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Queensland Maternity and Neonatal **Clinical Guideline**

Early onset Group B streptococcal disease

Queensland Government

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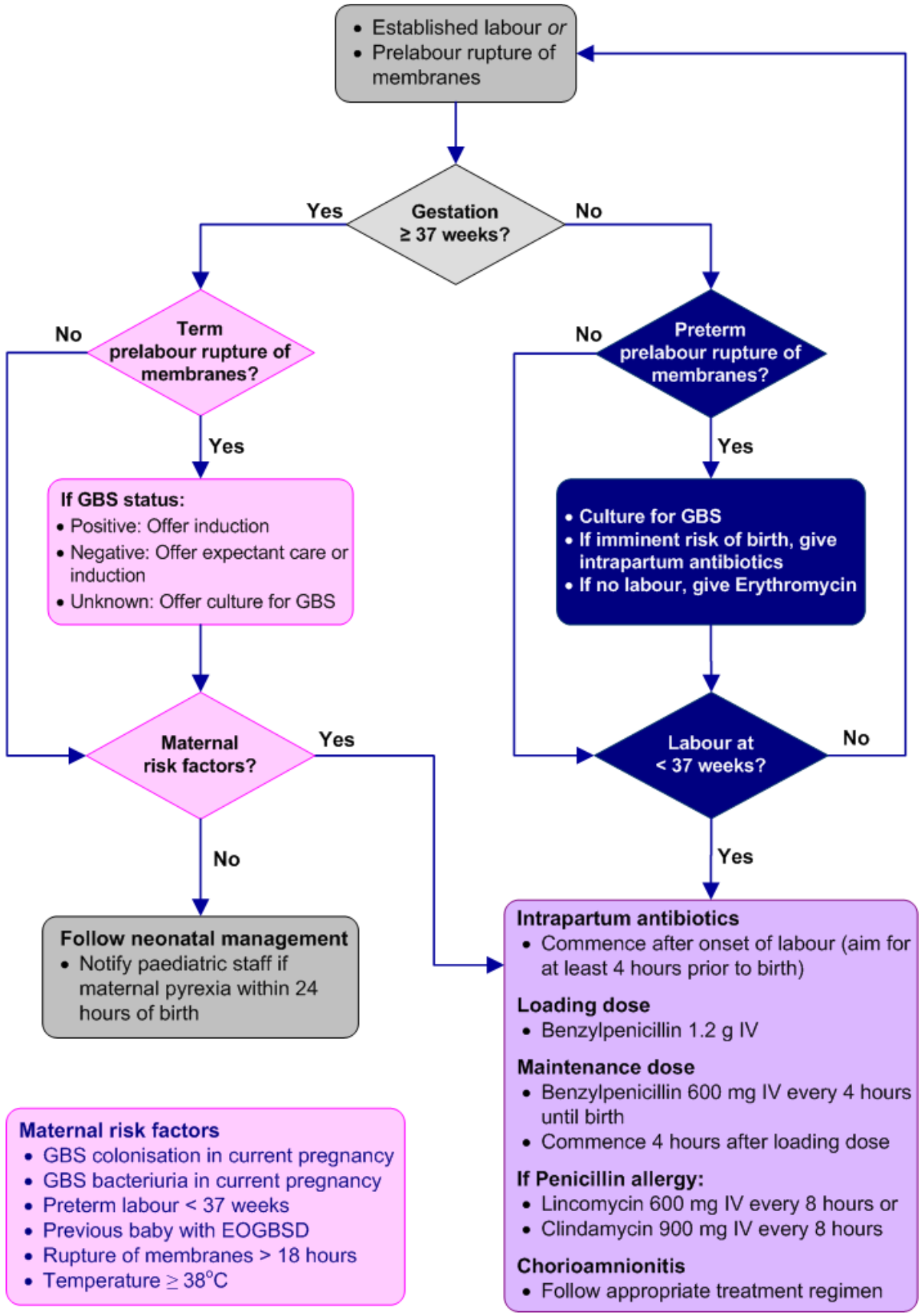
This Guideline does not address all elements of standard practice and assumes that individual clinicians are responsible to:

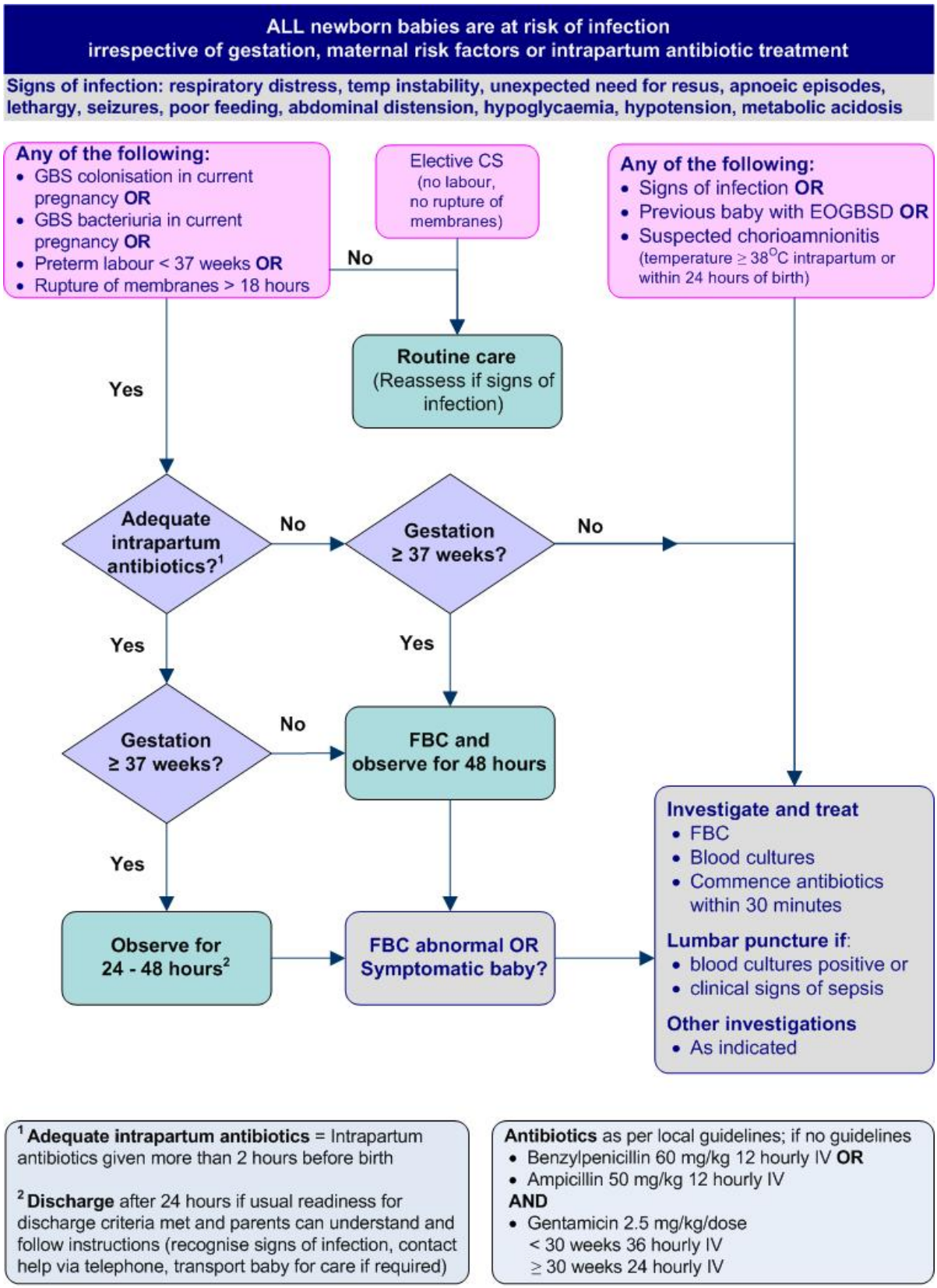
- Discuss care with consumers in an environment that is culturally appropriate and which enables respectful confidential discussion. This includes the use of interpreter services where necessary
- Advise consumers of their choice and ensure informed consent is obtained
- Provide care within scope of practice, meet all legislative requirements and maintain standards of professional conduct
- Apply standard precautions and additional precautions as necessary, when delivering care
- Document all care in accordance with mandatory and local requirements

Flow Chart: Maternal management of early onset Group B streptococcal disease



Adapted from Algorithm in: Flenady, V, Jenkins S (2007) Prevention of neonatal early onset Group B streptococcal disease Queensland Maternity and Neonatal Clinical Guidelines: Group B Streptococcus Guideline No: MN10.20-V2-R15

Flow Chart: Neonatal management of early onset Group B streptococcal disease



[1] **Adequate intrapartum antibiotics** = Intrapartum antibiotics given more than 2 hours before birth

[2] **Discharge** after 24 hours if usual readiness for discharge criteria met and parents can understand and follow instructions (recognise signs of infection, contact help via telephone, transport baby for care if required)

Antibiotics as per local guidelines; if no guidelines
- Benzylpenicillin 60 mg/kg 12 hourly IV **OR**
- Ampicillin 50 mg/kg 12 hourly IV

AND
- Gentamicin 2.5 mg/kg/dose
  < 30 weeks 36 hourly IV
  ≥ 30 weeks 24 hourly IV

Adapted from Algorithm in: Flenady, V, Jenkins S (2007) Prevention of neonatal early onset Group B streptococcal disease Queensland Maternity and Neonatal Clinical Guidelines: Group B Streptococcus Guideline No: MN10.20-V2-R15

Abbreviations

EOGBSD	Early onset Group B streptococcal disease
FBC	Full blood count
GBS	Group B streptococcus (Streptococcus agalactiae)
IM	Intramuscular
IV	Intravenous
LAM	List of approved medications
ROM	Rupture of membranes
PROM	Prelabour rupture of membranes
UTI	Urinary tract infection

Definition of Terms

Adequate prophylaxis	In order to maximise the window for administration of intrapartum prophylactic antibiotics, this guideline recommends aiming for administration of at least one dose of antibiotics 4 hours prior to birth while recognising administration 2 hours prior to birth as adequate prophylaxis in determining neonatal management
Early onset sepsis	Sepsis occurring within 48 - 72 hours of birth
Inadequate prophylaxis	Intrapartum antibiotics given to the mother less than 2 hours prior to birth or no antibiotics given
Preterm	Less than 37 weeks + 0 days gestation
Suspected chorioamnionitis	Maternal temperature greater than or equal to 38^{o}C intrapartum or within 24 hours of birth. Other signs and symptoms may include foul smelling amniotic fluid, uterine tenderness, maternal WCC>15000, fetal heart rate > 160 or maternal heart rate > 100 beats per minute
Term	Greater than or equal to 37 weeks + 0 days gestation
Threatened preterm labour	Preterm contractions without dilatation of the cervix and without substantial risk of imminent birth (within 24 hours) as clinically determined by the woman's health care provider

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1 Introduction

Group B streptococcus (GBS) is recognised as the most frequent cause of early onset neonatal sepsis.[1,2] Maternal colonisation of the lower genital tract with GBS during pregnancy increases the risk of neonatal infection by vertical transmission.[2,3] Intrapartum antibiotic prophylaxis to women at risk of transmitting GBS to their baby can substantially reduce the rate of (but not totally prevent[3]) early onset sepsis.[4,5] Intrapartum prophylaxis does not prevent late onset GBS disease.

1.1 Screening versus risk factor approach

There is a lack of expert consensus about whether a risk based or a screening approach should be used to identify pregnant women for intrapartum antibiotic prophylaxis.[1,2,4-8] Queensland has previously adopted a risk based approach.[7] This was based on an assessment of the declining rates of early onset GBS disease (EOGBSD) in Australia, the likely cost effectiveness of both strategies, the quality of the evidence in support of both approaches and issues of current practice, compliance and uptake.[7] [refer to Appendix A: Rationale for risk factor approach in Queensland]. In the absence of compelling new evidence, this guideline continues to advocate such an approach (i.e. decision to treat based on identification of maternal risk factors).

2 Maternal management

- Routine screening for antenatal GBS carriage is not recommended[1]
- Antenatal treatment of GBS carriage is not recommended[1,2,8]
- Intrapartum antibiotic prophylaxis should be recommended to women with risk factors[1]
- Document maternal risk factors and the need for intrapartum prophylactic antibiotics in the health record[7]
- Document history of any Penicillin allergy in the health record and advise women to alert carers[8]
- Discuss and provide information to women about GBS prevention strategies as a part of routine antenatal care[2,6]
- Vaginal disinfection with chlorhexidine in labour for the prevention of early onset GBS morbidity in preterm or term babies is not recommended[9]

2.1 Maternal risk factors

- Preterm labour at less than 37+ 0 weeks[2,4,5,7] (spontaneous or induced labour)
- Rupture of membranes greater than 18 hours prior to birth[1,2,4,5]
- Maternal temperature greater than or equal to 38^{O}C[1,2,5-7] (intrapartum or within 24 hours of giving birth)
- GBS colonisation in current pregnancy[1,7]
- Previous baby with EOGBSD[1,2,4-8]
- GBS bacteriuria in current pregnancy[1,2,6,7]

2.2 Conditions not requiring intrapartum prophylaxis

- Elective caesarean section (no labour, no rupture of membranes) irrespective of carriage[1,2,5,6,8] or gestational age
    - Antibiotic prophylaxis may be required for other reasons
- GBS carriage detected in a previous pregnancy[1,8] (even if GBS status is unknown in the current pregnancy)
- Threatened preterm labour with intact membranes

2.3 Intrapartum antibiotic regimen

There is limited high quality evidence regarding optimal timing of intrapartum prophylactic antibiotic administration.[10,11] Due to the rapidity of some labours, especially in multiparous women, it can be difficult to confidently estimate the time-to-birth interval. In order to maximise the window for administration of intrapartum prophylactic antibiotics, this guideline recommends aiming for administration 4 hours prior to birth[5] while recognising administration 2 hours prior to birth as adequate prophylaxis in determining neonatal management.[10]

- Benzylpenicillin is the drug of choice for EOGBSD prophylaxis[1,2,6,7]
    - If there is Benzylpenicillin hypersensitivity give Lincomycin or Clindamycin[1] [refer to Table 1]
    - Erythromycin is not recommended for intrapartum prophylaxis[12]
- Consensus recommendations are:
    - Administer Benzylpenicillin as soon as possible after the onset of labour[1]
    - Aim to administer one dose of Benzylpenicillin at least 4 hours prior to birth[7]
    - If labour continues beyond 4 hours then administer Benzylpenicillin 4 hourly
    - If birth is anticipated in less than 2 hours, intrapartum antibiotic prophylaxis should be administered as benefit may still occur[10,13]

Table 1. Intrapartum antibiotics for GBS prophylaxis

Benzylpenicillin	
Route	IV
Loading dose	1.2 g[5]
Maintenance dose	600 mg every 4 hours until birth[5] Commence 4 hours after loading dose
If Benzylpenicillin hypersensitivity	Lincomycin 600 mg IV every 8 hours or *Clindamycin 900 mg IV every 8 hours[2,8]
Comments	Where the woman is allergic to both Benzylpenicillin and Lincomycin consult with a medical microbiologist[6] or infectious diseases physician Consult with a medical microbiologist if there is GBS resistance to recommended antibiotics

* Clindamycin is not on the QH List of Approved Medications (LAM) therefore QH clinicians should give Lincomycin

2.4 Specimen collection for GBS detection

When specimen collection for GBS is clinically indicated:

- use one single dry swab stick[2,4]
    - insert into vaginal introitus[2,4] and then
    - insert into anus[2,4] (through the anal sphincter)[6,14,15]
- place into standard bacterial transport medium (e.g. Amies or Stuart's)
- label specimen clearly with "GBS screening in pregnancy"
- swabs may be self-collected by the woman[5,6]

2.5 Breastfeeding

Breastfeeding does not increase the risk of neonatal GBS disease and women concerned about late-onset disease should be given the usual advice about breastfeeding.[1]

2.6 Specific condition management

Recommendations for management of specific maternal conditions are outlined in Table 2.

Table 2. Specific maternal condition management

Condition	Recommendation
GBS bacteriuria	• Women with GBS urinary tract infections (UTI) in the current pregnancy (usually where quantitative count is greater than or equal to 10^5 cfu/ml[16]) should be offered: o appropriate treatment at the time of diagnosis *and* o intrapartum antibiotic prophylaxis[1,2,4,8]
Term prelabour rupture of membranes (PROM)	• Routine use of intrapartum prophylactic antibiotics for term PROM less than 18 hours duration is not recommended • Once labour commences, intrapartum prophylactic antibiotics are recommended for women with term PROM greater than 18 hours duration[7] (commence antibiotics as soon as PROM *anticipated* to be greater than 18 hours) • If known positive GBS status, recommend induction with IV oxytocin[4,17] and intrapartum prophylactic antibiotics • If known negative GBS status, offer expectant management or induction with IV oxytocin[7] • If unknown GBS status offer a low vaginal and rectal swab for GBS culture[7]
Preterm PROM	There is an increased prevalence of GBS colonisation amongst women giving birth preterm.[13,18,19]. • Recommend vaginal and rectal cultures for GBS[18] • If there is imminent risk of birth, commence intrapartum antibiotic prophylaxis[8] • If labour ensues, give intrapartum antibiotic prophylaxis irrespective of GBS status • If there is PPROM without labour, Erythromycin is the preferred antibiotic[20,21]
Intrapartum or postnatal maternal temperature greater than or equal to 38^{o}C	• Suspected chorioamnionitis in labour requires investigation and treatment • Broad spectrum antibiotic therapy that includes an agent active against GBS should replace GBS specific antibiotic prophylaxis[1,4,6,8] • Notify paediatric/neonatal/medical staff if there is maternal pyrexia (intrapartum or within 24 hours of birth) as it may have implications for neonatal management[7] • Advise women to seek advice from health care professionals if maternal temperature is greater than or equal to 38^{o}C within 24 hours of birth (especially if discharged within 24 hours of birth)

3 Neonatal management

All newborn babies are at risk of infection irrespective of gestational age, maternal risk factors or intrapartum antibiotic treatment.[7]

The vast majority (90%) of early onset Group B streptococcal disease (EOGBSD) occurs during the first 24 hours of life.[2,3] EOGBSD is usually evident as respiratory disease (54%), generalised sepsis (27%) or meningitis (15%).[3]

- About 10 - 30% of early onset neonatal septicaemia is complicated by bacterial meningitis[22]
- 30% of neonatal bacterial meningitis is caused by GBS[22]

3.1 Signs of sepsis

Clinical signs of sepsis can be non-specific and subtle and a high index of suspicion is required as delay in initiating treatment may significantly increase neonatal mortality and morbidity.[6] Signs may include one or more of the following:

- respiratory distress
- temperature instability
- poor peripheral perfusion
- unexpected need for resuscitation
- apnoeic episodes
- lethargy
- seizures
- poor feeding
- abdominal distension
- hypoglycaemia
- hypotension
- metabolic and/or respiratory acidosis

3.1.1 Observations

Where the guideline recommends neonatal observations in an otherwise well baby [refer to Flowchart: Neonatal management] minimum observations for EOGBSD should include:

- clinical surveillance for signs of sepsis [refer to 3.1 Signs of sepsis]
- temperature, pulse and respiratory rate 4 hourly

3.2 Investigation of sepsis

- Minimum investigations (prior to antibiotics) should include:
  - full blood count (FBC) with differential
  - blood cultures[23] (greater yield may be achieved with two sets)
- Lumbar puncture is recommended (where local capabilities permit) where there is either[2,6]:
  - positive blood cultures *or*
  - clinical signs suggestive of sepsis (as babies with meningitis may have sterile blood cultures[2,6])
- Consider:
  - chest X-ray if respiratory signs[2]
- Gastric aspirate or surface swabs may be useful to determine colonising flora if taken soon after birth, but have a poor correlation with invasive sepsis and are not routinely recommended

3.3 Treatment

- Babies require prompt investigation and treatment (within 30 minutes of decision[23]) with antibiotics regardless of the adequacy of intrapartum antibiotics[2] where:
  - there are clinical signs of infection[2]
  - the mother had suspected chorioamnionitis[2,4,6,8] (temperature greater than or equal to 38^{o}C intrapartum or within 24 hours of birth)
  - the mother has had a previous baby with EOGBSD
- Babies born by elective caesarean section (no labour, no rupture of membranes) at term do not require investigation or monitoring regardless of maternal GBS status
- Management of **asymptomatic** babies with maternal risk factors is determined by gestation and adequacy of intrapartum antibiotics. [refer to the flowchart: Neonatal management on page 4]

3.4 Antibiotic therapy

- Use broad-spectrum antibiotics which provide cover against EOGBSD as well as other common pathogens
- The type and duration of antibiotic treatment will be determined by the clinical indications and may be modified by results of the investigations
- If intravenous access cannot be established, antibiotics may be given via the intramuscular route as an interim measure
  - Seek further advice but do not delay initiation of treatment
- Where local guidelines for antibiotics do not exist, suggested antibiotic therapy is outlined in Table 3

Table 3. Neonatal antibiotic therapy if no local guidelines

Drug	Dose / Route	Comment
Benzylpenicillin ***OR***	60 mg/kg/dose 12 hourly[24] IV slow push	Halve the dose and double the dose interval if there is renal failure[24]
Ampicillin	50 mg/kg/dose 12 hourly[24,25] IV slow push	Increase the dosage interval if there is renal failure[24]
AND **Gentamicin**	**Gestation: less than 30 weeks** 2.5mg/kg/dose every 36 hours[26] IV slow push **Gestation: greater than or equal to 30 weeks** 2.5mg/kg/dose every 24 hours[26] IV slow push	Trough level prior to 3rd dose in babies less than 7 days old and where there is poor renal function[24]
	Caution: If oliguric, wait for a trough level result prior to 2nd dose **Trough Level:** Less than 2 mg/L is acceptable If greater than or equal to 2 mg/L then extend the dosage interval by 12 hours If dose or dose interval is altered, trough levels should be re checked prior to the third dose of the new order	

3.4.1 Duration of antibiotic therapy

- Discuss with a paediatrician or infectious diseases physician
- If blood cultures are negative, symptoms resolve and white count is normal, then antibiotics may be discontinued after 36 hours[23]
- If sepsis is proven or suspected then continue antibiotics for 5 - 7 days or longer as indicated

3.5 Discharge criteria

- Refer to the flow chart: Neonatal management on page 4 for recommendations regarding length of stay
- Readiness for discharge should be informed by usual discharge considerations[2]
- Consider parental ability to understand and follow instructions including[2]:
    - recognise and respond appropriately to signs of infection in the baby
    - communicate with health-care providers by telephone
    - transport the baby promptly to an appropriate healthcare facility if required

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Appendix A: Rationale for risk factor approach in Queensland

The following table is based on the rationale provided in *Flenady V, Jenkins-Manning S (2007) for the Queensland Clinical Practice Guidelines Working Party on the Prevention of Early Onset Group B Streptococcal Disease, Centre for Clinical Studies, Mater Health Services Brisbane.*

Consideration	Comment
Approach description	**Screening approach** • Universal antenatal screening for GBS carriage at 35 - 37 weeks gestation and treat all women with positive cultures, women with a preterm birth where GBS carriage status is unknown or previous infant with EOGBSD with intrapartum antibiotics[7] **Risk factor approach** • No universal antenatal screening, treat all women with risk factors for EOGBSD with intrapartum antibiotics[7]
Status of national and international guidelines	**Risk factor approach is recommended by:** • Royal College of Obstetricians and Gynaecologists[1] • National Institute for Clinical Excellence[27] • New Zealand GBS Consensus Working Party[6] • Denmark, Netherlands and Norway National Guidelines[28] **Screening Approach is recommended by:** • Centre for Disease Control and Prevention[2] • The Society of Obstetricians and Gynaecologists of Canada[4] • American Committee on Obstetric Practice[16] • Spanish National Guideline[28] **An "either approach" (i.e. risk factor or screening) is recommended by:** • The Royal Australian and New Zealand College of Obstetricians and Gynaecologists[5] • Australasian Society for Infectious Diseases[15]
Cost-effectiveness	• Attempts to evaluate the cost-effectiveness of the strategies have produced differing results[7] • Most of these analyses have been based on theoretical decision analyses and have not been examined in clinical studies[7] • The differences in conclusions across these cost-effectiveness studies may be due to factors such as the variability in maternal colonisation rates, the frequency of EOGBSD and the management practices of neonates born to mothers treated with antibiotics[7] • In Australia, universal screening is more expensive than the risk factor approach[29]
Declining rates of EOGBSD	• There appears to have been a gradual decline in the rate of EOGBSD in Australia from 2/1000 births in 1991 - 1993 to 0.29/1000 in 1999 - 2000[7] • During 2000 - 2004 the overall rate of EOGBSD in Queensland was 0.34/1000 live births[7]

Other considerations	• Uniform compliance with a single strategy is likely to be the major determinant in making further reductions in early-onset neonatal GBS disease[6,7,16]
	• In situations where most women attend their general practitioner or community based midwife for share care, routine screening for GBS status at 35 - 37 weeks is logistically difficult[7]
	• RCOG estimated the following Number Needed to Treat (NNT)[1]
	  o Using a screening strategy, 750 women who screened positive to GBS would need to be treated to prevent one case of GBS disease and 7034 women treated to prevent one neonatal death
	  o Using a risk based strategy 625 women with a GBS risk factor would need to be treated to prevent one case of GBS disease and 5882 women treated to prevent one neonatal death

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