Prevention, Diagnosis and Treatment of Early-Onset Neonatal Bacterial Infection
Clinical Guideline
V2.0

February 2019
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1. **Aim/Purpose of this Guideline**
   1.1. To provide guidance on antenatal and intrapartum clinical management to reduce risk of neonatal early-onset infection (EOI).
   
   1.2. To provide guidance on the assessment and management of newborns at increased risk of EOI, and infants with suspected or proven EOI.
   
   1.3. **Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation**

   The Trust has a duty under the DPA18 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed and documented. We can’t rely on Opt out, it must be Opt in.

   The DPA18 covers how the Trust obtains, hold, record, use and store all personal and special category (e.g. Health) information in a secure and confidential manner. This Act covers all data and information whether held electronically or on paper and extends to databases, videos and other automated media about living individuals including but not limited to Human Resources and payroll records, medical records, other manual files, microfilm/fiche, pathology results, images and other sensitive data.

   DPA18 is applicable to all staff; this includes those working as contractors and providers of services.

   For more information about your obligations under the DPA18 please see the ‘information use framework policy’, or contact the Information Governance Team rch-tr.infogov@nhs.net

2. **The Guidance**

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

2.2. **Background**

   **Abbreviations**

   IAP   Intra-partum antibiotic prophylaxis
   EOI   Early-onset bacterial infection
   GBS   Group-B Streptococcus
   EOGBS Early-onset Group-B Streptococcus infection
   PROM  Pre-labour rupture of membranes
2.2.1. 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.

2.2.2. 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.

2.2.3. 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. Reducing the risk of neonatal infection has to be balanced against the increased medicalisation of childbirth, the adverse risk of antibiotics (fatal anaphylaxis to mothers given IV penicillin is estimated to be 1:100,000) and neonatal infection with resistant organisms.

2.2.4. This local guideline follows the NICE Clinical Guideline 149, “Antibiotics for early-onset neonatal infection”, related NICE Clinical Guidelines (see reference list) and the Third Edition RCOG Green Top Guideline 36, “Prevention of Early-onset Neonatal Group B Streptococcal Disease” (published Sept 2017). The guidance aims to promote:

- 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.

2.3. Patient-centered care

2.3.1. 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.

2.3.2. 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.

2.3.3. 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.

2.3.4. If the mother had GBS colonisation in a previous pregnancy but without infection in the baby, she should be informed that there is a 50% chance of GBS carriage in this pregnancy. She should be offered IAP, or a swab 3-5 weeks before anticipated delivery date (ie at 35-37 weeks for singletons and 32-34 weeks for multiple pregnancy) with the offer of IAP if still positive (New, 2018).

2.3.5. 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.

2.3.6. 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.

2.3.7. 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.
2.4. Strategies during pregnancy to prevent neonatal EOI

2.4.1. **Samples for bacterial culture during pregnancy**

2.4.1.1. 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.

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

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

2.4.2. **Antenatal antibiotic therapy (before onset of labour)**

2.4.2.1. **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.

2.4.2.2. **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.

2.4.2.3. **Preterm pre-labour rupture of membranes:**

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

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

2.4.3.1. The following women should be clearly identified as eligible for IAP:

- 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.
- Women in preterm labour (New, 2018).
- Women with GBS colonization in a previous pregnancy should be informed that there is a 50% chance of GBS carriage in this pregnancy. She should be offered IAP, or a swab in late pregnancy (35-37 weeks for singletons and 32-34 weeks for multiple pregnancy) to determine whether to offer IAP (New, 2018).

2.4.3.2. If swabs are not transported immediately to the laboratory, they should be refrigerated. The request form should state that the swab is being taken for GBS Women delivering by elective caesarean section in the absence of labour and with intact membranes, regardless of GBS colonisation status in the current pregnancy.

2.4.3.3. All women identified antenatally with an indication 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.

2.4.4. **Avoidance of Listeria monocytogenes infection in pregnancy**

2.4.4.1. 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.

2.5. **Intrapartum care to prevent neonatal EOI**

2.5.1. **Pre-labour rupture of membranes (PROM) at term**

2.5.1.1. IAP should be offered immediately in women who meet the above criteria for IAP.

2.5.1.2. For women who present with PROM at term who do not have an indication for IAP, expectant management should not extend beyond 24 hours (New, 2018). All 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.
2.5.2. **Preterm Prelabour ROM**

2.5.2.1. IAP should be given once labour is confirmed or induced irrespective of GBS status *(New, 2018)*.

2.5.2.2. Expectant management is appropriate before 34 weeks’ gestation. After 34+0 weeks’ gestation ’it may be beneficial to expedite delivery’ if a woman is a known GBS carrier *(New, 2018)*. Evidence is grade D based upon secondary analysis of a single study and needs to be balanced against the risks of prematurity. In the absence of any clinical concerns regarding infection or other maternal or fetal wellbeing, IOL should only be discussed in detail and offered by a Consultant obstetrician. This consultation does not need to take place as an emergency.

2.5.3. **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.

2.5.4. **Management of maternal GBS colonization in women who decline IAP**

Women with known GBS colonization who decline IAP should be advised that the baby should be very closely monitored for 12 hours after birth, and discouraged from seeking very early discharge from the maternity unit *(New, 2018)*.

2.5.5. **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.

2.5.5.1. **Recommended regime for IAP against GBS:**

Benzyl penicillin 3g IV then 1.5g at 4 hourly intervals until delivery. *(See obstetric and midwifery GBS guideline for guidance in cases of penicillin allergy).*
2.5.5.2. **Definition of “adequate” IAP against GBS:**

There is evidence that benzylpenicillin levels in cord blood exceed the minimum inhibitory concentration for GBS as early as 1 hour after maternal administration, but is it not known how this relates to neonatal colonisation or disease. Giving penicillin 2 hours before delivery may reduce neonatal colonisation, but penicillin 4 hours before delivery may be more effective than 2 hours at reducing the risk of EOGBS disease. *(New, 2018).*

Term babies who are clinically well at birth and whose mothers have received IAP more than 4 hours before delivery do not require special observations *(New, 2018).*

2.5.5.3. **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
- Women in preterm labour *(New, 2018).*
- Women with GBS colonization in a previous pregnancy should be informed that there is a 50% chance of GBS carriage in this pregnancy. She should be offered IAP, or a swab in late pregnancy (35-37 weeks for singletons and 32-34 weeks for multiple pregnancy) to determine whether to offer IAP *(New, 2018).*

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

When antibiotics are administered during labour this should be signed for on the prescription chart and documented in the woman’s intrapartum records.

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

Women delivering by elective caesarean section in the absence of labour and with intact membranes, regardless of GBS colonisation status in the current pregnancy. Maternal request in the absence of a past history and/or microbiological evidence of GBS.
2.6. Management of the Neonate

2.6.1. Identifying infants with possible EOI

2.6.1.1. 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.

2.6.1.2. 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.

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

(See summary algorithm Appendix 3)

2.6.2.1. Infant with any red flag:

- Investigate (Section 2.8) and Treat (Section 2.9)

2.6.2.2. No red flags, but two or more non-red flag risk factors or clinical indicators:

- Investigate (Section 2.8) and Treat (Section 2.9)

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

- Consider withholding antibiotics
- Observe and Monitor (section 2.7)
- If one or more further clinical indicator develops: Investigate (Section 2.8) and Treat (Section 2.9)
- If no further concerns arise during observation and monitoring period, reassure parents and give advice to parents and carers.

2.6.2.4. No risk factors or clinical indicators:

- Continue routine postnatal care.

2.6.2.5. NB:

- Term babies born to mothers colonized with GBS who are clinically well at birth and whose mothers received IAP more than 4 hours before delivery do not require
special observations (assuming there are no other risk factors). Given that adequate IAP reduces the risk of EOGBS to a level approaching that of the general population, the RCOG Green Top guideline advises that it is reasonable to manage these babies as low risk (New, 2018).

- 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.

2.7. **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.

2.8. **Neonatal investigations for suspected EOI**

2.8.1. 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.

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

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

2.8.4. 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.

2.8.5. 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

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

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

2.9.1. Babies commenced on antibiotic treatment should receive the first dose as soon as possible and always within 1 hour of the decision to treat.
2.9.2. 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.

2.9.3. 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.

2.9.4. 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.

2.10. **Gentamicin prescribing and monitoring**

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

2.10.2. 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.

2.10.3. 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.

2.10.4. 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.

2.11. **Care of babies receiving antibiotics for suspected EOI.**

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:

2.11.1. **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.

2.11.2. **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.

2.11.3. **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.

2.11.4. **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
diagnosis and treatment plan are appropriate and that parents are adequately informed.

2.11.5. **Decisions 36 hours after starting treatment in babies with negative cultures**

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.

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

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.

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

2.12.1. **Neonatal early-onset bacteraemia:**

2.12.1.1. 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.

2.12.1.2. GBS or Listeria grown on blood culture:

- Continue Benzylpenicillin and Gentamicin.

2.12.1.3. Gram-positive species other than GBS or Listeria grown on blood culture:

- Seek expert Clinical Microbiological advice.
2.12.2. **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).

2.12.3. **Neonatal early-onset meningitis:**

2.12.3.1. Empirical treatment pending CSF culture:

- IV Amoxicillin and Cefotaxime

2.12.3.2. 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.

2.12.3.3. Gram-positive species identified on CSF Gram-stain:

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

2.12.3.4. 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.

2.12.3.5. 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.
2.12.3.6. Gram-positive species other than GBS or Listeria isolated from CSF culture:

- Seek senior Clinical Microbiological advice.

2.12.3.7. 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.

2.13. **Localised infections of the eye**

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.

2.14. **Localised infections of the umbilical cord**

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. If culture shows a Gram-positive organism, the gentamicin should be stopped.

2.15. **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 2.3.5 and a point of contact for advice.
3. Monitoring compliance and effectiveness

<table>
<thead>
<tr>
<th>Element to be monitored</th>
<th>Key changes in practice recommended by guidance.</th>
</tr>
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<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>
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<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>
<tr>
<td>Acting on recommendations and Lead(s)</td>
<td>Andrew Collinson, Consultant Paediatrician Karen Watkins, Consultant Obstetrician</td>
</tr>
<tr>
<td>Change in practice and lessons to be shared</td>
<td>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.</td>
</tr>
</tbody>
</table>

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Inclusion & Human Rights Policy' or the Equality and Diversity website.

4.2. Equality Impact Assessment
The Initial Equality Impact Assessment Screening Form is at Appendix 2.
## Appendix 1. Governance Information

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Prevention, Diagnosis and Treatment of Early-Onset Neonatal Bacterial Infection Clinical Guideline V2.0</th>
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</thead>
<tbody>
<tr>
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<tr>
<td>Directorate / Department responsible (author/owner):</td>
<td>Neonatology (Dr Andrew Collinson)</td>
</tr>
<tr>
<td>Contact details:</td>
<td>01872 252681</td>
</tr>
<tr>
<td>Brief summary of contents</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>
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<tr>
<td>Suggested Keywords:</td>
<td>Neonatal, infection, antibiotics, bacterial infection</td>
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<tr>
<td><strong>Target Audience</strong></td>
<td>RCHT</td>
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<tr>
<td>Executive Director responsible for Policy:</td>
<td>Medical Director</td>
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<td>Date revised:</td>
<td>Version 2: 19 December 2018</td>
</tr>
<tr>
<td>This document replaces (exact title of previous version):</td>
<td>FOR THE PREVENTION, DIAGNOSIS AND TREATMENT OF EARLY-ONSET NEONATAL BACTERIAL INFECTION – NEONATAL CLINICAL GUIDELINE V1.2</td>
</tr>
<tr>
<td>Approval route (names of committees)/consultation:</td>
<td>Neonatal Guidelines Group</td>
</tr>
<tr>
<td>Divisional Manager confirming approval processes</td>
<td>Debra Shields, care Group general Manager</td>
</tr>
<tr>
<td>Name and Post Title of additional signatories</td>
<td>Not Required</td>
</tr>
<tr>
<td>Name and Signature of Divisional/Directorate Governance Lead confirming approval by specialty and divisional management meetings</td>
<td>{Original Copy Signed} Name: Caroline Amukusana, Divisional Governance Lead, WC+SH</td>
</tr>
<tr>
<td>Signature of Executive Director giving approval</td>
<td>{Original Copy Signed}</td>
</tr>
</tbody>
</table>
Related Documents:

- RCOG Green Top Guideline no. 44: Preterm prelabour rupture of membranes.
- NICE Clinical Guideline 70: Induction of labour
- NICE Clinical Guideline 102: Bacterial meningitis and meningococcal septicaemia

Training Need Identified? No

Version Control Table

<table>
<thead>
<tr>
<th>Date</th>
<th>Version No</th>
<th>Summary of Changes</th>
<th>Changes Made by (Name and Job Title)</th>
</tr>
</thead>
<tbody>
<tr>
<td>19 Mar 13</td>
<td>V1.0</td>
<td>Initial Issue</td>
<td>Andrew Collinson, Consultant in Paediatrics and Neonatology</td>
</tr>
<tr>
<td>21 Oct 13</td>
<td>V1.1</td>
<td>Para ‘7.7. Care of babies receiving antibiotics for suspected EOI’ amended</td>
<td>Andrew Collinson, Consultant in Paediatrics and Neonatology</td>
</tr>
<tr>
<td>30 Sept 15</td>
<td>V1.2</td>
<td>Addition of explanatory paragraph to support table in Appendix 1. Approved at neonatal Guidelines Meeting.</td>
<td>Andrew Collinson, Consultant in Paediatrics and Neonatology</td>
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<tr>
<td>Date</td>
<td>Version</td>
<td>Description</td>
<td>Author</td>
</tr>
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<td>---------</td>
<td>-------------------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>19 Dec 18</td>
<td>V 2.0</td>
<td>Addition of revised guidance, per RCOG Green Top Guideline 3rd edition.</td>
<td>Andrew Collinson, Consultant in Paediatrics and Neonatology</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Revision of explanatory notes Appendix 1.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Very Minor name change</td>
<td></td>
</tr>
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This document is to be retained for 10 years from the date of expiry.
This document is only valid on the day of printing

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## Appendix 2. Initial Equality Impact Assessment Form

*This assessment will need to be completed in stages to allow for adequate consultation with the relevant groups.*

### Prevention, Diagnosis and Treatment of Early-Onset Neonatal Bacterial Infection Clinical Guideline V2.0

<table>
<thead>
<tr>
<th>Name of the strategy / policy / proposal / service function to be assessed</th>
<th>Directorate and service area: Neonatal</th>
<th>Is this a new or existing Policy: Existing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention, Diagnosis and Treatment of Early-Onset Neonatal Bacterial Infection Clinical Guideline V2.0</td>
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<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name of individual completing assessment: Andrew Collinson and Karen Watkins</th>
<th>Telephone: 01872 252681</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention, Diagnosis and Treatment of Early-Onset Neonatal Bacterial Infection Clinical Guideline V2.0</td>
<td></td>
</tr>
</tbody>
</table>

### 1. Policy Aim*

**Who is the strategy / policy / proposal / service function aimed at?**

- 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 Who did you consult with

<table>
<thead>
<tr>
<th>Workforce</th>
<th>Patients</th>
<th>Local groups</th>
<th>External organisations</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>x</td>
</tr>
</tbody>
</table>

### b). Please identify the groups who have been consulted about this procedure.

Consultant led neonatal guideline group

### What was the outcome of the consultation?

Guideline approved 13/02/2019
7. The Impact
Please complete the following table. **If you are unsure/don’t know if there is a negative impact you need to repeat the consultation step.**

<table>
<thead>
<tr>
<th>Equality Strands:</th>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
<th>Rationale for Assessment / Existing Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex (male, female, trans-gender / gender reassignment)</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Race / Ethnic communities /groups</td>
<td>✓</td>
<td></td>
<td></td>
<td>Information provided should be in an accessible format for the parent/carer’s needs – i.e available in different languages if required/access to an interpreter if required</td>
</tr>
<tr>
<td>Disability - Learning disability, physical impairment, sensory impairment, mental health conditions and some long term health conditions.</td>
<td>✓</td>
<td></td>
<td></td>
<td>Those parent/carer’s with any identified additional needs will be referred for additional support as appropriate - i.e to the Liaison team or for specialised equipment. Written information will be provided in a format to meet the family’s needs e.g. easy read, audio etc</td>
</tr>
<tr>
<td>Religion / other beliefs</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marriage and Civil partnership</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnancy and maternity</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian</td>
<td>✓</td>
<td></td>
<td></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 this relates to 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.

No areas indicated
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

This EIA will not be uploaded to the Trust website without the signature of the Human
Rights, Equality & Inclusion Lead.

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

Signed ___ Andrew Collinson___________
Date ____06/02/2019___________
### Appendix 3

**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]</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 - <a href="#">See note 1 below</a></td>
<td></td>
</tr>
<tr>
<td>Pre-labour rupture of membranes. - <a href="#">See note 2 below</a></td>
<td></td>
</tr>
<tr>
<td>Preterm birth following spontaneous labour (before 37 weeks’ gestation)</td>
<td></td>
</tr>
<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>
<td></td>
</tr>
</tbody>
</table>

**Note 1:**  
Term babies born to mothers colonized with GBS who are clinically well at birth and whose mothers received IAP more than 4 hours before delivery do not require special observations (assuming there are no other risk factors). Given that adequate IAP reduces the risk of EOGBS to a level approaching that of the general population, the RCOG Green Top guideline advises that it is reasonable to manage these babies as low risk *(New, 2018)*.

**Note 2:**  
Prelabour ROM at Term is not further defined in the NICE Guideline 149 or Third Edition RCOG Green Top guideline 36. The RCOG Green Top guideline recommends that:

- in women who are known GBS carriers, IAP and induction of labour should be offered immediately;
- in women whose GBS carrier status is negative or unknown, induction of labour can be offered immediately or deferred with expectant management up to 24 hours.

Therefore we suggest defining Term Prelabour ROM as a risk factor if there has been ROM of any duration before onset of labour in a woman who is known to meet criteria for IAP, or more than 24 hours before onset of labour in a woman who does not meet criteria for IAP.
## Appendix 4

### 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 5

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."