FOR THE PREVENTION, DIAGNOSIS AND TREATMENT OF EARLY-ONSET NEONATAL BACTERIAL INFECTION – NEONATAL CLINICAL GUIDELINE

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1. **Aim/Purpose of this Guideline**
   - To provide guidance on antenatal and intrapartum clinical management to reduce risk of neonatal early-onset infection (EOI).
   - To provide guidance on the assessment and management of newborns at increased risk of EOI, and infants with suspected or proven EOI.

2. **Scope of guideline**
   - Pregnant women and newborn infants.
   - Prevention, diagnosis and treatment of neonatal infection with onset in the first 72 hours of life.

3. **Background**
   3.1. Early-onset bacterial infection is a significant cause of mortality and morbidity in newborn babies. The great majority of babies do not experience EOI but critical illness can develop quickly in affected babies. Professional and public concern about the possibility of infection is common, but there has been wide variation in how the risk of early-onset neonatal infection is managed in mothers and healthy babies.

   3.2. Organisms responsible for neonatal EOI come from the maternal genital tract. The predominant pathogens causing EOI in the UK are GBS, non-pyogenic Streptococci, and E coli, though the list includes a range of other Gram positive and Gram negative organisms. Listeria monocytogenes currently accounts for only 1% of UK culture isolates in early onset sepsis.

   3.3. Group B Streptococcus (GBS, Streptococcus agalactiae) is the most frequent cause of severe neonatal EOI in the UK, accounting for 40% of all isolates in culture-positive cases. GBS is carried by approximately 25% of UK women of reproductive age, though EOI due to GBS affects less than 0.5% of babies born to GBS carriers. The estimated UK incidence of early-onset GBS (EOGBS) is 0.5 per 1000 births, though this incidence is may be an underestimate as it represents culture proven infection.

   3.4. This local guideline follows the NICE Clinical Guideline 149, “Antibiotics for early-onset neonatal infection”, which together with relevant guidance from the RCOG Green Top Guideline 36 “The Prevention of Early-onset Group B Streptococcal Disease” (2nd edition, 2012), and related NICE Clinical Guidelines (see reference list) is designed to ensure that:
   - Implementation of consistent preventive antenatal and intrapartum strategies;
   - rapid treatment of babies with suspected EOI;
   - limitation of antibiotic exposure in babies who do not have an EOI.

3.5. **Abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>IAP</td>
<td>Intra-partum antibiotic prophylaxis</td>
</tr>
<tr>
<td>EOI</td>
<td>Early-onset bacterial infection</td>
</tr>
<tr>
<td>GBS</td>
<td>Group-B Streptococcus</td>
</tr>
<tr>
<td>EOGBS</td>
<td>Early-onset Group-B Streptococcus infection</td>
</tr>
<tr>
<td>PROM</td>
<td>Pre-labour rupture of membranes</td>
</tr>
</tbody>
</table>
**4. Patient-centred care**

4.1. Except where it would be dangerous to do so, families should be offered choice. Families should be supported to make choices through provision of information and, where appropriate, reassurance.

4.2. Healthcare professionals should involve the mother in any handover of care, either when additional expertise is brought in because of the risk of infection or during planned changes in staff. The handover should include an update about the presence of any infection.

4.3. Parents should be reassured that babies at increased risk of, or with, EOI can usually continue to breastfeed, and that every effort will be made to facilitate this. If a baby is temporarily unable to breastfeed, the mother should be supported to express breast milk if she wishes to do so.

4.4. If the mother had GBS colonisation in a previous pregnancy but without infection in the baby, she should be reassured that she does not require IAP in this pregnancy or any special precautions for her baby.

4.5. If there have been any concerns about early-onset neonatal infection before a baby is discharged, the parents should be advised that they should seek medical advice if they are concerned that the baby:

- is showing abnormal behaviour (for example, inconsolable crying or listlessness), or
- is unusually floppy, or
- has developed difficulties with feeding or with tolerating feeds, or
- has an abnormal temperature unexplained by environmental factors (lower than 36°C or higher than 38°C), or
- has rapid breathing, or
- has a change in skin colour.

4.6. When a baby who has had a GBS infection is discharged from hospital, the mother should be advised that if she becomes pregnant again:

- there will be an increased risk of early-onset neonatal infection;
- she should inform her maternity care team that a previous baby has had a group B streptococcal infection;
- IAP will be recommended.

4.7. When a baby who has had a GBS infection is discharged from hospital, the mother’s GP should be advised that there is a risk of:

- recurrence of group B streptococcal infection in the baby, and
- Group B streptococcal infection in babies in future pregnancies.

4.8. If the mother has had GBS colonisation in the pregnancy but without infection in the baby, she should be informed that if she becomes pregnant again, this will not affect the management of the birth in the next pregnancy.
5. Strategies during pregnancy to prevent neonatal EOI

5.1. Samples for bacterial culture during pregnancy

5.1.1. Women should be offered routine screening for asymptomatic bacteriuria (bacterial colonisation of the urinary tract without urinary tract symptoms) by midstream urine culture early in pregnancy.

5.1.2. Routine antenatal screening for asymptomatic bacterial vaginosis is not recommended.

5.1.3. Routine antenatal screening of pregnant women for GBS carriage is not recommended.

5.2. Antenatal antibiotic therapy (before onset of labour)

5.2.1. Vaginal GBS colonisation:

Benzylpenicillin prophylaxis during pregnancy (before onset of labour) does not reduce the likelihood of GBS colonisation at delivery and is not an effective preventive strategy. Women found to have vaginal or rectal colonisation with GBS during pregnancy should be offered IAP from the start of labour.

5.2.2. Bacteriuria:

Treatment of asymptomatic bacteriuria in pregnancy reduces the risk of maternal pyelonephritis. Therefore women with significant bacteriuria should receive antibiotic treatment appropriate to the organism identified. Women treated in pregnancy for GBS bacteriuria should also be offered IAP.

5.2.3. Preterm pre-labour rupture of membranes:

Oral erythromycin should be offered for 10 days following a diagnosis of preterm pre-labour rupture of membranes.

5.3. Antenatal “flagging” of women who should be offered IAP

5.3.1. The following women should be clearly identified as eligible for intrapartum antibiotic therapy:

- Women with previous baby affected by neonatal GBS disease;
- Women with GBS on rectal or high vaginal swab in current pregnancy;
- Women with GBS bacteriuria in current pregnancy.

5.3.2. All women identified antenatally with any of these indications for IAP should have a yellow GBS sticker placed on the ‘maternity management plan page’ and a letter sent to the delivery suite ‘risk’ folder.

5.3.3. When antibiotics are administered during labour this should be signed for on the prescription chart and documented in the woman’s intrapartum records.
5.4. Avoidance of Listeria monocytogenes infection in pregnancy

5.4.1. Information offered to pregnant women should include how to reduce the risk of listeriosis by:

- drinking only pasteurised or ultra-heat treated (UHT) milk
- avoiding ripened soft cheeses, for example camembert, brie and blue-veined cheese
- (there is no risk with hard cheeses, such as cheddar, or cottage cheese or processed cheese)
- not eating pâté of any kind (including vegetable pâté)
- not eating uncooked or undercooked ready-prepared meals.

6. Intrapartum care to prevent neonatal EOI

6.1. Pre-labour rupture of membranes at term

Women who present with PROM but have not had GBS detected in their urine or on swab in the current pregnancy or have not had a previously infected baby, then induction of labour should be advised 24 hours after rupture of membranes, unless there is a clinical indication to induce earlier. See ‘Clinical Guideline for the Management of Pre-labour Rupture of Membrane at Term (Term PROM) 2012’. Routine IAP is not advocated. Mothers of babies born following PROM should be asked to inform their healthcare professionals immediately of any concerns they have about their baby’s wellbeing in the first 5 days following birth, particularly in the first 12 hours when the risk of infection is greatest.

6.2. Suspected chorioamnionitis

Women with a fever > 38°C in labour or with clinically suspected chorioamnionitis should:

- Have a blood sample sent for blood culture.
- Commence broad spectrum IV antibiotic therapy, including an antibiotic active against GBS.
- Have placenta sent for culture and histology following delivery.

6.3. Intra-partum antibiotic prophylaxis against early-onset GBS infection

IAP reduces the risk of neonatal EOI in babies born to women colonized or infected with GBS. The recommendations on use of IAP against GBS seek to balance the reduction in risk of neonatal infection with the increased medicalisation of childbirth, risk of adverse antibiotic reaction, and the potential promotion of resistant organisms.

6.3.1. Recommended regime for IAP against GBS:

- Benzyl penicillin 3g IV then 1.5g at 4 hourly intervals until delivery
- If the woman is allergic to penicillin Clindamycin 900mg IV every 8 hours until delivery

6.3.2. Definition of “adequate” IAP against GBS:
Adequate IAP is defined as at least one dose of one the above antibiotic regimes, given at least 2 hours before delivery.

6.3.3. **Indications for IAP to prevent neonatal early-onset GBS infection:**

IAP against GBS should be offered to:

- Women who have had a previous baby with invasive GBS infection
- Women who have been found to have GBS colonisation, bacteriuria or infection in the current pregnancy

NB - Erythromycin does not provide effective prophylaxis against early-onset GBS.

6.3.4. **Women who are not recommended to receive IAP:**

- Women with GBS colonisation, bacteriuria or infection in previous pregnancies or at any other time before the current pregnancy, unless there is a history of neonatal GBS disease.
- Women delivering by elective caesarean section in the absence of labour, regardless of GBS colonisation status in the current pregnancy.
- Women in preterm labour with intact membranes who are not known to have been colonised with GBS in the current pregnancy.
- Women in preterm labour following pre-labour ROM, unless there is evidence of overt infection (in which case commence broad spectrum IV antibiotic therapy including an agent active against GBS, as per 6.3).

7. **Management of the Neonate**

7.1. **Identifying infants with possible EOI**

- Management of the newborn infant within the first 72 hours of life should be based on an assessment of risk factors and clinical indicators (see Tables, Appendix 1 and 2). Certain risk factors and clinical indicators in Tables 1 and 2 are “red flags” which signify a high likelihood of early-onset neonatal infection.

- Any risk factor or clinical indicator identified by maternity staff before or following delivery should prompt a careful clinical assessment of the baby without delay. This should include a review of the maternal and neonatal history and a physical examination of the baby including an assessment of vital signs.

7.2. **Neonatal care-pathways based on risk factors and clinical indicators**

(See summary algorithm Appendix 3)

7.2.1. **Infant with any red flag:**

- Investigate (Section 7.4) and Treat (Section 7.5)

7.2.2. **No red flags, but two or more non-red flag risk factors or clinical indicators:**
- Investigate (Section 7.4) and Treat (Section 7.5)

7.2.3. **No red flags, and only one non-red flag risk factor or clinical indicator:**

- Consider withholding antibiotics
- Observe and Monitor (section 7.3)
- If one or more further clinical indicator develops: Investigate (Section 7.4) and Treat (Section 7.5)
- If no further concerns arise during observation and monitoring period, reassure parents and give advice to parents and carers.

7.2.4. **No risk factors or clinical indicators:**

- Continue routine postnatal care.

**NB:**

- Maternal GBS colonisation, bacteriuria or infection in the current pregnancy constitutes a risk factor after delivery of the baby if the mother has not received adequate IAP (see definition of adequate IAP, Section 2.37).

- If maternal GBS colonisation is first identified after birth but within the first 72 hours of life, the baby should be assessed for any other risk factors and any clinical indicators of infection. Then follow the algorithm in this section above.

### 7.3. Observation and Monitoring

- Monitoring is appropriate for babies with only one non-red flag risk factor or clinical indicator. Monitoring should include documentation of clinical condition and vital signs (temperature, pulse and respiratory rate) at 0, 1, and 2 hours, and then 2-hourly for at least a further 10 hours.

### 7.4. Neonatal investigations for suspected EOI

7.4.1. A Blood Culture and sample for CRP should always be taken before administering the first dose of antibiotic. Routine urine flow cytometry/ culture is not recommended.

7.4.2. A second CRP should be measured 18-24 hours after presentation.

7.4.3. Surface skin swabs for culture are not recommended in either well or unwell babies, in the absence of clinical signs of a localised infection.

7.4.4. A lumbar puncture should be performed before starting antibiotics if it is safe to do so and there is a strong clinical suspicion of infection. If performing lumbar puncture would delay starting antibiotics beyond a safe duration (maximum 1 hour), perform the LP as soon as possible after starting antibiotics.

7.4.5. If an LP was not done at presentation, an LP should be considered if:
- the baby has a CRP greater than 10 mg/l, or
- blood culture is positive, or
- there is an unsatisfactory response to antibiotic treatment

7.4.6. A chest X-Ray should be performed if there are clinical signs of respiratory disease (NB: no recommendation in NICE guideline).

7.5. **Empirical antibiotic therapy for suspected EOI**

7.5.1. Babies commenced on antibiotic treatment should receive the first dose as soon as possible and always within 1 hour of the decision to treat.

7.5.2. Babies commenced on antibiotics for suspected early-onset neonatal infection should receive:

- IV Benzylpenicillin 25 mg/kg every 12 hours (8-hourly if very ill), and
- IV Gentamicin, starting dose 5 mg/kg.

7.5.3. If a second Gentamicin dose is needed it should be given 36 hours after the first dose, or after 24 hours if the baby is very ill or the blood culture shows a Gram-negative organism.

7.5.4. Babies commenced on antibiotics should be assessed regularly and the antibiotic regimen reviewed on the basis of the baby’s clinical condition and culture results.

7.6. **Gentamicin prescribing and monitoring**

7.6.1. RCHT policy on safe prescribing and administration of gentamicin must be followed.

7.6.2. If a second dose of gentamicin is given, measure the trough gentamicin level immediately before the second dose. Check the result of the pre-second dose gentamicin level before giving a third dose.

7.6.3. If the baby is continued on gentamicin, re-check the trough level before every 3rd dose, or more frequently if necessary. Aim to achieve trough concentrations below 2 mg/l, or below 1 mg/l for course lengths exceeding three doses.

7.6.4. Consider measuring peak blood gentamicin levels 1 hour after gentamicin dose in babies with:

- Oedema
- Macrosomia
- Unsatisfactory response to antibiotic therapy
- Proven Gram-negative infection

If measured, consider increasing the gentamicin dose if peak level is less than 8 mg/l.

7.7. **Care of babies receiving antibiotics for suspected EOI.**
7.7.1. All babies started on antibiotics in the first 72 hours of life should receive the first dose on NNU with a set of observations recorded at the time. Care of the baby should then be guided by clinical presentation as follows:

7.7.2. **Antibiotics started for risk factors with no clinical indicators:**

Babies started on antibiotics when there are no clinical indicators of infection (i.e. treated on basis of risk factors only), and no red flag risk factors, can be nursed with their mothers on the Postnatal Ward. They should have initial observations at 1, 2, 4, 8, and 12 hours, and subsequently at least 6 times in each 24 hours until the cannula has been removed following completion of antibiotic therapy (where appropriate, timed to coincide with feeds or other cares). All observations should be documented on the Neonatal Early Warning Score (Neonatal NEWS) chart.

7.7.3. **Antibiotics started in presence of one clinical indicator:**

Babies started on antibiotics when there are one or more risk factors but only one clinical indicator of infection should be assessed by a paediatric Consultant, Middle Grade Doctor or ANNP to decide whether continuing care should be on NNU, transitional care or postnatal ward. Assessment should take into account the nature and severity of symptoms, the potential for babies with symptoms of sepsis to deteriorate, as well as the disadvantages of separating mother and baby.

They should have initial observations at 1, 2, 4, 8, and 12 hours, and subsequently at least 6 times in each 24 hours until the cannula has been removed following completion of antibiotic therapy (where appropriate, timed to coincide with feeds or other cares). All observations should be documented on the Neonatal Early Warning Score (Neonatal NEWS) chart.

7.7.4. **Antibiotics started in presence of more than one clinical indicator:**

Babies with more than one clinical indicator should be nursed on NNU for at least 12 hours after the first antibiotic dose, and should remain on NNU until considered fit to be nursed with mother on postnatal ward. They should then have observations documented at least 6 times in each 24 hours until the cannula has been removed following completion of antibiotic therapy (where appropriate, timed to coincide with feeds or other cares). All observations should be documented on the Neonatal Early Warning Score (Neonatal NEWS) chart.

7.7.5. **Senior oversight of babies with EOI**

The Neonatal Service consultant (or on-call consultant on weekends) should be informed of all infants considered to have EOI (defined as infant with positive culture from blood, or CSF, or considered to require antibiotics for more than 36 hours on clinical grounds). The consultant has responsibility to ensure that the diagnosis and treatment plan are appropriate and that parents are adequately informed.
7.8. **Decisions 36 hours after starting treatment in babies with negative cultures**

7.8.1. The usual duration of antibiotic treatment for babies with a negative blood culture but in whom there has been strong suspicion of sepsis should be 7 days.

7.8.2. Consider stopping antibiotics 36 hours after starting antibiotics if:

- The blood culture is negative, and
- The initial suspicion of infection was not strong, and
- The baby’s clinical condition is reassuring with no clinical indicators of possible infection, and
- The levels and trend of CRP are reassuring

7.8.3. If blood culture is negative but it is decided to continue beyond 36 hours, the baby should have a clinical review at least once every 24 hours. At each review, consider whether to stop or continue antibiotic treatment, taking account of:

- the level of initial clinical suspicion of infection
- the baby’s clinical progress and current condition, and
- the levels and trends of C-reactive protein concentration.

7.9. **Targeted antibiotic therapy for culture-positive EOI**

7.9.1. Neonatal early-onset bacteraemia:

- Gram-negative organism grown on blood culture:
  - Add another antibiotic active against Gram-negatives (e.g. Cefotaxime).
  - If gram-negative infection is confirmed, stop the Benzylpenicillin.
- GBS or Listeria grown on blood culture:
  - Continue Benzylpenicillin and Gentamicin.
- Gram-positive species other than GBS or Listeria grown on blood culture
  - Seek expert Clinical Microbiological advice.

7.9.1.1. Duration of therapy:

The standard antibiotic treatment length for blood culture-positive EOI is 7 days. Consider a longer duration if the baby has not fully recovered or if advisable based on the isolated pathogen (seek Clinical Microbiology advice).

7.9.2. Neonatal early-onset meningitis:

- Empirical treatment pending CSF culture:
I V Amoxicillin and Cefotaxime

Gram-negative species identified on CSF Gram-stain or culture:

- Stop the Amoxicillin and treat with Cefotaxime alone.
- Continue treatment for at least 21 days unless directed otherwise by the results of antibiotic susceptibilities.
- If the clinical course is complicated consider extending the duration of treatment and obtain expert advice.

Gram-positive species identified on CSF Gram-stain:

- Continue Amoxicillin and Cefotaxime pending CSF culture result
- Seek Clinical Microbiological advice.

GBS isolated from CSF culture:

- Consider changing antibiotic combination to:
  - Benzylpenicillin 50 mg/kg every 12 hours for at least 14 days, and
  - Gentamicin, starting dose 5 mg/kg every 36 hours* for 5 days.

*or every 24 hours if the baby is very ill or a Gram-negative organism is cultured.

Listeria isolated from CSF (or from blood culture in neonate with meningitis):

- Stop Cefotaxime and treat with Amoxicillin and Gentamicin.
- Continue IV Amoxicillin for at least 21 days
- Treat with Gentamicin for at least the first 7 days.

Gram-positive species other than GBS or Listeria isolated from CSF culture:

- Seek senior Clinical Microbiological advice.

Gram-stain and culture negative meningitis:

- Treat with Cefotaxime and Amoxicillin for at least 14 days.
- If the clinical course is complicated, consider extending the duration of treatment and seek advice.

7.10. Localised infections of the eye

7.10.1. Babies with a significant purulent eye discharge within first 72 hours should have standard eye swabs sent urgently for gram stain and culture, and Chlamydia eye swab for PCR. Start topical and systemic antibiotic therapy for possible gonococcal infection whilst awaiting swab results (topical Neomycin plus single dose IV Ceftriaxone if infant not jaundiced; if jaundiced, start IV Cefotaxime and seek Clinical Microbiology advice). Specific therapy should be guided by microbiology results.
7.11. **Localised infections of the umbilical cord**

7.11.1. Babies with purulent umbilical discharge or peri-umbilical cellulitis should have blood culture, CRP, and umbilical swab for Gram stain and culture. Start IV Flucloxacillin and Gentamicin, following the gentamicin regime and guidance in Section 2.47. If culture shows a Gram-positive organism, the gentamicin should be stopped.

7.12. **Discharge after stopping antibiotic therapy**

It is not necessary to keep a well baby in hospital for observation after stopping antibiotics. Consider prompt discharge but parents/ carers should be given support and information as per Section 2.2 and a point of contact for advice.

7.13. **Footnote – IAP in preterm labour**

Multiple poor-quality clinical trials have together failed to yield sufficient evidence to determine whether IAP against GBS should be offered to women presenting with preterm labour, in the absence of clinical chorioamnionitis or known GBS colonisation/bacteriuria in the current pregnancy. For women with preterm pre-labour ROM, NICE Guideline 149 says “consider” IAP, whilst the 2nd ed RCOG Green Top Guideline no.36 says IAP should not be offered to this group.

Neither guideline recommends IAP against GBS in preterm labour with intact membranes.

8. **Monitoring compliance and effectiveness**

<table>
<thead>
<tr>
<th>Element to be monitored</th>
<th>Key changes in practice recommended by guidance.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead</td>
<td>Dr Andrew Collinson, Operational Lead for Neonatology</td>
</tr>
<tr>
<td>Tool</td>
<td>Audit proforma to be developed.</td>
</tr>
<tr>
<td>Frequency</td>
<td>First audit 6 months after introduction, then as dictated by audit findings.</td>
</tr>
<tr>
<td>Reporting arrangements</td>
<td>Child Health Directorate Audit and Clinical Guidelines Meetings</td>
</tr>
</tbody>
</table>
| Acting on recommendations and Lead(s) | Andrew Collinson, Consultant Paediatrician  
Karen Watkins, Consultant Obstetrician |
| Change in practice and lessons to be shared | Required changes to practice will be identified and actioned within 3 month of first audit. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders. |

9. **Equality and Diversity**

9.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the ‘Equality, Diversity & Human Rights Policy’ or the Equality and Diversity website.
9.2. *Equality Impact Assessment*

The Initial Equality Impact Assessment Screening Form is at Appendix 5.
Appendix 1. Table 1 Risk factors for early-onset neonatal infection, including 'red flags'

<table>
<thead>
<tr>
<th>Risk factor</th>
<th>Red flag?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parenteral antibiotic treatment given to the woman for confirmed or suspected invasive bacterial infection (such as septicaemia) at any time during labour, or in the 24-hour periods before and after the birth [This does not refer to intrapartum antibiotic prophylaxis] – see note below</td>
<td>Yes</td>
</tr>
<tr>
<td>Suspected or confirmed infection in another baby in the case of a multiple pregnancy</td>
<td>Yes</td>
</tr>
<tr>
<td>Invasive group B streptococcal infection in a previous baby</td>
<td></td>
</tr>
<tr>
<td>Maternal group B streptococcal colonisation, bacteriuria or infection in the current pregnancy</td>
<td></td>
</tr>
<tr>
<td>Pre-labour rupture of membranes. (Defined in Term pregnancies as onset of labour more than 24 hours after rupture of membranes).</td>
<td></td>
</tr>
<tr>
<td>Preterm birth following spontaneous labour (before 37 weeks' gestation)</td>
<td></td>
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<tr>
<td>Suspected or confirmed rupture of membranes for more than 18 hours in a preterm birth</td>
<td></td>
</tr>
<tr>
<td>Intrapartum fever higher than 38°C, or confirmed or suspected chorioamnionitis</td>
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</tr>
</tbody>
</table>

*Note: Neonatal risk assessment and management when suspected maternal infection:

Mother's MEOWS score total 5, or MEOWS score 3 in one parameter AND Mother started on antibiotics

= Red Flag for neonatal sepsis. Inform neonatal team. Neonatal team to screen and treat baby even if baby asymptomatic

Mother started on antibiotics for pyrexia alone (below 39 degrees C) BUT MEOWS score total less than 5 and no individual score 3

= Risk factor for neonatal sepsis. Inform neonatal team. Neonatal team to assess baby - if other risk factor or clinical indicator identified, or maternal indicators escalate to red flag, screen baby and start antibiotics.

MEOWS score total 5, or MEOWS score 3 in one parameter BUT Alternative maternal pathology suspected, mother not started on antibiotics

= Not risk factor for neonatal sepsis. Inform neonatal team if maternal illness has other implications for health of baby.
### Appendix 2. Table 2 Clinical indicators of possible early-onset neonatal infection (observations and events in the baby), including 'red flags'

<table>
<thead>
<tr>
<th>Clinical indicator</th>
<th>Red flag?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory distress starting more than 4 hours after birth</td>
<td>Yes</td>
</tr>
<tr>
<td>Need for mechanical ventilation in a term baby</td>
<td>Yes</td>
</tr>
<tr>
<td>Signs of shock</td>
<td>Yes</td>
</tr>
<tr>
<td>Seizures</td>
<td>Yes</td>
</tr>
<tr>
<td>Altered behaviour or responsiveness</td>
<td></td>
</tr>
<tr>
<td>Altered muscle tone (for example, floppiness)</td>
<td></td>
</tr>
<tr>
<td>Feeding difficulties (for example, feed refusal)</td>
<td></td>
</tr>
<tr>
<td>Feed intolerance, including vomiting, excessive gastric aspirates and abdominal distension</td>
<td></td>
</tr>
<tr>
<td>Abnormal heart rate (bradycardia or tachycardia)</td>
<td></td>
</tr>
<tr>
<td>Signs of respiratory distress</td>
<td></td>
</tr>
<tr>
<td>Hypoxia (for example, central cyanosis or reduced oxygen saturation level)</td>
<td></td>
</tr>
<tr>
<td>Jaundice within 24 hours of birth</td>
<td></td>
</tr>
<tr>
<td>Apnoea</td>
<td></td>
</tr>
<tr>
<td>Signs of neonatal encephalopathy</td>
<td></td>
</tr>
<tr>
<td>Need for cardio–pulmonary resuscitation</td>
<td></td>
</tr>
<tr>
<td>Need for mechanical ventilation in a preterm baby</td>
<td></td>
</tr>
<tr>
<td>Persistent fetal circulation (persistent pulmonary hypertension)</td>
<td></td>
</tr>
<tr>
<td>Temperature abnormality (lower than 36°C or higher than 38°C) unexplained by environmental factors</td>
<td></td>
</tr>
<tr>
<td>Unexplained excessive bleeding, thrombocytopenia, or abnormal coagulation (International Normalised Ratio greater than 2.0)</td>
<td></td>
</tr>
<tr>
<td>Oliguria persisting beyond 24 hours after birth</td>
<td></td>
</tr>
<tr>
<td>Altered glucose homeostasis (hypoglycaemia or hyperglycaemia)</td>
<td></td>
</tr>
<tr>
<td>Metabolic acidosis (base deficit of 10 mmol/litre or greater)</td>
<td></td>
</tr>
<tr>
<td>Local signs of infection (for example, affecting the skin or eye)</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 3: Neonate Assessment Algorithm – determining the need for antibiotic therapy

*Reproduced from: NCC-WCH/NICE/RCOG/RCM Clinical Guideline. Antibiotics for early-onset neonatal infection: antibiotics for the prevention and treatment of early-onset neonatal infection. London: RCOG; 2012, with the permission of the Royal College of Obstetricians and Gynaecologists on behalf of the NCC-WCH.*
### Appendix 4. Governance Information

<table>
<thead>
<tr>
<th><strong>Document Title</strong></th>
<th>Clinical Guideline for the Prevention, Diagnosis and Treatment of Early-Onset Neonatal Bacterial Infection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Date Issued/Approved:</strong></td>
<td>30 September 2015</td>
</tr>
<tr>
<td><strong>Date Valid From:</strong></td>
<td>November 2015</td>
</tr>
<tr>
<td><strong>Date Valid To:</strong></td>
<td>November 2018</td>
</tr>
<tr>
<td><strong>Directorate / Department responsible (author/owner):</strong></td>
<td>Andrew Collinson, Consultant in Paediatrics and Neonatology</td>
</tr>
<tr>
<td><strong>Contact details:</strong></td>
<td>01872 255081</td>
</tr>
<tr>
<td><strong>Brief summary of contents</strong></td>
<td>This guideline is designed to ensure the implementation of consistent preventive antenatal and intrapartum strategies; the rapid treatment of babies with suspected EOI and the limitation of antibiotic exposure in babies who do not have an EOI.</td>
</tr>
<tr>
<td><strong>Suggested Keywords:</strong></td>
<td>Neonatal, infection, antibiotics, bacterial infection</td>
</tr>
<tr>
<td><strong>Target Audience</strong></td>
<td>RCHT</td>
</tr>
<tr>
<td><strong>Executive Director responsible for Policy:</strong></td>
<td>Medical Director</td>
</tr>
<tr>
<td><strong>Date revised:</strong></td>
<td>30 September 2015</td>
</tr>
<tr>
<td><strong>This document replaces (exact title of previous version):</strong></td>
<td>Prevention, Diagnosis and Treatment of Early-Onset Neonatal Bacterial Infection – Neonatal Clinical Guideline</td>
</tr>
<tr>
<td><strong>Approval route (names of committees)/consultation:</strong></td>
<td>Not Required</td>
</tr>
<tr>
<td><strong>Divisional Manager confirming approval processes</strong></td>
<td>Andrew Collinson, Consultant in Paediatrics and Neonatology</td>
</tr>
<tr>
<td><strong>Name and Post Title of additional signatories</strong></td>
<td>Not Required</td>
</tr>
<tr>
<td><strong>Signature of Executive Director giving approval</strong></td>
<td>{Original Copy Signed}</td>
</tr>
<tr>
<td><strong>Publication Location (refer to Policy on Policies – Approvals and Ratification):</strong></td>
<td>Internet &amp; Intranet</td>
</tr>
<tr>
<td><strong>Document Library Folder/Sub Folder</strong></td>
<td>Clinical / Neonatal</td>
</tr>
<tr>
<td><strong>Links to key external standards</strong></td>
<td>None</td>
</tr>
<tr>
<td><strong>Related Documents:</strong></td>
<td>• NICE Clinical Guideline 149: Antibiotics for early-onset neonatal infection.</td>
</tr>
<tr>
<td>Date</td>
<td>Version No</td>
</tr>
<tr>
<td>------------</td>
<td>------------</td>
</tr>
<tr>
<td>19 Mar 13</td>
<td>V1.0</td>
</tr>
<tr>
<td>21 Oct 13</td>
<td>V1.1</td>
</tr>
<tr>
<td>30 Sept 15</td>
<td>V1.2</td>
</tr>
</tbody>
</table>

**Training Need Identified?** No

**Version Control Table**

---

**All or part of this document can be released under the Freedom of Information Act 2000**

**This document is to be retained for 10 years from the date of expiry.**

**This document is only valid on the day of printing**

**Controlled Document**

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Appendix 5. Initial Equality Impact Assessment Screening Form

| Name of service, strategy, policy or project (hereafter referred to as policy) to be assessed: Prevention, Diagnosis and Treatment of Early-Onset Neonatal Bacterial Infection- Neonatal Clinical Guideline |
| Directorate and service area: Neonatal | Is this a new or existing Procedure? New |
| Name of individual completing assessment: Andrew Collinson and Karen Watkins | Telephone: 01872 255081 |
| 1. Policy Aim* | To provide guidance on antenatal and intrapartum clinical management to reduce risk of neonatal early-onset infection (EOI).  To provide guidance on the assessment and management of newborns at increased risk of EOI, and infants with suspected or proven EOI. |
| 2. Policy Objectives* | As above. |
| 3. Policy – intended Outcomes* | This guideline is designed to ensure the implementation of consistent preventive antenatal and intrapartum strategies; the rapid treatment of babies with suspected EOI and the limitation of antibiotic exposure in babies who do not have an EOI. |
| 4. How will you measure the outcome? | See section 3 of this guideline. |
| 5. Who is intended to benefit from the Policy? | Neonatal patients |
| 6a. Is consultation required with the workforce, equality groups, local interest groups etc. around this policy? | No. Consultant led neonatal guideline group approved. |
| b. If yes, have these groups been consulted? | N/A |
| c. Please list any groups who have been consulted about this procedure. | N/A |

7. The Impact
Please complete the following table.

<table>
<thead>
<tr>
<th>Equality Strands:</th>
<th>Yes</th>
<th>No</th>
<th>Rationale for Assessment / Existing Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex (male, female, trans-gender / gender reassignment)</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Prevention, Diagnosis and Treatment of Early-Onset Neonatal Bacterial Infection - Neonatal Clinical GuidelinePage 19 of 20
<table>
<thead>
<tr>
<th>Race / Ethnic communities/groups</th>
<th>✓</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disability - Learning disability, physical disability, sensory impairment and mental health problems</td>
<td>✓</td>
</tr>
<tr>
<td>Religion / other beliefs</td>
<td>✓</td>
</tr>
<tr>
<td>Marriage and civil partnership</td>
<td>✓</td>
</tr>
<tr>
<td>Pregnancy and maternity</td>
<td>✓</td>
</tr>
<tr>
<td>Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian</td>
<td>✓</td>
</tr>
</tbody>
</table>

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:
- You have ticked “Yes” in any column above and
- No consultation or evidence of there being consultation - this excludes any policies which have been identified as not requiring consultation. or
- Major service redesign or development

8. Please indicate if a full equality analysis is recommended. | Yes | No |
--- | --- |

9. If you are not recommending a Full Impact assessment please explain why.

Signature of policy developer / lead manager / director  
Paul Munyard  
Date of completion and submission. 09:11:2015

Names and signatures of members carrying out the Screening Assessment
1.  
2.  

Keep one copy and send a copy to the Human Rights, Equality and Inclusion Lead, c/o Royal Cornwall Hospitals NHS Trust, Human Resources Department, Knowledge Spa, Truro, Cornwall, TR1 3HD

A summary of the results will be published on the Trust’s web site.

Signed _______Kim Smith_________

Date ________09:11:2015_________