenting part (above the pelvic inlet)
- > Polyhydramnios
- > Ruptured membranes
- > Signs of fetal compromise on cardiotocography
- > Any contraindication to vaginal birth
- Maternal refusal

Additional criteria for outpatient management

The following additional criteria are based on trial protocols that demonstrated appropriate safety profiles:^{22,28,46-48}

Inclusion

- > Residing within 60 minutes of the hospital
- > Singleton pregnancy
- > ≥ 39 weeks gestation
- > Cephalic presentation
- > Low risk indication for IOL (e.g. post-dates)
- > Normal CTG after balloon catheter inserted

Exclusion

- > Indication for IOL is suspected/proven maternal or fetal compromise
- > Previous caesarean section, myometrial surgery or cervical surgery
- > Maternal blood-borne virus (HIV, Hepatitis B & C)
- > Uncontrolled essential hypertension
- > Preeclampsia
- Any diabetes other than GDM where BGLs remain in the target range with lifestyle modification only
- > Parity ≥ 5
- > Abnormal placentation
- > Oligohydramnios / polyhydramnios
- > Macrosomia
- > Small for gestational age (< 10th percentile) / intrauterine growth restriction
- > Fetal anomaly
- > High head (≥ 4/5ths palpable above brim)
- > Abnormal CTG prior to or following insertion of balloon catheter



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Equipment

- > Speculum
- > Balloon catheter, either
 - 16/18 gauge catheter with double balloon (e.g. Cook cervical ripening balloon)
 - Cervical ripening single balloon catheter with balloon capacity of at least 30 mL.
 Note: Use of Foley catheter for IOL is considered 'off-label'. Sites should follow their own risk management procedures if used.
- > Sponge forceps
- > Sterile water or 0.9% sodium chloride (200 mL)
- > Syringe (20 mL)
- > Sterile lubricating gel
- > Swabs
- > Tape

Before procedure

- > Ensure the woman has emptied her bladder
- > Undertake assessment at time of IOL (as above)

Insertion of transcervical single balloon catheter

- > The procedure may be done by the midwife or attending medical officer
- > Insert speculum and visualise the cervix
- Pass the balloon catheter through the internal os of the cervix using sponge forceps to assist
- > Spigot the catheter
- > Inflate the balloon with sterile water 30-50 mL
- > Gently withdraw the catheter until it rests at the level of the internal os
- > Place the balloon on moderate traction by taping it to the inner aspect of the woman's thigh

Insertion of transcervical double balloon catheter

- > The procedure may be done by the midwife or attending medical officer
- > Insert speculum and visualise the cervix (the use of a speculum may not be necessary if an introducer is used with the balloon catheter)
- > Pass the cervical ripening balloon catheter through the cervix (using sponge forceps) until both balloons have entered the cervical canal
- > Inflate the uterine balloon with 40 mL of water or 0.9 % sodium chloride. Once the uterine balloon is inflated, pull the catheter back until the balloon abuts the internal cervical os
- > The vaginal balloon is now visible outside the external cervical os and is inflated with 20 mL of water or 0.9 % sodium chloride
- > Once the balloons are situated on either side of the cervix, water or 0.9 % sodium chloride is added up to a maximum of 80 mL per balloon
- > Secure device by taping catheter to the inner aspect of the woman's thigh
- > Placement of the balloon should be timed so that it is in place no longer than 18 hours before active labour is induced. May be removed after 12 hours.

Management after insertion of balloon catheter

- > Repeat/continue 20 minute CTG tracing and ensure meets accepted criteria as per *Fetal Surveillance (cardiotocography)* PPG available at www.sahealth.sa.gov.au/perinatal
- > If the woman experiences undue discomfort following the procedure perform a vaginal examination to ensure the correct placement of the catheter and adjust as necessary.
- > If the woman has difficulty passing urine after insertion of the balloon catheter consider removing 20 mL of fluid from the uterine and vaginal balloons.

Remove the catheter after 12-18 hours



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Indications for early removal of catheter

- > Rupture of the membranes
- > Uterine hyperstimulation
- > Maternal request

If the catheter falls out

Undertake VE:

- > Confirm favourable cervix for ARM (plan ARM at 12 hours or sooner if workload / timing allows)
- > If the cervix is unfavourable, consult medical officer regarding management (e.g.re-insertion of catheter or prostaglandins)
- > If labour has commenced, transfer to labour ward/birth unit
- > If membranes have ruptured, consider transfer to labour ward/birth unit depending on uterine activity, timing from balloon insertion and other clinical factors.

Additional information for women undergoing outpatient management

Plan for the woman to return to the hospital for ARM 12-18 hours following insertion of the balloon catheter

Inform the woman to contact her maternity care provider if:

- > The catheter falls out
- > Membranes rupture
- > There is PV bleeding more than a 'show'
- > She is requiring more support to manage contractions
- > Fetal movements reduce or stop
- > She develops a temperature > 37.5 C
- > There is unexpected pain
- > She is unable to pass urine
- > Any other concerns or changes her mind about being at home

Cervical ripening – Prostaglandin E₂

Prostaglandin E_2 is available as vaginal gel 1 mg and 2 mg OR 10 mg vaginal pessary and is currently used for cervical ripening. The onset of labour after prostaglandin E_2 administration is variable (6 – 18 hours).

Indications

- > Unfavourable cervix (MBS < 6)
- > May be used following balloon catheter where there has been no/minimal effect on cervical ripening and ARM is not technically possible.

Contraindications

- > Pre-existing regular uterine activity is a relative contraindication³²
- > Known hypersensitivity to Prostaglandin E₂
- > Ruptured membranes
- > Grand multiparity (parity > 5)
- > Previous caesarean section or any uterine surgery
- > Malpresentation
- > Abnormal CTG/fetal compromise
- > Unexplained PV bleeding during current pregnancy.



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Dosage and administration

Prostaglandin E2 gel

Dosage

The initial dose for Prostaglandin E₂ gel is:

- > 2 mg per vaginam (PV) in nulliparous women with an unfavourable cervix
- > 1 mg PV for multiparous women and
- > 1 mg PV in cases of suspected fetal compromise (intrauterine growth restriction)

If the woman is not in established labour

> a second dose of 1 or 2 mg of Prostaglandin E2 gel may be administered after 6 hours

The maximum dose in a 12 hour period is:

- > 4 mg Prostaglandin E₂ gel for nulliparous women with an unfavourable cervix
- > 3 mg for all other women

In situations where the maximum recommended dose has been used and amniotomy is not possible, depending on the indication for induction of labour:

> a third dose of 1 or 2 mg of Prostaglandin E₂ gel may be considered after discussion with an obstetric consultant

Before procedure:

- > Ensure the woman has emptied her bladder
- > Undertake assessment (as above)

Administration

> Insert Prostaglandin E₂ gel into the posterior fornix of vagina

Prostaglandin E₂ pessary

Dosage

Single dose of 10 mg of Prostaglandin E_2 pessary (releases approximately 0.3 mg Prostaglandin E_2 per hour over a maximum duration of 24 hours)

Administration

- > Remove Prostaglandin E₂ pessary from freezer immediately before insertion
- > Use the retrieval tape to gently pull the product out of the sachet
- > Insert Prostaglandin E₂ pessary high in the vagina, positioning pessary transversely into the posterior fornix of the vagina (use small amount of water soluble lubricant to aid insertion)

Precautions

Remove pessary if:

- > Uterine hyperstimulation occurs
- > Labour becomes established
- > After SROM or before performing ARM

After the prostaglandin administration

- > Advise the woman to remain recumbent in 30° left lateral tilt for at least thirty minutes (allows prostaglandin absorption) before sitting up or walking around
- > Continue CTG monitoring for 20 minutes after insertion of Prostaglandin E₂ gel or pessary. Discontinue CTG if accepted criteria are met. See *Fetal Surveillance (cardiotocography)* PPG available at www.sahealth.sa.gov.au/perinatal
- > Perform regular observation of maternal uterine activity, vaginal loss, pulse, blood pressure, respiration rate and FHR 4 hourly or more frequently if contractions commence
- > Inform the woman to notify the midwife should uterine contractions become regular and / or painful, or if the woman has any vaginal loss
- > Assess cervix after 12-18 hours as per local policy. Maximum time in situ is 24 hours.



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Adverse effects

- > Gastrointestinal (e.g. nausea, vomiting), back pain, fever.
- > Increased intraocular pressure in women with a history of glaucoma
- > Uterine hypercontractility (hypertonus or tachysystole)
- > Placental abruption or uterine rupture
- > Burning sensation in the vagina

Best practice notes

Simultaneous use of prostaglandins or oxytocin is not recommended.

The second dose of prostaglandins should be withheld if:

- > An ARM can be performed
- > The woman is established in labour
- > 4 or more contractions are present over each ten minute period review in 2 4 hours to assess whether the woman is in established labour
- > There is unexpected pain or FHR abnormalities

After the maximum dose has been administered or if the cervix is favourable (MBS \geq 6) and the woman is not in labour, negotiate an appropriate time to perform ARM as clinically indicated.

Oxytocin augmentation may be commenced 6 hours after the last dose of Prostaglandin E_2 gel has elapsed or 30 minutes after removal of Prostaglandin E_2 pessary, following ARM.

Women who have an established clinical indication for continuous fetal monitoring in labour should be continuously monitored from the commencement of regular uterine activity.

Ensure there is a documented plan for ongoing management in the woman's medical record.

Initial cervical priming not successful

Women undergoing IOL for medical indications may require a caesarean section if cervical priming is not successful.

The decision to use a balloon catheter following failed cervical priming with prostaglandins must be made by a senior obstetrician/GP, taking into account timing (6 hours after the last dose of Prostaglandin E_2 gel has elapsed or 30 minutes after removal of Prostaglandin E_2 pessary), as well as individual risks and benefits.

In cases where cervical ripening with a balloon catheter fails (Bishops score < 6 or unable to successfully rupture the membranes), the obstetrician/GP may consider one of the following, depending on the individual risks and benefits:

- > Insertion of prostaglandins (as above)
- > Reinsertion of another balloon catheter (after 24 hours)

Management of uterine hypercontractility or hyperstimulation

The following interventions may be instituted:

- > If Prostaglandin E₂ pessary in situ: remove pessary by pulling the withdrawal tape
- > If Prostaglandin E₂ gel is used, consider manually removing the gel. This is usually achieved by flushing the vagina with normal saline (1 litre normal saline through a giving set, with the end of the giving set placed high into the vagina)
- > Change maternal position
- > Continuous CTG monitoring
- > Prepare and administer emergency tocolysis if indicated (see *Tocolysis for Uterine Hypercontractility* PPG (available at www.sahealth.sa.gov.au/perinatal)
- > Consider fetal scalp blood sampling (where possible and available) or caesarean section if hypercontractility and fetal compromise (hyperstimulation) persist



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Artificial rupture of membranes (ARM)

Amniotomy refers to the surgical artificial rupture of the membranes (ARM) to induce or augment labour. ARM may be used alone or in combination with oxytocin therapy to induce labour.

Indications

- > IOL when the cervix is favourable MBS ≥ 6 (see Table 1)
- > Augmentation of labour
- > To observe the colour and amount of liquor when clinically indicated

Contraindications

- > Unstable lie
- > Fetal head not engaged
- > Any contraindication for vaginal birth

Associated risks

- > Cord prolapse or compression
- > Maternal or neonatal infection
- > Fetal heart rate abnormalities
- > Bleeding from placenta praevia, vasa praevia (very rare)

Procedure

- > Abdominal palpation to determine fetal lie, presentation, engagement and position
- > Undertake VE to identify the cervix and membranes
- > Introduce an appropriate instrument (usually an amnihook or amnicot) into the vagina (sliding through fingers to avoid vaginal wall) and pierce the membranes
- > Note and document the colour of the amniotic fluid
- > The fetal heart rate is recorded immediately following ARM and should continue to be recorded every 1-4 hours until the woman is in established labour
- > Inform woman to monitor PV loss, contractions and notify midwife if any concerns

Best Practice Notes

To reduce the risk of cord prolapse, the clinician should ensure that the fetal head is positioned in or directly above the pelvis, is well-applied to the cervix and the umbilical cord or other fetal part is not presenting).⁴

If the presenting part is high, encourage the woman to ambulate / empty her bladder before attempting to perform an ARM.

If the presenting part still remains high, consult with medical officer regarding further management, ensure availability of medical staff / theatre before attempting ARM.

An obstetrician should perform a controlled amniotomy in the following situations:

- > Unstable lie
- > Polyhydramnios
- > High presenting part (presenting part is not engaged and is poorly applied to the cervix)



Intravenous oxytocin

Induction of labour using a combination of amniotomy and intravenous oxytocin is the preferred method of induction for women who have a favourable cervix (MBS \geq 6).⁴

There is no hard evidence to recommend a particular dosage of oxytocin for induction or augmentation of labour infusion regimens.⁴ Oxytocin infusion regimens in this guideline are based on medical expert consensus.

Waiting for labour to commence following ARM for up to 12 hours³⁵ rather than immediately commencing oxytocin may be an appropriate option for women who are GBS negative. The amount of time after ARM to await onset of contractions prior to commencement of synthetic oxytocin should be discussed with the woman and influenced by other clinical factors such as:

- > Indication for IOL
- > Parity
- > Previous rapid labour
- > GBS status
- > Antibiotic prophylaxis when membranes ruptured > 18 hours
- > Woman's preference to avoid medical intervention / pharmacological pain relief

Augmentation of labour carries a risk of hyperstimulation with the potential consequences of fetal compromise and uterine rupture.^{1,4,36}

Latent phase has recently been redefined to include dilatation up to 5 cm (see *Labour and Birth. Routine care in normal labour and birth* PPG at www.sahealth.sa.gov.au/perinatal). A systematic review involving over 100,000 women found that it can take 4 hours to progress from 3-4 cm and a further 4 hours to progress from 4-5 cm. ⁴⁹ For women undergoing induction of labour, the time to dilate 1cm during latent phase is significantly longer than in women with spontaneous onset. ⁵⁰

> The use of medical interventions to accelerate labour (including augmentation with oxytocin), before 5 cm dilatation in spontaneous labour is therefore not recommended providing maternal and fetal assessment is reassuring.⁵¹

Indications

Induction of labour (IOL)

- > At the commencement of IOL; following amniotomy with a favourable cervix (MBS ≥ 6), if labour does not establish following ARM alone
- > Following cervical ripening to promote uterine contractions
 - After removal of a balloon catheter
 - After 6 hours from the last dose of Prostaglandin E₂ gel has elapsed or 30 minutes after removal of Prostaglandin E₂ pessary

Augmentation of labour

- > Slow progress in active first stage (<1cm over 2 hours from 5 cm dilatation)
- Minimal descent of presenting part (<1 cm) in second stage after 60-90 minutes of active pushing with contractions less than 3/10 minutes

Contraindications

Hypersensitivity to synthetic oxytocin

Clinical contraindications:

- > Prior classical or other high risk caesarean incision
- > Transmural incision that entered the uterine cavity
- > Prior uterine rupture
- > Invasive cervical cancer
- > Placenta praevia or vasa praevia
- > Transverse lie



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Precautions

Synthetic oxytocin should only be used in women who have undergone **previous caesarean section** following discussion with a obstetrician.

In women with **cardiovascular disorders** the infusion volume should be kept low by using a more concentrated oxytocin solution (see *Cardiac disease in pregnancy* PPG available at www.sahealth.sa.gov.au/perinatal).

In women who have diabetes mellitus or abnormal glucose tolerance in pregnancy, oxytocin should be administered with 0.9 % sodium chloride to prevent hyponatraemia.

Administration

- > Run oxytocin infusion as a separate line piggybacked into the mainline.
- > Use the minimum dose possible and aim for a maximum of 3 4 contractions in ten minutes
- > Prescribe and record the dose of oxytocin being delivered (i.e. mU/minute)
- > Consider reducing or ceasing the infusion once adequate contractions in active labour are achieved

See Appendix 1 for routine oxytocin infusion regimen

See Appendix 2 for High concentration / low volume oxytocin infusion regimen

Observations

Routine labour observations from commencement of oxytocin infusion.

Continuous cardiotocograph from commencement of oxytocin infusion (see *Fetal Surveillance (Cardiotocography)* PPG available at www.sahealth.sa.gov.au/perinatal).

> Observe for uterine hypercontractility and/or signs of fetal compromise.

Observe for signs of water intoxication.

Best practice notes

Amniotomy should be performed prior to commencement of oxytocin infusion.

Aim for a maximum of 3 - 4 contractions in ten minutes.

If the oxytocin infusion has been ceased for < 30 minutes, recommence at half the previous rate. If the oxytocin infusion has been ceased for > 30 minutes, it is likely that oxytocin would have been cleared from maternal circulation, thus recommence at initial starting dose/rate (2 mU/min).

When adequate contractions are achieved with corresponding labour progress, there is no consensus as to whether the oxytocin infusion should be decreased or ceased during active labour to minimise the chance of hyperstimulation. However, contraction strength and frequency needs to be monitored, with the oxytocin infusion recommenced if contractions are inadequate. 1,4,36

Women with an oxytocin infusion should not be left unattended.

In an otherwise uncomplicated induction process, caesarean section should not be undertaken for 'failed IOL' in the latent phase of labour until after a minimum of 15 hours from commencement of synthetic oxytocin (after ARM) (see Failed IOL).

There is no established length of time to continue the oxytocin infusion following birth. Consideration should be given to the infusion rate at the time of birth, length of labour and risk factors for postpartum haemorrhage.

Uterine hypercontractility without signs of fetal compromise (hypertonus / tachysystole)

- > Reduce oxytocin infusion rate and seek medical review
- > Maternal reposition
- > Increase intravenous fluids
- > Consider tocolysis



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Uterine hypercontractility with signs of fetal compromise (hyperstimulation)

- > Reduce or discontinue oxytocin infusion
- > Position woman on her left side
- > Increase intravenous fluids
- > Review by medical officer
- > Palpate the uterus to determine uterine response to management
- > Consider need for uterine tocolytic (see *Tocolysis for Uterine Hypercontractility* PPG available at www.sahealth.sa.gov.au/perinatal)

Water intoxication (Hyponatraemia)

High doses of oxytocin or prolonged periods of infusion of oxytocin in electrolyte-free fluids may interfere with vasopressin receptors. This can result in water intoxication.

Avoid large volumes of oral and IV fluids with oxytocin administration.

Symptoms and signs of water intoxication:

- > Headache,
- Nausea, vomiting and abdominal pain
- > Lethargy, drowsiness, unconsciousness
- > Grand mal type seizures
- > Low blood electrolyte concentration

Treatment

- > Discontinue oxytocin infusion
- > Restrict fluid intake
- > Promote diuresis
- > Correct electrolyte imbalance
- > Control convulsions
- If coma is present; maintain a free airway, and carry out the routine measures for care of an unconscious patient (see *Maternal Collapse PPG* available at www.sahealth.sa.gov.au/perinatal)

Failed IOL

There are limited definitions for failed IOL. Grobman et al⁴ discusses the evidence in relation to this, stating that nearly all women will enter the active phase of labour within 15 hours of synthetic oxytocin administration following ARM. Unless there are other complications, caesarean section should therefore be reserved until after this time, providing that maternal and fetal condition is reassuring.



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Appendices

Oxytocin induction / augmentation of labour dosage regimen

Oxytocin induction / augmentation of labour dosage regimen			
Preparation ¹	>	Add 10 units of oxytocin to 1000 mL (1L) of Hartmann's solution or sodium chloride 0.9 %, to prepare a 10 unit per 1000mL solution	
	>	Use an appropriate volumetric infusion pump	
	>	Infuse as a separate line piggybacked into the mainline	
Initial rate:	>	12 mL / hour (2 milliunits / minute)	
Increments:	>	Increase every 30 minutes by 12 mL / hour (2 milliunits / minute) until adequate contractions are achieved (i.e. 3-4 in 10 minutes)	
Maximum:*	>	192 mL / hour (32 milliunits / minute)	

Prolonged oxytocin infusion

If a second litre of oxytocin infusion is required, consider doubling the dose per litre and running the infusion at half the rate (e.g. increase oxytocin dose to 20 units per litre and infuse dose at half the previous rate)

*Maximum oxytocin infusion dosage

- The Product Information recommends a maximum dose of IV oxytocin 20 milliunits / minute
- In cases where labour progress is unresponsive, higher doses may be used but should not exceed 32 milliunits / minute



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High concentration / low volume oxytocin IOL dosage regimen

High concentration / low volume oxytocin IOL dosage regimen

This is a modification of the above oxytocin induction of labour regimen, allowing the same dose of oxytocin to be administered in one tenth $(1 / 10^{th})$ the volume of 0.9 % sodium chloride

Suitable for women with a cardiovascular disorder, who are sensitive to fluid overload

Preparation ¹	A A A	Add 10 units of oxytocin to a 100 mL bag of 0.9 % sodium chloride, to prepare a concentration of 100 milliunits / mL Use an appropriate syringe pump Infuse as a separate line piggybacked into the mainline at the IV insertion point
Initial rate:	>	0.6 to 1.2 mL / hour (1 to 2 milliunits / minute)
Increments:	>	Increase every 30 minutes by 1.2 mL / hour (2 milliunits / minute) until adequate contractions are achieved (i.e. 3-4 in 10 minutes)
Maximum:*	>	19.2 mL / hour (32 milliunits / minute)

*Maximum oxytocin infusion dosage

- ➤ The Product Information1,2 recommends a maximum dose of IV oxytocin 20 milliunits / minute
- In cases where labour progress is unresponsive, higher doses may be used but should not exceed 32 milliunits / minute



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V5.1 for Oxytocin Augmentation

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Approval Date	Version	Who approved New/Revised Version	Reason for Change
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