

Clinical Guideline:

Authors: Adapted from the all Wales Neonatal Network Early Onset Sepsis Risk assessment for Infants > 34 weeks gestation Guideline

For use in: EoE Neonatal Units
Guidance specific to the care of neonatal patients.

Used by:

Key Words: Sepsis, Kaiser sepsis calculator

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Approved by:

Neonatal Clinical Oversight Group	
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Audit Standards:

- Total number of babies assessed using the calculator
- Number of babies correctly identified by the calculator who develop a culture-confirmed neonatal infection
- Number of babies incorrectly identified by the calculator who do not develop a culture-confirmed neonatal infection
- Number of babies missed by the calculator who develop a culture-confirmed neonatal infection

East of England (EOE) Guideline** Early Onset Sepsis Risk Assessment for Infants ≥ 34 Weeks Gestation

Adapted from all Wales Early Onset Sepsis Guideline

(* Midwifery led units may choose to risk assess and continue to follow existing guidelines. Families should be informed of this so that they can make an informed choice of the place for delivery)

Purpose:

To provide guidance on risk assessment and management of early onset sepsis (EOS) in neonates of greater than or equal to 34 weeks gestation, including the use of the Kaiser Permanente Sepsis Risk Calculator (SRC).

Background:

Culture proven EOS in the UK in term and near-term infants is infrequent (about 0.5/1000 live births) but is associated with high morbidity & mortality. Group B streptococcus (GBS) is the commonest organism identified in EOS followed by Gram-negative infections. Nearly 15-20% infants on the postnatal wards are screened by category risk-based algorithms (e.g. NICE and RCOG guidelines) and offered prophylactic antibiotics, until investigations clear the infant of infection. These risk-based strategies can identify only 50-60% of all EOS cases. In addition, a significant proportion of EOS cases are symptomatic at birth and do not require any algorithm for identification. Thus, the number of infants needing treatment to identify a case of culture proven sepsis in the early asymptomatic phase is estimated as 1 in 600-800 near term live births.

Developed in the USA, The Kaiser Permanente Sepsis Risk Calculator (SRC) is a multivariate model of assessing the risk of EOS using maternal risk factors and the infant's clinical state after birth (<https://neonatalesepsiscalculator.kaiserpermanente.org>). The use of SRC in the USA has been shown to reduce antibiotic initiation in newborn infants by 50% without missing additional cases of true sepsis and this finding has been replicated in other parts of the developed world with consistent results. For more information, please review references at the end of this document.

No sepsis algorithm can function without excellent clinical care and professional judgment. The following generic principles apply in all situations and supersede any sepsis algorithm-

Kaiser Permanente sepsis calculator should be applied up to 1 hour of age.

Infants who present after this period or where further information regarding risk of sepsis is identified should receive a **FULL** clinical examination, review and plan of care.

1. All infants symptomatic of sepsis must be investigated and treated promptly with antibiotics within 1 hour of the decision to treat. This is irrespective of their sepsis risk score. See appendix 1 for common signs of clinical sepsis. If you are unsure, seek senior help.
2. Investigations for sepsis should include a blood culture (a minimum of 1ml of blood must be inoculated into the blood culture bottle), FBC and a CRP. The latter should be repeated in 18-24 hours.
3. Where there is a history of confirmed Group B Streptococcal sepsis or death of a neonate in previous pregnancy, **and** the mother has not received adequate intrapartum prophylaxis in this pregnancy, the newborn infant should be screened and presumptively treated irrespective of the sepsis risk score.

Guidance: The following parameters should be collected as routine during labour or at elective caesarean section by attending midwives in all infants:

- Gestational age – Weeks + days
- Highest maternal intrapartum temperature in °C (i.e., from onset of established labour to first hour after delivery)
- Duration of rupture of membranes in hours – membrane rupture to time of birth
- GBS status – positive / negative / unknown
- Type of intrapartum antibiotics and time of first dose

The midwife should contact the neonatal team if according to NICE infants ≥ 34 weeks gestation have 1 red flag or 2 amber (non-red flags).

Risk Factors	
Suspected or confirmed infection in another baby in the case of a multiple pregnancy	Red
Invasive group B streptococcal infection in a previous baby or maternal GBS colonisation, bacteriuria or infection in the current pregnancy	Amber
Pre-labour rupture of membranes at term for more than 24 hours before onset of labour	Amber
Preterm birth following spontaneous labour (before 37 weeks' gestation)	Amber
Confirmed rupture of membranes more than 18 hours before a pre-term birth	Amber
Intrapartum fever higher than 38°C if there is suspected or confirmed bacterial infection	Amber
Clinical diagnosis of chorioamnionitis	Amber

Clinical Signs	
Apnoea	Red
Seizures	Red
Need for CPR	Red
Need for mechanical ventilation	Red
Signs of shock	Red
Altered behaviour or responsiveness	Amber
Altered muscle tone (e.g. floppiness)	Amber
Feeding difficulties (e.g. feed refusal)	Amber
Feeding intolerance (e.g. vomiting, abdominal distension)	Amber
Abnormal heart rate (bradycardia or tachycardia)	Amber
Signs of respiratory distress (including grunting, recession, tachypnoea)	Amber
Hypoxia (for example central cyanosis or reduced oxygen saturation levels)	Amber
Persistent pulmonary hypertension of newborn	Amber
Jaundice within 24 hours of birth	Amber
Signs of neonatal encephalopathy	Amber
Temperature abnormality (lower than 36°C or higher than 38°C)	Amber
Unexplained or excessive bleeding, thrombocytopenia or abnormal coagulation	Amber
Altered glucose homeostasis (hypoglycaemia / hyperglycaemia)	Amber
Metabolic acidosis (base deficit of 10mmol/litre or greater)	Amber

Kaiser Permanente sepsis calculator should be applied up to 1 hour of age.

Infants who present after this period or where further information regarding risk of sepsis is identified should receive a FULL clinical examination, review and plan of care

Neonatal team should thoroughly examine the baby and follow the steps as below:

Step 1: Apply the NICE criteria (see above)

a) If one red flag or two amber (non-red) flags maternal or infant – proceed to Steps 2 and 3

b) No red flags and only one amber (non-red) flag – In line with current local guidance

■ This excludes where there is history of a previous GBS sepsis or death related to sepsis of an infant AND the mother has not received adequate Intrapartum prophylaxis. The infant should be screened and treated

Step 2: Assign the infant to one of the following three 'CLINICAL STATUS' using the guide in this table. If infant falls into the category of clinical illness move straight to sepsis screen and commencing antibiotics:

Clinical Exam	Description
Well appearing	No persistent physiologic abnormalities
Equivocal	<p>Any one persistent physiologic abnormality lasting ≥ 4 hrs after birth</p> <ul style="list-style-type: none"> • Tachycardia (HR ≥ 160) • Tachypnoea (RR ≥ 60) • Temperature instability (<36.4°C OR ≥ 38° C) • Respiratory distress (grunting, nasal flaring or chest recessions) not requiring supplemental oxygen
Equivocal	<p>Two or more physiologic abnormalities lasting ≥2 hours after birth</p> <ul style="list-style-type: none"> • Tachycardia (HR ≥ 160) • Tachypnoea (RR ≥ 60) • Temperature instability (<36.4°C OR ≥ 38°C) • Respiratory distress (grunting, nasal flaring or chest recessions) not requiring supplemental oxygen
Clinical Illness	<p>Abnormalities can be intermittent</p> <ul style="list-style-type: none"> • Equivocal state persisting beyond 6 hours after birth should be classed as 'clinical illness'. • Late onset symptoms, presenting after any asymptomatic period should trigger a clinical review as this may indicate 'clinical illness'
Clinical Illness	<ul style="list-style-type: none"> • Need for mechanical ventilation (outside delivery room) • Haemodynamic instability requiring fluid bolus or inotropes • Persistent need for CPAP/HFNC • Need for supplemental oxygen ≥ 1 hours to maintain oxygen saturation >90% • Neonatal encephalopathy / Perinatal depression <ul style="list-style-type: none"> * Neonatal seizure * Apgar score < 5 @ 5 minutes • Any other symptoms of serious illness – clinician determined

Step 3: Calculate Sepsis Risk Score to determine individual infant's risk for EOS.

The Sepsis Risk Score can be accessed at the following websites

- <https://kp.org/eoscalc>
- This is a shortcut for: <https://neonatalesepsiscalculator.kaiserpermanente.org>
- Guidance on how to enter the risk factors used to determine the Sepsis Risk Score can be found in Appendix 2 and training slides.
- In the unlikely scenario that the SRC tool is not available, follow NICE guidance

Incidence of Early-Onset Sepsis	1.0/1000 live births Use 1.0 to calculate Sepsis Risk Score
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Step 4:

Use the sepsis risk score **after clinical examination THEN** follow the EOE “**Modified Observations**” management plan as shown in the table below :

Clinical examination	Clinical recommendation as per SRC	Modified Observations management plan as per EOE
Well appearing	No culture, no antibiotics, routine vitals	Routine observations at 1 hour, 2 hours and then 2 hourly until 12 hours of age. Thereafter continue observations every 4 hours until the end of the observation period (24-36 hours) Observe for a minimum of 24 hours on postnatal ward; Follow observation guidance using NATT/NEWTTS chart
	No culture, no Antibiotics, vitals every 4 hours	Observe for minimum of 36 hours on postnatal ward; Follow observation guidance using NATT/NEWTTS chart Routine observations at 1 hour, 2 hours and then 2 hourly until 12 hours of age. Thereafter continue observations every 4 hours until the end of the observation period (24-36 hours)
	Blood culture	Sepsis screen and treat empirically Routine observations at 1 hour, 2 hours and then 2 hourly until 12 hours of age. Thereafter continue observations every 4 hours until the end of the observation period (24-36 hours)

	Empiric antibiotics	<p>Sepsis screen and treat empirically</p> <p>Routine observations at 1 hour, 2 hours and then 2 hourly until 12 hours of age. Thereafter continue observations every 4 hours until the end of the observation period (24-36 hours)</p>
Equivocal	No culture, no antibiotics, vitals every 4 hours	<p>Hourly observations until all observations within normal range x 2. Thereafter follow guidance for well appearing child.</p> <p>Once symptoms have resolved, observe for minimum of 36 hours on postnatal ward; Follow observation guidance using NATT/NEWTTS chart</p>
	Blood culture	<p>Sepsis screen and treat empirically</p> <p>Hourly observation until within normal range X2 then follow guidance for well appearing child</p> <p>Once symptoms have resolved, observe for minimum of 36 hours on postnatal ward; Follow observation guidance using NATT/NEWTTS chart</p>
	Empiric antibiotics	<p>Sepsis screen and treat empirically</p> <p>Hourly observation until within normal range X2 then follow guidance for well appearing child</p> <p>Once symptoms have resolved, observe for minimum of 36 hours on postnatal ward; Follow observation guidance using NATT/NEWTTS chart</p>
Clinical illness	Empiric antibiotics	<p>Sepsis screen and treat empirically</p> <p>Admit to NICU and observe as per clinical direction</p>

If at any point during observations, there is clinical worsening then perform sepsis screen and treat with antibiotics and further management as per your current practice

The tool may be reapplied if new information regarding maternal risk factors become available i.e. GBS status or maternal fever within 1 hour post delivery.

Change in clinical condition of the baby should be acted on based on clinical assessment.

Risk per 1000/births			
EOS Risk @ Birth	0.48		
EOS Risk after Clinical Exam	Risk per 1000/births	Clinical Recommendation	Vitals
Well Appearing	0.20	No culture, no antibiotics	Routine Vitals
Equivocal	2.38	Blood culture	Vitals every 4 hours for 24 hours
Clinical illness	10.02	Empiric antibiotics	Vitals per NICU

Classification of Infant's Clinical Presentation: Clinical illness, Equivocal, Well Appearing

Observations:

Clinical Status	Well Appearing	Equivocal	Clinical illness
Observation Schedule	Routine observations at 1 hour, 2 hours and then 2 hourly until 12 hours of age. Thereafter continue observations every 4 hours until the end of the observation period (24-36 hours)	Hourly until all observations within normal range x 2. Thereafter follow guidance for well appearing child.	Admit to NICU and observation as directed by clinician.

Use guidance for NATT/NEWTTS chart.

Discharge: All infants on observation pathway should be re-examined by the neonatal team before discharge to confirm well-being. Parents should be given the '**Screening for infection in newborn babies information for parents**' leaflet.

Appendix 1:

Calculator Input	Value to be entered	Notes
Incidence of Early-Onset Sepsis	1.0/1000 live births Use 1.0 to calculate Sepsis risk score	Based on consensus decision and variable range differences from 0.5 -1.2/1000
Gestational Age (GA)	GA at birth, in weeks and days	"Weeks" value range 34-43 "Days" value range 0-6
Highest Maternal Intrapartum Temperature (°C)	Enter the value and remember to choose "Celsius" for the temperature unit. Note: Highest intrapartum maternal temperature including up to 1 hour following delivery	Value may be whole number or number with single decimal place Examples: 37, 37.1, 37.0 are all acceptable entry values Note: Midwives to document and flag up to the neonatal team, if postpartum temperature taken within 1 hour of birth is at least 0.5°C higher than intrapartum temperature so that the correct figure is used in calculation.
ROM (hours)	Duration of time between rupture of membrane and birth, in hours *Please enter for SRC the actual duration of rupture of membranes till birth and not just pre-labour duration	Value may be whole number rounded up to the nearest 0.1 hours (single decimal place) Example: ROM time 4 hours and 30 minutes should be entered as 4.5 hours. Example: ROM time 4 hours and 55 minutes can be entered as 5.0 hours
GBS	Enter maternal GBS screening result if available. If not known enter 'unknown'	
Type of Intrapartum Antibiotics and interval from first dose to birth	GBS-specific antibiotics are defined ONLY as Benzylpenicillin This should apply only to mothers who are GBS positive or GBS unknown. If erythromycin, clindamycin or vancomycin ALONE are given for GBS prophylaxis, choose the option "No antibiotics or any antibiotics given < 2 hours prior to delivery." Broad-spectrum antibiotics (BSAB) are defined as <u>two or more antibiotics given in combination</u> when there is concern for the mother developing chorioamnionitis. Timing of administration of GBS-specific antibiotics or BSAB administration = interval between the first dose of Benzyl penicillin or the second antibiotic in the combination to the time of birth. Example: Cefuroxime is given at 2:00 PM; Metronidazole is given at 3:30 PM. Birth is at 4:30 PM. Because the second antibiotic of the combination was given 1 hour prior to delivery, choose option "No antibiotics or any antibiotics given < 2 hours prior to delivery." If a mother has been given BOTH GBS-specific antibiotics and BSAB – of the 4 possible options, select the category with the longest duration of treatment. Example: Mother is given Benzyl Penicillin at 8:00 AM and 12:00 PM for GBS +ve. She develops a fever to 38.3° C at 2:00 PM, and Cefuroxime is given at 3:00 PM. Penicillin G is given at 4:00 PM. Birth is at 4:30 PM. In this case, GBS-specific antibiotics were given > 4 hours prior to delivery, but BSAB were given only 1 ½ hours prior to delivery. For calculating the SRS, in this case choose "GBS specific antibiotics given > 2 hours prior to birth."	

Appendix 3:

Possible systemic signs and symptoms of sepsis:

System	Signs and Symptoms
Respiratory	Grunting, flaring, retracting, cyanosis, oxygen requirement, apnoea, tachypnoea
Neurological	Hypotonia, hypertonia, lethargy, irritability, bulging/full/tense fontanel, seizures (associated with meningitis)
Cardiovascular	Bradycardia, tachycardia, hypotension, hypertension, decreased perfusion
Gastrointestinal	Feeding intolerance, abdominal distention, visible loops of bowel, gastric aspirates, emesis, diarrhoea, bloody stools
Other	Temperature instability, unexplained blood glucose instability, metabolic acidosis, rash, petechiae, purpura, unexplained jaundice

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Exceptional Circumstances Form

Form to be completed in the **exceptional** circumstances that the Trust is not able to follow ODN approved guidelines.

Details of person completing the form:	
Title:	Organisation:
First name:	Email contact address:
Surname:	Telephone contact number:
Title of document to be excepted from:	
Rationale why Trust is unable to adhere to the document:	
Signature of speciality Clinical Lead:	Signature of Trust Nursing / Medical Director:
Date:	Date:
Hard Copy Received by ODN (date and sign):	Date acknowledgement receipt sent out:

Please email form to: kelly.hart5@nhs.net requesting receipt.

Send hard signed copy to:

Kelly Hart
EOE ODN Executive Administrator
Box 93
Cambridge University Hospital
Hills Road
Cambridge CB2 0QQ

In addition to blood tests, some babies will require a lumbar puncture test. The lumbar puncture is to look for meningitis (infection affecting the tissues around the brain) and involves collecting fluid from around the spine by inserting a small needle into the space between the vertebrae (spinal bones). This will need to be done if your baby is unwell with signs and symptoms of meningitis or has signs of infection on their blood tests.

If tests show evidence of bacterial infection in your baby, they will need to stay in hospital for intravenous antibiotics for a longer time; usually 7 days but sometimes up to 3 weeks if meningitis is diagnosed

After discharge:

Once your baby has been treated for suspected or confirmed infection they would be expected to make a full recovery, although ongoing follow-up may be needed – particularly if they have had meningitis. All babies who have had a confirmed infection will have an outpatient follow-up appointment.

No special measures are required once you are home but you should seek medical help by contacting your midwife, health visitor or GP if your baby shows signs of:

- changes in behaviour (eg inconsolable crying/irritability)
- listlessness or being floppy
- poor feeding
- abnormal temperature (high or low)
- rapid breathing

- change in skin colour especially if they are very pale or mottled
- **Subsequent pregnancies:**
- If your baby has had a confirmed Group B Streptococcus infection, any babies you have in the future will also be at risk of early-onset neonatal bacterial infection and should be managed according to the guidance within this leaflet.
- **Further information:**
- If you have any questions about the information in this document or questions not covered here you should ask the midwifery or medical teams looking after you and your baby.
- This information is based on the National Institute for Health and Clinical Excellence (NICE) guidance which can be accessed at: <https://www.nice.org.uk/guidance/NG195>

And the Kaiser sepsis risk calculator:

<https://neonatalsepsiscalculator.kaiserpermanente.org/InfectionProbabilityCalculator.aspx>

Early-onset neonatal infection

Parent Information



Definition:

Early-onset neonatal infection refers to a bacterial infection within the first 72 hours after birth. Most infections are caused by bacteria normally found in the birth canal and Group B Streptococcus is the commonest cause of neonatal bacterial infection.

Sepsis is when the body's response to infection damages its own tissues and organs. The symptoms of infection or sepsis in newborn babies can be very varied and sometimes quite difficult to identify in the early stages of infection, however some newborn babies with infection or sepsis can become very unwell very suddenly. For these reasons we try to identify babies who are most at risk of developing infection or sepsis in order to prevent them becoming unwell.

Risk factors for early neonatal infection:

- if you had a previous baby that had Group B Streptococcus infection (GBS)
- if you have had a GBS infection in this pregnancy
- if your baby is born early (before 37 weeks)
- if your membranes ruptured ("waters have broken") more than 24 hours before labour
- if your membranes were ruptured for more than 18 hours before your baby was born **AND** they are born before 37
- if you had a high temperature (usually above 38°C) or felt unwell during labour, and there is suspected or confirmed bacterial infection
- if you have suspected infection of the placenta and amniotic fluid ("water" surrounding baby)

If you were known to have GBS in a previous pregnancy but your baby did NOT have an infection, then there is no increased risk in the current pregnancy.

Before delivery:

If your baby is at risk of early-onset infection, then you should receive antibiotics via a drip (not always) during labour to reduce this risk. If you are aware that any of the above risk factors apply to you, please let your midwife know when you attend for delivery.

After delivery:

If your baby has some risk factors for early-onset infection, they will require monitoring (for a **minimum of 24 to 36 hours**) in hospital and may need blood tests and antibiotics. If antibiotics are required, they are normally given via a cannula ("a drip") usually in the back of the hand or the foot.

There are certain factors that suggest a higher risk of infection when extra monitoring and antibiotics should always be given to your baby. These include:

- if a baby is a twin or triplet (or more) and the other baby is being treated for suspected or confirmed infection.
- if your baby needs to go to NICU for help with breathing they may receive antibiotics
- if your baby has seizures
- if your baby has signs of shock (impaired circulation)

Deciding if your baby needs observations or antibiotics:

The hospital is using the Kaiser early onset sepsis calculator in conjunction with NICE guidance to assess whether your baby will require observations or antibiotics. This was developed by the Kaiser Permanente health system in California and has been shown to be effective at identifying the level of risk of infection for an individual baby. The neonatal sepsis calculator published by Kaiser Permanente is being used at several Neonatal Intensive Care Units nationwide and has been proven to decrease the number of babies getting antibiotics just because of a risk of infection. Many of these babies can simply be observed safely and only given antibiotics if their observations are not normal.

If your baby is assessed to need observations, these will need to be performed at regular intervals as part of the assessment and for between 24 to 36 hours. These observations are important and will identify any baby who starts to show signs of infection. Observations do not mean you baby is not receiving treatment; they are receiving vital regular reviews. Your baby will be able to stay with you on the postnatal ward or in the transitional care unit.

If your baby needs antibiotics:

Once your baby has started antibiotics they will require at least one further blood test and will need to remain in hospital for at least 36 hours after starting antibiotics to make sure that no bacteria are growing in the blood sent to the laboratory. If tests are clear, antibiotics are stopped and you should be able to take your baby home as long as they are feeding well and there are no other concerns.