

Clinical Guideline

Preterm Labour Clinical Guideline

Policy developed by: SA Maternal & Neonatal Clinical Network

Approved SA Health Safety & Quality Strategic Governance Committee on:
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Summary Clinical practice guideline for the management of preterm labour.

Keywords PPRM, preterm labour, threatened preterm labour, chorioamnionitis, corticosteroids, fetal fibronectin, fFN, tocolytics, salbutamol, indomethacin, progesterone, clinical guideline

Policy history Is this a new policy? **N**
Does this policy amend or update an existing policy? **Y**
Does this policy replace an existing policy? **N**

Applies to All SA Health Portfolio
All Department for Health and Ageing Divisions
All Health Networks
CALHN, SALHN, NALHN, CHSALHN, WCHN, SAAS

Staff impact All Staff, Management, Admin, Students, Volunteers
All Clinical, Medical, Nursing, Allied Health, Emergency, Dental,
Mental Health, Pathology

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Version control and change history

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1.0	10 May 2004	29 Dec 2008	Original version
2.0	29 Dec 2008	21 Mar 2011	Reviewed
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6.0	07 Sept 2015	Current	

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preterm 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

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 depicts a pregnant women. The 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 together 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.

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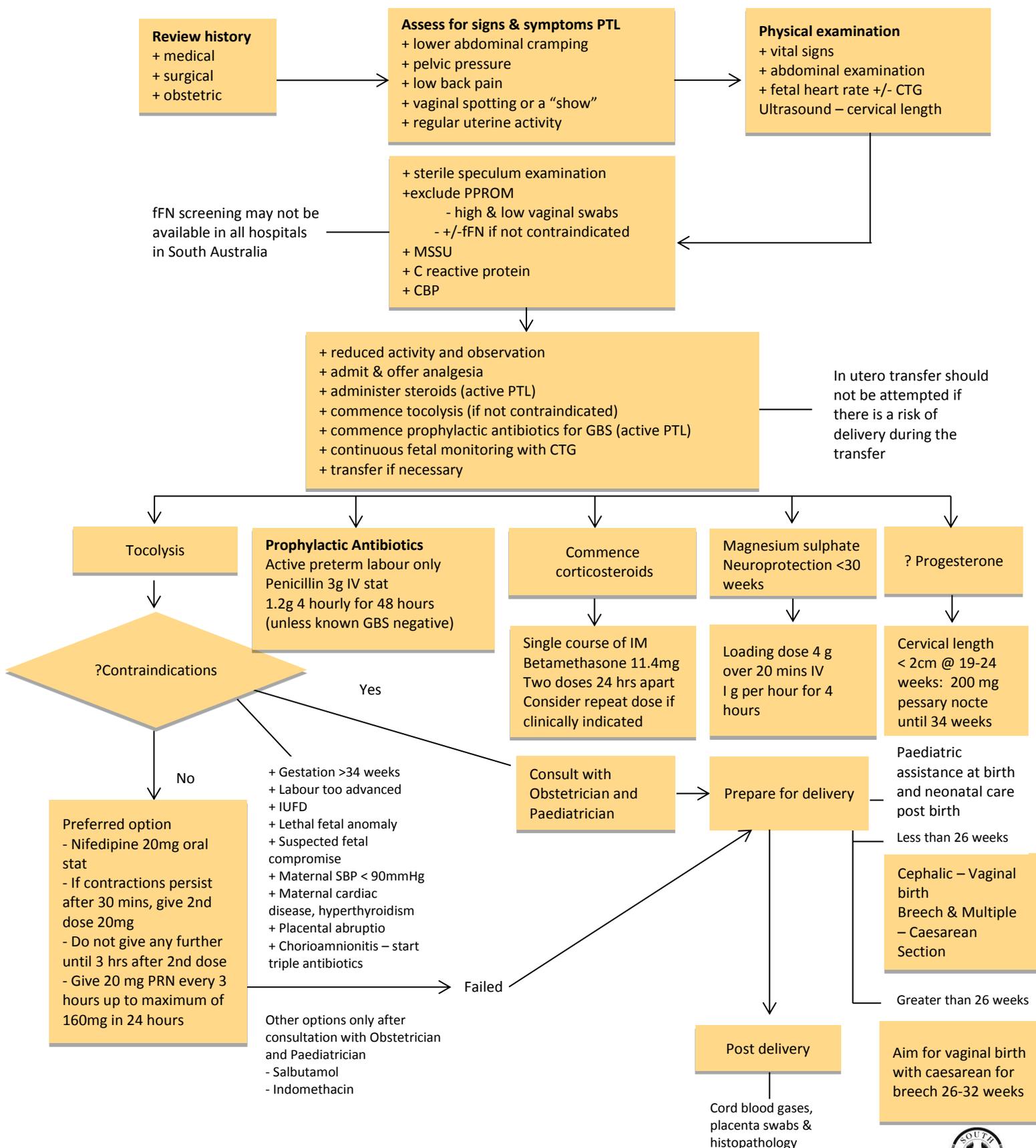


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Assessment and management of Preterm labour (PTL)



Definition

- > Preterm means a gestational age of less than 37⁺⁰ completed weeks of gestation (less than 259 days^{1,2})

Diagnosis

- > Uterine contractions – may be difficult to differentiate from uterine irritability – frequency and especially regularity may be more meaningful than pain perception
- > Shortening and dilatation of the cervix – reliable estimation essentially requires at least two observations separated in time
- > Observational studies and placebo-controlled trials indicate that more than 50 % of women who present in preterm labour will continue their pregnancy³

Screening tests

- > Fetal fibronectin (fFN) is a glycoprotein promoting adhesion between the fetal chorion and maternal decidua. Fetal fibronectin is typically absent from cervicovaginal secretions between 24 and 36 weeks' gestation, becoming detectable again as term approaches. Elevated levels of fFN (typically > 50ng/ml) in cervicovaginal secretions between 24 and 36 weeks' gestation are associated with an increased risk of preterm birth⁴
- > A negative fetal fibronectin (fFN) is associated with a 97% negative predictive value for preterm delivery in the next 7 days⁴
- > Fetal fibronectin testing is commonly used in labour and delivery units in South Australia; however, evidence to recommend its use is lacking. A Cochrane review found an association between knowledge of fFN results and a lower incidence of preterm birth before 37 weeks, but recommends further studies, including cost-effect analyses be undertaken⁵

Initial assessment

- > History and examination
- > Abdominal palpation to determine fetal size and presentation
- > Speculum examination to:
 - > Exclude PPRM
 - > Visualise pooling of liquor (note presence of vernix)
 - > Collect cervical and vaginal microbiological swabs (including GBS). See also fetal fibronectin test below
 - > Make a smear to look for ferning on microscopical examination
 - > Estimate cervical dilatation

Fetal fibronectin test (fFN)⁴

- > On sterile speculum examination (only use sterile water as a lubricant), if the cervix is < 3 cm and no blood (moderate amount) or amniotic fluid are seen, obtain a sample from the posterior fornix of the vagina using the appropriate fetal fibronectin kit

False positive result

- > Fetal fibronectin is found in blood and semen. Recent coitus, digital vaginal examination or transvaginal ultrasound may affect test reliability

False negative result

- > The use of intravaginal lubricants or disinfectants may interfere with the antibody reaction

Transfer or retrieval for access to specialised obstetric and neonatal services

- > In units without neonatal facilities suitable for the gestation, consult with tertiary centre. Consider maternal transfer if delivery is not imminent or consult with neonatal retrieval service if delivery is anticipated (for further information link to 'perinatal advice and emergency transport' in the A to Z index at www.sahealth.sa.gov.au/perinatal)

Surveillance / fetal assessment

- > Assess fetal wellbeing:
 - > Cardiotocography (CTG) to assess fetal condition - interpretation should take early gestational age into account
 - > Ultrasound examination for fetal number, size, presentation, fetal malformations (if morphology unknown), liquor volume and placenta localisation
 - > Consider assessment of cervical length and dilatation (by vaginal scan) and umbilical artery flow

Bed rest in preventing preterm birth	
Singleton pregnancy	> There is no evidence to support or refute bed rest in singleton pregnancies in preventing preterm birth ⁶
Multiple pregnancy	> Evidence is also lacking to support a policy of routine hospitalisation for bed rest in multiple pregnancy. No reduction in the risk of preterm birth or perinatal death is evident, although there is a suggestion that fetal growth may be improved. For women with an uncomplicated twin pregnancy the results of this review show no benefit from routine hospitalisation for bed rest ⁷
Counselling	<ul style="list-style-type: none"> > The advice of bed rest for women with threatened preterm birth is based on the observation that hard work and hard physical activity could be associated with preterm birth and the idea that bed rest may reduce uterine activity⁶ > Ensure the woman is also aware of adverse effects of bed rest⁶
Adverse effects of bed rest	<ul style="list-style-type: none"> > increased likelihood of venous thrombosis > muscle atrophy and symptoms of musculoskeletal and cardiovascular deconditioning > weight loss > Increased stress for the woman and her family (psychosocial and financial)⁶

Laboratory investigations

- > C-Reactive Protein
- > Complete blood picture
- > Low and high vaginal swabs for microscopy and culture, weekly after initial swabs if TPL continues / recurs
- > Midstream specimen of urine for bacteriology

Management

- > Inform neonatologists of admission so they can arrange to meet and counsel parents if necessary
- > Outcomes for preterm infants depend on place of birth and access to neonatal intensive care. Maternal transfer is generally safer than neonatal retrieval if delivery is not imminent

Antibiotic prophylaxis and treatment

Controlled trials

- > Show a reduction in maternal infection with the use of antibiotics (prophylactically) for preterm labour with intact membranes but show no benefit in neonatal outcomes⁷
- > Show that antibiotic treatment for bacterial vaginosis does not reduce the risk of preterm birth before 37⁺⁰ weeks or the risk of preterm prelabour rupture of the membranes⁹

No evidence of chorioamnionitis

- > Consider tocolysis dependent on gestational age
- > In the absence of **active** preterm labour, routine administration of prophylactic antibiotics to women in threatened preterm labour with intact membranes and without evidence of infection is not recommended
- > If **labour is not arrested**, give IV benzylpenicillin 3g loading dose, then 1.2 g IV every 4 hours for 48 hours or until delivery if this occurs before 48 hours, (unless GBS status is documented to be negative at presentation)
 - > If allergic to penicillin, give clindamycin 600 mg IV in 50 – 100 mL over at least 20 minutes every 8 hours for 48 hours or until delivery if this occurs earlier

Signs of chorioamnionitis:

- > The diagnosis of chorioamnionitis relies on the clinical presentation and may be difficult in its early manifestations
- > The clinical picture may include **maternal fever** with two or more of the following:
 - > Increased white cell count (> 15 x 10⁹ / L)
 - > Maternal tachycardia (> 100 bpm)
 - > Fetal tachycardia (>160 bpm)
 - > Uterine tenderness
 - > Offensive smelling vaginal discharge
 - > C-Reactive Protein > 40

- > Consideration should also be given to check for any other site of infection (e.g. urinary or respiratory tract) which could cause these changes
- > If in doubt consultation with a senior obstetrician, maternal fetal medicine or infectious disease physician should be considered
- > Histological examination of placenta and membranes with evidence of acute inflammation may confirm diagnosis after birth

If signs of chorioamnionitis

- > Ampicillin (or amoxicillin) 2 g IV every 6 hours
- > Gentamicin 5 mg/kg IV daily
- > Metronidazole 500 mg IV every 12 hours
 - > If allergic to penicillin, give clindamycin 600 mg IV in 50 – 100 mL over at least 20 minutes every 8 hours AND gentamicin 5 mg / kg IV daily until delivery
- > Do not inhibit labour, but consider hastening delivery under intravenous antibiotic cover
- > Consider optimal mode of delivery (LSCS versus vaginal birth) on the basis of the findings and the anticipated duration until birth

Postnatal maternal antibiotics

- > If chorioamnionitis, consider treatment with continued:
 - > Ampicillin (or amoxicillin) 2g IV every 6 hours for 5 days
 - > Gentamicin IV 5 mg / kg as a single daily dose for 5 days
 - > Metronidazole 500 mg IV every 12 hours for 5 days
- > May change to oral antibiotics once the woman is afebrile and tolerating oral medication e.g. amoxicillin 500 mg every 8 hours AND metronidazole 400 mg every 12 hours OR amoxicillin / clavulanic acid (Augmentin Duo Forte® x 1 every 12 hours) for the rest of the 5 days
 - > If allergic to penicillin, give metronidazole 400 mg orally every 12 hours for the rest of the 5 days AND azithromycin 1 g as a single oral dose, repeated after 7 days

Tocolytics

Controlled trials

- > Show that tocolytic drugs may delay birth and reduce the occurrence of preterm birth
- > Have thus far failed to show effects of betamimetics, magnesium sulphate or atosiban on significant adverse perinatal outcomes, such as respiratory distress and perinatal mortality
- > The use of calcium channel blockers is associated with fewer side effects, but a systematic review on the subject¹² provides more questions than answers on its effectiveness and perinatal outcome

Calcium channel blockers –nifedipine

- > Advantages over betamimetics (in the comparative studies):
 - > Oral administration
 - > Possibly higher efficacy
 - > Fewer side effects
- > Indicated for suppression of preterm labour at less than 34⁺⁰ weeks

Dosage

- > Follow link to 'Nifedipine use in preterm labour' in the A to Z index at www.sahealth.sa.gov.au/perinatal)

Betamimetics (salbutamol)^{14,15}

- > Salbutamol is the betamimetic used in Australia
- > Salbutamol has never been compared with either placebo or no treatment in preterm labour; all evidence in favour of its use is derived from analogy with other betamimetic agents
- > Available evidence does not support the use of oral betamimetics for maintenance after threatened preterm labour
- > Intravenous betamimetic treatment may cause pulmonary oedema (especially when associated with fluid overload) and has been responsible for maternal deaths

Indications

- > Given as IV salbutamol infusion (see below)
- > Suppression of preterm labour at less than 34⁺⁰ weeks
- > May be used as tocolytic cover for in-utero transfer of a woman in threatened preterm labour to a level IV or V hospital

Contraindications

- > Cardiac disease
- > Hyperthyroidism
- > Poorly controlled maternal diabetes mellitus
- > Placental abruption or significant bleeding of unknown cause
- > Chorioamnionitis
- > Doses that create excessive maternal (140 bpm) or fetal (180 bpm) tachycardia should be avoided
- > Relative contraindication in multiple pregnancy

Salbutamol intravenous infusion regimens

- > IV access
- > Mainline of 1,000 mL Hartmann's or 0.9 % sodium chloride
- > Attach salbutamol infusion (with medication added label) using a three way tap to mainline (minimise dead space)
- > Administer salbutamol either from the syringe or volumetric pump

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Syringe pump	Infusion pump
<p>Set up</p> <ul style="list-style-type: none"> > Add 7.5 mg salbutamol (7.5 mL) to 42.5 mL sodium chloride 0.9 % OR 5 % glucose in syringe (50 mL total) > Using medication added label write “salbutamol 150 micrograms per mL” and attach label to syringe 	<p>Set up</p> <ul style="list-style-type: none"> > Withdraw 15 mL from a 100 mL bag of sodium chloride 0.9 % or glucose 5 % > Add 15 mg (15 mL) Salbutamol to the remaining 85 mL bag of sodium chloride 0.9 % or glucose 5 % (100 mL total) > Using medication added label write “salbutamol 150 micrograms per mL” and attach label to bag
<p>Dosage and administration</p> <ul style="list-style-type: none"> > Commence at 1 mL / hr = 2.5 micrograms per minute > Increase rate at 10 minute intervals until response shown by decreased frequency, strength and length of contractions > Increase rate slowly thereafter, until contractions cease > Maintain infusion at same rate for 24 hours and then decrease at 1 mL / hr <p>Decrease if:</p> <ul style="list-style-type: none"> > Maternal pulse > 140 bpm > Fetal heart rate > 180 bpm > Hypotension > Other side effects, e.g. dyspnoea, chest pain, palpitations, nausea and vomiting > Women should also be warned about tremors, anxiety, dizziness and headaches > Evaluate decreased contractions, maternal and fetal well-being > The dose is determined by the woman’s tolerance (i.e. clinical indicators) of adverse effects against desired response > The dose should never exceed 45 micrograms / min (18 mL / hr) > Betamimetics can cause a fall in serum potassium (K+). This is related to the movement of K+ intracellularly and is usually limited and self-reversing. No treatment is needed unless ECG changes occur or the serum potassium falls below 2.5 mmol / L 	

Inhibitors of prostaglandin synthesis (indomethacin)¹⁶

- > Inhibitors of prostaglandin synthesis (indomethacin in particular) are the most potent inhibitors of uterine contractility currently available. They inhibit the cyclo-oxygenase (COX) enzyme of which two varieties exist (Cox-1 and Cox-2). Inhibitors currently used inhibit both enzymes although more specific Cox-2 inhibitors have been developed
- > Few adequate trials of prostaglandin synthesis inhibitors in preterm labour exist in the literature and information needs to be derived from other sources to obtain sufficiently valid guidelines on their use

Indications

- > Because of the potential adverse fetal and neonatal effects the use of indomethacin (the most commonly used cyclo-oxygenase inhibitor in preterm labour) should probably be restricted to:
 - > Gestational ages of < 28⁺⁰ weeks
 - > Failure to achieve tocolysis with other tocolytic regimens
 - > Contraindications to other tocolytics (e.g. cardiac disease)

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- > Administration for a short period of time (1 – 3 days)

Contraindications and risks

- > Risks for the fetus and neonate include:
 - > Constriction of the fetal ductus arteriosus (the risk increases with advancing gestational age; the effects are transient and reversible with short term administration; longer administration may lead to pulmonary hypertension in the fetus and neonate)
 - > Alteration of fetal (especially cerebral) blood flow
- > Reduced fetal renal function (may result in oligohydramnios)

Dosage

- > Indomethacin has a short half-life and frequent administration of low doses is recommended instead of administering higher doses infrequently
- > Start treatment with 50 mg or 100 mg (absorption after rectal and oral administrations are similar)
- > Repeat after 4 hours (reduce to half of the starting dose if some uterine quiescence is achieved)
- > Administer 25 mg (or 12.5 mg) every 4-hours, but for no longer than 48-72 hours
- > **With indomethacin administration, ensure close monitoring of fetal wellbeing**

Progesterone

- > A systematic review¹⁷ has shown convincing evidence that daily vaginal administration of progesterone reduces the risk of preterm birth in women with a short cervix demonstrated by ultrasound in mid-pregnancy. There might also be benefit in women with other significant risk factors for preterm birth (see risk factors in cervical incompetence and cerclage)
- > Doses of vaginal progesterone have been 90 mg in gel preparation and 100 mg and 200 mg in pessary form. A 200 mg pessary nocte to women who are shown to have a cervix less than 20 mm at 19-24⁺⁰ weeks gestation until 34 weeks gestation, prelabour rupture of the membranes or delivery can be recommended^{17,18,19}

Corticosteroids^{22,23}	
<ul style="list-style-type: none"> > Corticosteroids are effective in preventing adverse perinatal outcomes, most notably respiratory distress syndrome, and in increasing the likelihood of neonatal survival²² > Repeated doses of corticosteroids reduce the occurrence and severity of neonatal lung disease and the risk of serious health problems in the first few weeks of life²² 	
Single course	<p>Indications</p> <ul style="list-style-type: none"> > Gestational age is between 23⁺⁰ and 34⁺⁶ weeks and in PTL > Risk of preterm imminent birth > Preterm birth is planned or expected within the next seven days <p>Dosage</p> <ul style="list-style-type: none"> > Administer IM betamethasone in two doses of 11.4 mg (5.7 mg x 2) 24 hours apart to the woman > If betamethasone is unavailable, give IM dexamethasone in two doses of 12 mg, 24 hours apart²²
	<ul style="list-style-type: none"> > Where appropriate, estimate the risk of preterm birth by considering the use of adjunct prediction tests including fetal fibronectin and assessment of cervical length
Repeat course(s)	<p>Indications</p> <ul style="list-style-type: none"> > When the gestational age is 32⁺⁶ days or less, a repeat antenatal corticosteroid dose may be given 7 days or more after the first course in women still considered at risk of early preterm birth <p>Dosage</p> <ul style="list-style-type: none"> > Either: A single repeat dose of IM betamethasone 11.4 mg IM (5.7 mg x 2) > OR A single repeat course of IM betamethasone in two doses of 11.4 mg (5.7 mg x 2) 24 hours apart > If betamethasone is unavailable, give IM dexamethasone 12 mg
Further repeat single dose(s)	<ul style="list-style-type: none"> > Seven days after the first, single, repeat dose (and less than 14 days since the first repeat dose), if the woman is still considered to be at risk of preterm birth within the next seven days, a further, single, repeat dose of antenatal corticosteroids (IM betamethasone 11.4 mg IM [5.7 mg x 2]) can be given > Use up to a maximum of three, single, repeat doses only > NB: Do not give any further repeat courses if a single repeat course (11.4 mg, as two intramuscular doses, 24 hours apart) of betamethasone has been given already

Magnesium sulphate for neuroprotection of the fetus

Controlled trials

- > Show that fetal exposure to magnesium sulphate given before preterm birth has a neuroprotective role. The number of women needed to be treated to benefit one baby by avoiding cerebral palsy is 63²⁴
- > This systematic review also showed a significant reduction in the rate of gross motor dysfunction in early childhood²⁴

Indications

- > Neuroprotection of the fetus for women at risk of preterm birth who are at least 24⁺⁰ weeks of gestation and < 30⁺⁰ weeks of gestation
- > When birth is anticipated within 24 hours or in cases of expected planned delivery as close to four hours before expected delivery time and regardless of;
 - > plurality
 - > why the women is at risk of preterm birth
 - > parity
 - > anticipated mode of birth
 - > whether antenatal corticosteroids have been given or not

Dosage and administration

- > See 'Magnesium sulphate for women at risk of preterm birth for neuroprotection of the fetus' in the A to Z index at www.sahealth.sa.gov.au/perinatal)

Mode of delivery

- > The available trials of caesarean section versus vaginal birth to determine the best route of delivery are too small to draw clinical conclusions from them²⁴
- > The following general suggestions are reasonably well supported by clinicians:

Less than 26⁺⁰ weeks

- > Cephalic presentation - Vaginal birth
- > Breech presentation – If aggressive neonatal management anticipated then caesarean section may be the safest mode of delivery if time permits. If the baby is at borderline viability and for example in a non-tertiary setting then vaginal birth may be more appropriate
- > Multiple pregnancy – Caesarean section
- > In the case of spontaneous vaginal birth of the first multiple, consider delayed delivery of the remaining fetuses in utero
- > Consider the use of uterine relaxation techniques (e.g. glycerol trinitrate) for difficult delivery of the head (either vaginal birth or caesarean section)
 - > The recommended dose of glycerine trinitrate is 50-200 micrograms IV or one metred dose of sublingual spray (400 micrograms)

26⁺⁰ weeks or greater

- > Cephalic presentation - vaginal birth
- > Breech presentation - caesarean section

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Care of the newborn infant

Place of delivery

- > Singleton pregnancy \leq 32 weeks, Multiple pregnancy \leq 32 weeks - birth in a hospital with neonatal intensive care (Level VI) facilities
- > Singleton or Multiple pregnancy at a gestation \geq 32 weeks, when the neonate has a birth weight \geq 1,500g - birth in a hospital with neonatal Level V or VI neonatal care
- > Singleton pregnancy or Multiple pregnancy \geq 34 weeks when the neonate has a birth weight \geq 2,000g - birth in a hospital with at least level IV facilities
- > Consider discussion with the neonatal care provider at your hospital
- > \geq 37 weeks – birth in a hospital with at least level II or level III facilities
- > For further information, see 'Standards for Maternal and Neonatal Services in South Australia 2015' under pregnancy policies and consumer brochures at www.sahealth.sa.gov.au/perinatal

Care at delivery

- > Attendance of a paediatrician / neonatologist / neonatal nurse practitioner at the time of birth is essential
- > May also require assistance from a neonatology nurse
- > Postnatal (neonatal) care is the responsibility of the neonatologist (taking the maternal history and the condition of the infant at birth into account)

Cord blood and placenta

- > Cord blood samples (arterial and venous) should be collected for blood gas analysis
- > Collect and send placenta for:
 - > Histopathology (including check for chorioamnionitis)
 - > Swabbing for microbiological evidence of infection

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Abbreviations

bpm	Beats per minute
CTG	Cardiotocography
C	Celsius
CBP	Complete blood picture
CRP	C-reactive protein
COX	cyclo-oxygenase enzyme
° C	Degrees Celsius
e.g.	For example
et al.	And others
fFN	Fetal fibronectin
FIGO	International Federation of Gynecology and Obstetrics
g	Gram(s)
GBS	Group B Streptococcus
IM	Intramuscular
IV	Intravenous
kg	Kilogram/s
mg	Milligram/s
mL	Millilitre/s
WHO	World Health Organisation

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