NICE National Institute for Health and Care Excellence

NICE quality standard

Neonatal infection

Quality standard

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Contents

This standard is based on CG149.

This standard should be read in conjunction with QS37, QS4, QS15, QS19, QS22, QS32, QS36, QS64, QS60, QS46, QS105, QS113, QS121, QS135 and QS161.

Introduction

This quality standard covers the use of antibiotics to prevent and treat infection in newborn babies (both term and preterm) from birth to 28 days in primary (including community) and secondary care. It includes antibiotics that are given to newborn babies or to mothers during intrapartum care to prevent neonatal infection (antibiotic prophylaxis). For more information see the topic overview.

Why this quality standard is needed

Neonatal infection is a significant cause of mortality and morbidity in newborn babies. It may be early-onset (infection arising within 72 hours of birth) or late-onset (infection arising more than 72 hours after birth). Neonatal infection can lead to life-threatening sepsis and accounts for 10% of all neonatal mortality. Early-onset neonatal infection, although less common than late-onset neonatal infection, is often more severe.

Neonatal infection is present in 8 of every 1000 live births and 71 of every 1000 neonatal admissions. Of these infections, 82% occur in premature babies (less than 37 weeks) and 81% in low birthweight babies (below 2500 grams).

Early-onset neonatal infection is present in 0.9 of every 1000 live births and 9 of every 1000 neonatal admissions. Group B *Streptococcus* and *Escherichia coli* are the most common organisms identified, accounting for 58% and 18% of infections respectively.

Late-onset neonatal infection is present in 7 of every 1000 live births and 61 of every 1000 neonatal admissions. Coagulase-negative staphylococci, *Enterobacteriaceae* and *Staphylococcus aureus* are the most common organisms identified, accounting for 54%, 21% and 18% of infections respectively.

Prompt antibiotic treatment for neonatal infection can save lives. However, most newborn babies who are given antibiotics do not have any infection. Antibiotics given in the first few days after birth may increase the risk of conditions such as eczema and asthma in later life, but these risks cannot

be quantified. Widespread antibiotic use may also be associated with a risk of antimicrobial resistance. For these reasons, babies should have minimal exposure to antibiotics.

The quality standard is expected to contribute to improvements in the following outcomes:

- infant mortality
- admissions and readmissions to neonatal care units
- maternity and neonatal length of hospital stay
- neonatal neurological and auditory development.

How this quality standard supports delivery of outcome frameworks

NICE quality standards are a concise set of prioritised statements designed to drive measurable quality improvements within a particular area of health or care. They are derived from high-quality guidance, such as that from NICE or other sources accredited by NICE. This quality standard, in conjunction with the guidance on which it is based, should contribute to the improvements outlined in the following 2 outcomes frameworks published by the Department of Health:

- NHS Outcomes Framework 2014/15
- Improving outcomes and supporting transparency: a public health outcomes framework for England 2013–2016, Parts 1A, 1B and 2.

Tables 1 and 2 show the outcomes, overarching indicators and improvement areas from the frameworks that the quality standard could contribute to achieving.

Table 1 NHS Outcomes Framework 2014/15

Domain	Overarching indicators and improvement areas

1 Preventing people from dying prematurely	*Overarching indicator* 1a Potential Years of Life Lost (PYLL) from causes considered amenable to healthcare ii Children and young people *Improvement area* **Reducing deaths in babies and young children** 1.6 ii Neonatal mortality and stillbirths
4 Ensuring that people have a positive experience of care	*Overarching indicator* 4b Patient experience of hospital care *Improvement area* **Improving women and their families' experience of maternity services** 4.5 Women's experience of maternity services

5 Treating and caring for people in a safe environment and protecting them from avoidable harm	*Overarching indicators* 5a Patient safety incidents reported 5b Safety incidents involving severe harm or death 5c Hospital deaths attributable to problems in care *Improvement areas* **Reducing the incidence of avoidable harm** 5.2 Incidence of healthcare associated infection (HCAI) i MRSA 5.4 Incidence of medication errors causing serious harm **Improving the safety of maternity services** 5.5 Admission of full-term babies to neonatal care **Delivering safe care to children in acute settings** 5.6 Incidence of harm to children due to 'failure to monitor'

Table 2 Public health outcomes framework for England, 2013–2016

Domain	Objectives and indicators
4 Healthcare public health and preventing premature mortality	*Objective* Reduced numbers of people living with preventable ill health and people dying prematurely, while reducing the gap between communities *Indicator* 4.3 Mortality rate from causes considered preventable** (NHSOF 1a)
Alignment across the health and social care system ** Indicator complementary with NHS Outcomes Framework (NHSOF)	

Patient experience and safety issues

Ensuring that care is safe and that people have a positive experience of care is vital in a high-quality service. It is important to consider these factors when planning and delivering services relevant to antibiotics for neonatal infection.

Coordinated services

The quality standard for antibiotics for neonatal infection specifies that services should be commissioned from and coordinated across all relevant agencies encompassing the whole neonatal care pathway. A person-centred, integrated approach to providing services is fundamental to delivering high-quality care to pregnant women and babies who are at risk of or who have a neonatal infection (within 28 days of birth) in primary (including community) and secondary care.

The Health and Social Care Act 2012 sets out a clear expectation that the care system should consider NICE quality standards in planning and delivering services, as part of a general duty to secure continuous improvement in quality. Commissioners and providers of health and social care should refer to the library of NICE quality standards when designing high-quality services. Other quality standards that should also be considered when choosing, commissioning or providing a high-quality neonatal infection service are listed in related quality standards.

Training and competencies

The quality standard should be read in the context of national and local guidelines on training and competencies. All healthcare professionals involved in assessing, caring for and treating pregnant women and babies who are at risk of or who have a neonatal infection (within 28 days of birth) in primary (including community) and secondary care should have sufficient and appropriate training and competencies to deliver the actions and interventions described in the quality standard. Quality statements on staff training and competency are not usually included in quality standards. However, recommendations in the development source on specific types of training for the topic that exceed standard professional training are considered during quality statement development.

Role of parents and carers

The quality standard recognises the key role parents and carers have in identifying and caring for babies who are at risk of or who have a neonatal infection (within 28 days of birth) in primary (including community) and secondary care. Healthcare professionals should ensure that parents or carers are involved in the decision-making process about investigations, treatment and care.

List of quality statements

Statement 1. Pregnant women whose babies are at risk of early-onset neonatal infection are offered intrapartum antibiotic prophylaxis and given the first dose as soon as possible.

Statement 2. Pregnant women and newborn babies receive a comprehensive clinical assessment for the risks or indicators of early-onset neonatal infection.

Statement 3. Newborn babies who need antibiotic treatment receive it within 1 hour of the decision to treat.

Statement 4. Newborn babies who start antibiotic treatment for possible early-onset neonatal infection have their need for it reassessed at 36 hours.

Statement 5. Parents or carers of newborn babies in whom early-onset neonatal infection has been a concern are given verbal and written information about neonatal infection before discharge.

Statement 6 (placeholder). Antibiotic treatment for late-onset neonatal infection.

Quality statement 1: Intrapartum antibiotics

Quality statement

Pregnant women whose babies are at risk of early-onset neonatal infection are offered intrapartum antibiotic prophylaxis and given the first dose as soon as possible.

Rationale

Giving intrapartum antibiotic prophylaxis to women whose babies are at risk of early-onset neonatal infection (for example, from group B *Streptococcus*) can prevent early-onset neonatal infection. The first dose should be given as soon as possible after the onset of labour because intrapartum antibiotic prophylaxis is most effective when the baby has sufficient exposure to the antibiotic.

Quality measures

Structure

Evidence of local arrangements to ensure that pregnant women whose babies are at risk of early-onset neonatal infection are offered intrapartum antibiotic prophylaxis and given the first dose as soon as possible.

Data source: Local data collection.

Process

a) Proportion of pregnant women whose babies are at risk of early-onset neonatal infection who receive intrapartum antibiotic prophylaxis.

Numerator – the number in the denominator who receive intrapartum antibiotic prophylaxis.

Denominator – the number of pregnant women whose babies are at risk of early-onset neonatal infection.

Data source: Local data collection. Data can be collected using NICE's intrapartum antibiotics clinical audit tool, audit standards 1 and 2.

b) Proportion of pregnant women receiving intrapartum antibiotic prophylaxis who are given it as soon as possible.

Numerator – the number in the denominator whose intrapartum antibiotic prophylaxis is given as soon as possible.

Denominator – the number of pregnant women who receive intrapartum antibiotic prophylaxis.

Data source: Local data collection. Data can be collected using NICE's intrapartum antibiotics clinical audit tool, audit standard 3a, which includes a note on potential timeframes for audit purposes.

Outcome

Rates of early-onset neonatal infection.

Data source: Local data collection.

What the quality statement means for service providers, healthcare professionals and commissioners

Service providers (maternity care services) ensure that systems and protocols are in place to enable intrapartum antibiotic prophylaxis to be offered to pregnant women whose babies are at risk of early-onset neonatal infection, and ensure that they are given the first dose as soon as possible.

Healthcare professionals adhere to protocols and offer intrapartum antibiotic prophylaxis to pregnant women whose babies are at risk of early-onset neonatal infection, ensuring that they are given the first dose as soon as possible and record this.

Commissioners (clinical commissioning groups) specify that maternity care providers have systems and protocols in place for healthcare professionals to offer intrapartum antibiotic prophylaxis to pregnant women whose babies are at risk of early-onset neonatal infection, and ensure that they are given the first dose as soon as possible.

What the quality statement means for patients, service users and carers

Pregnant women who had a previous baby with an infection called group B *Streptococcus*, or whose tests during this pregnancy show group B *Streptococcus* bacteria in their bodies, are offered antibiotics and given the first dose as soon as possible after their labour has started.

Source guidance

- Antibiotics for early-onset neonatal infection (2012) NICE guideline CG149, recommendations 1.3.1.1 (key priority for implementation) and 1.3.1.2.

Definitions of terms used in this quality statement

As soon as possible

Antibiotics for early-onset neonatal infection (NICE guideline CG149) recommendation 1.3.1.2 states that if a woman decides to take intrapartum antibiotic prophylaxis, the first dose should be given as soon as possible. A suggested definition for audit purposes is that the first dose is given within 1 hour of the onset of active labour, or within 1 hour of admission if the woman is already in active labour. [Adapted from NICE's intrapartum antibiotics clinical audit tool, audit standard 3a]

Babies who are at risk of early-onset neonatal infection

Babies are at risk of early-onset neonatal infection if the mother has had a previous baby with an invasive group B streptococcal infection, or has group B streptococcal colonisation, bacteriuria or infection in the current pregnancy. [Adapted from Antibiotics for early-onset neonatal infection (NICE guideline CG149) recommendation 1.3.1.1]

Intrapartum antibiotic prophylaxis

Intravenous benzylpenicillin is given during labour, starting as soon as possible after labour has begun, and is continued until the baby is born.

For women who have an allergy to penicillin, clindamycin is used, unless individual group B *streptococcus* sensitivity results or local microbiological surveillance data indicate a different antibiotic. [Adapted from Antibiotics for early-onset neonatal infection (NICE guideline CG149) recommendations 1.3.1.2 and 1.3.1.5, and Group B streptococcal disease, early-onset (green-top guideline no. 36) (Royal College of Obstetricians and Gynaecologists)]

Quality statement 2: Clinical assessment for early-onset neonatal infection

Quality statement

Pregnant women and newborn babies receive a comprehensive clinical assessment for the risks or indicators of early-onset neonatal infection.

Rationale

A comprehensive clinical assessment can identify babies who are at increased risk, or showing signs, of possible early-onset neonatal infection and enable healthcare professionals to start antibiotic treatment promptly if needed.

Quality measures

Structure

Evidence of local arrangements and written protocols to ensure that pregnant women and newborn babies receive a comprehensive clinical assessment for the risks or indicators of early-onset neonatal infection.

Data source: Local data collection.

Process

a) Proportion of pregnant women who are assessed for risk factors for early-onset neonatal infection.

Numerator – the number in the denominator who are assessed for risk factors for early-onset neonatal infection.

Denominator – the number of pregnant women.

Data source: Local data collection.

b) Proportion of newborn babies who are assessed for clinical indicators of early-onset neonatal infection.

Numerator – the number in the denominator who are assessed for clinical indicators of early-onset neonatal infection.

Denominator – the number of newborn babies.

Data source: Local data collection.

c) Proportion of newborn babies with risk factors or clinical indicators of early-onset neonatal infection who receive an immediate physical examination including an assessment of the vital signs.

Numerator – the number in the denominator who receive an immediate physical examination including an assessment of the vital signs.

Denominator – the number of newborn babies identified with risk factors or clinical indicators of early-onset neonatal infection.

Data source: Local data collection.

What the quality statement means for service providers, healthcare professionals and commissioners

Service providers (maternity care services) develop protocols to ensure that healthcare professionals are trained to identify the risk factors and clinical indicators of early-onset neonatal infection and perform a physical examination of the baby (including an assessment of the vital signs) if any have been identified.

Healthcare professionals monitor for risk factors and clinical indicators of early-onset neonatal infection and perform an immediate physical examination of the baby (including an assessment of the vital signs) if any have been identified.

Commissioners (clinical commissioning groups) specify that maternity care providers develop and adhere to protocols to support the identification of risk factors and clinical indicators of early-onset neonatal infection and perform immediate physical assessments of newborn babies if any have been identified.

What the quality statement means for patients, service users and carers

Mothers and their newborn babies have an assessment to check whether the baby is at risk of infection.

Source guidance

- Antibiotics for early-onset neonatal infection (2012) NICE guideline CG149, recommendations 1.2.1.1, 1.2.1.2, 1.2.2.1, 1.2.2.2 and 1.2.3.1.

Definitions of terms used in this quality statement

Comprehensive clinical assessment

Comprehensive clinical assessment for early-onset neonatal infection is a continuing process that begins before the baby is born and continues until 72 hours after the birth. It includes identifying whether there are any risk factors or clinical indicators for early-onset neonatal infection and performing a physical examination of the baby (including an assessment of the vital signs) without delay if any are identified. Risk factors and clinical indicators below marked **[red flag]** prompt a high level of concern.

Risk factors

- invasive group B streptococcal infection in a previous baby
- maternal group B streptococcal colonisation, bacteriuria or infection in the current pregnancy
- prelabour rupture of membranes
- preterm birth following spontaneous labour (before 37 weeks' gestation)
- suspected or confirmed rupture of membranes for more than 18 hours in a preterm birth
- intrapartum fever higher than 38°C, or confirmed or suspected chorioamnionitis
- 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) **[red flag]**
- suspected or confirmed infection in another baby in the case of a multiple pregnancy **[red flag]**.

Clinical indicators

- altered behaviour or responsiveness
- altered muscle tone (for example, floppiness)
- feeding difficulties (for example, feed refusal)
- feed intolerance, including vomiting, excessive gastric aspirates and abdominal distension
- abnormal heart rate (bradycardia or tachycardia)
- signs of respiratory distress
- respiratory distress starting more than 4 hours after birth **[red flag]**
- hypoxia (for example, central cyanosis or reduced oxygen saturation level)
- jaundice within 24 hours of birth
- apnoea
- signs of neonatal encephalopathy
- seizures **[red flag]**
- need for cardiopulmonary resuscitation
- need for mechanical ventilation in a preterm baby
- need for mechanical ventilation in a term baby **[red flag]**
- persistent fetal circulation (persistent pulmonary hypertension)
- temperature abnormality (lower than 36°C or higher than 38°C) unexplained by environmental factors
- signs of shock **[red flag]**
- unexplained excessive bleeding, thrombocytopenia, or abnormal coagulation (international normalised ratio greater than 2.0)
- oliguria persisting beyond 24 hours after birth
- altered glucose homeostasis (hypoglycaemia or hyperglycaemia)

- metabolic acidosis (base deficit of 10 mmol/litre or greater)
- local signs of infection (for example, affecting the skin or eye).

[Adapted from Antibiotics for early-onset neonatal infection (NICE guideline CG149) recommendation 1.2.3.1]

Newborn babies

Babies under 72 hours old. [Adapted from Antibiotics for early-onset neonatal infection (NICE guideline CG149)]

Quality statement 3: Prompt antibiotic treatment for early-onset neonatal infection

Quality statement

Newborn babies who need antibiotic treatment receive it within 1 hour of the decision to treat.

Rationale

If the decision to treat is made, antibiotic treatment for early-onset neonatal infection should be started without delay (and without waiting for test results) and always within 1 hour to improve clinical outcomes for the baby.

Quality measures

Structure

Evidence of local arrangements to ensure that newborn babies who need antibiotic treatment receive it within 1 hour of the decision to treat.

Data source: Local data collection.

Process

Proportion of newborn babies who need antibiotic treatment who receive it within 1 hour of the decision to treat.

Numerator – the number in the denominator who receive antibiotics within 1 hour of the decision to treat.

Denominator – the number of newborn babies who need antibiotic treatment.

Data source: Local data collection. Data can be collected using NICE's empirical treatment of suspected infection clinical audit tool, audit standard 3.

What the quality statement means for service providers, healthcare professionals and commissioners

Service providers (maternity care services) develop protocols to ensure that healthcare professionals give antibiotic treatment within 1 hour of the decision to treat.

Healthcare professionals adhere to protocols for antibiotic treatment to be started within 1 hour of the decision to treat and record this.

Commissioners (clinical commissioning groups) specify that maternity care providers give antibiotic treatment to newborn babies who need it within 1 hour of the decision to treat the early-onset neonatal infection.

What the quality statement means for patients, service users and carers

Newborn babies less than 72 hours old who need antibiotic treatment for an infection receive it within 1 hour.

Source guidance

- Antibiotics for early-onset neonatal infection (2012) NICE guideline CG149, recommendations 1.2.3.2 and 1.2.3.4 (key priorities for implementation).

Definitions of terms used in this quality statement

Newborn babies

Babies under 72 hours old. [Adapted from Antibiotics for early-onset neonatal infection (NICE guideline CG149)]

Newborn babies who need antibiotic treatment

Babies with 2 or more of the risk factors listed below, and babies with any risk factor marked **[red flag]**.

Risk factors

- invasive group B streptococcal infection in a previous baby

- maternal group B streptococcal colonisation, bacteriuria or infection in the current pregnancy
- pre-labour rupture of membranes
- preterm birth following spontaneous labour (before 37 weeks' gestation)
- suspected or confirmed rupture of membranes for more than 18 hours in a preterm birth
- intrapartum fever higher than 38°C, or confirmed or suspected chorioamnionitis
- 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) **[red flag]**
- suspected or confirmed infection in another baby in the case of a multiple pregnancy **[red flag].**

Clinical indicators

- altered behaviour or responsiveness
- altered muscle tone (for example, floppiness)
- feeding difficulties (for example, feed refusal)
- feed intolerance, including vomiting, excessive gastric aspirates and abdominal distension
- abnormal heart rate (bradycardia or tachycardia)
- signs of respiratory distress
- respiratory distress starting more than 4 hours after birth **[red flag]**
- hypoxia (for example, central cyanosis or reduced oxygen saturation level)
- jaundice within 24 hours of birth
- apnoea
- signs of neonatal encephalopathy
- seizures **[red flag]**
- need for cardiopulmonary resuscitation
- need for mechanical ventilation in a preterm baby

- need for mechanical ventilation in a term baby **[red flag]**
- persistent fetal circulation (persistent pulmonary hypertension)
- temperature abnormality (lower than 36°C or higher than 38°C) unexplained by environmental factors
- signs of shock **[red flag]**
- unexplained excessive bleeding, thrombocytopenia, or abnormal coagulation (international normalised ratio greater than 2.0)
- oliguria persisting beyond 24 hours after birth
- altered glucose homeostasis (hypoglycaemia or hyperglycaemia)
- metabolic acidosis (base deficit of 10 mmol/litre or greater)
- local signs of infection (for example, affecting the skin or eye).

[Adapted from Antibiotics for early-onset neonatal infection (NICE guideline CG149) recommendation 1.2.3.2]

Quality statement 4: Reassessing antibiotic treatment for early-onset neonatal infection

Quality statement

Newborn babies who start antibiotic treatment for possible early-onset neonatal infection have their need for it reassessed at 36 hours.

Rationale

Newborn babies should have their antibiotic treatment reassessed 36 hours after starting treatment to ensure that they are not receiving antibiotics unnecessarily. Reassessment (including consideration of any blood test results) is needed so that antibiotic treatment can be stopped if there are clinical indications that a baby does not have an infection. This will help to improve safety by reducing the likelihood of local antimicrobial resistance as well as improve the experience of the postnatal period for these babies and their parents or carers.

Quality measures

Structure

Evidence of local arrangements to ensure that newborn babies who start antibiotic treatment for possible early-onset neonatal infection have their need for it reassessed at 36 hours.

Data source: Local data collection.

Process

Proportion of newborn babies who start antibiotic treatment for possible early-onset neonatal infection who have their need for it reassessed at 36 hours.

Numerator – the number in the denominator who have their need for antibiotic treatment reassessed at 36 hours.

Denominator – the number of newborn babies who start antibiotic treatment for possible early-onset neonatal infection.

Data source: Local data collection.

What the quality statement means for service providers, healthcare professionals and commissioners

Service providers (maternity care services) have protocols in place to ensure that healthcare professionals reassess antibiotic treatment at 36 hours, and have systems in place for blood culture results to be returned within 36 hours.

Healthcare professionals adhere to protocols and reassess the need for antibiotic treatment at 36 hours to enable antibiotic treatment to be stopped if there are clinical indications that a baby does not have an infection.

Commissioners (clinical commissioning groups) specify that maternity care providers reassess the need for antibiotic treatment at 36 hours and include consideration of blood culture results.

What the quality statement means for patients, service users and carers

Newborn babies being given antibiotic treatment for an infection have their treatment checked at 36 hours to see whether they need to continue it.

Source guidance

- Antibiotics for early-onset neonatal infection (2012) NICE guideline CG149, recommendation 1.7.2.1 (key priority for implementation).

Definitions of terms used in this quality statement

Newborn babies

Babies under 72 hours old. [Adapted from Antibiotics for early-onset neonatal infection (NICE guideline CG149)]

Reassessment of the need for antibiotic treatment

Includes blood culture, C-reactive protein level, clinical condition and the strength of the initial clinical suspicion of infection. Antibiotic treatment may be stopped if blood culture is negative, initial suspicion of infection was not strong, the baby has no clinical indicators of infection and C-reactive protein levels are reassuring. [NICE guideline CG149, recommendation 1.7.2.1]

Hospitals should consider establishing systems to provide blood culture results 36 hours after starting antibiotic treatment to facilitate the timely discontinuation of treatment. [Adapted from Antibiotics for early-onset neonatal infection (NICE guideline CG149) recommendation 1.7.2.2]

Quality statement 5: Information and support for identification of neonatal infection

Quality statement

Parents or carers of newborn babies in whom early-onset neonatal infection has been a concern are given verbal and written information about neonatal infection before discharge.

Rationale

Prompt identification of neonatal infection is essential to ensure that babies receive appropriate treatment as soon as possible to prevent complications and achieve the best clinical outcomes. Advising parents or carers about what to look for and when to contact a healthcare professional will help them recognise signs of infection promptly and avoid unnecessary delay in treatment of the baby.

Quality measures

Structure

Evidence of local arrangements and protocols to ensure that parents or carers of newborn babies in whom early-onset neonatal infection has been a concern are given verbal and written information about neonatal infection before discharge.

Data source: Local data collection.

Process

Proportion of parents or carers of newborn babies in whom early-onset neonatal infection has been a concern who are given verbal and written information about neonatal infection before discharge.

Numerator – the number in the denominator whose parents or carers receive verbal and written information about neonatal infection before discharge.

Denominator – the number of newborn babies in whom early-onset neonatal infection has been a concern.

Data source: Local data collection.

What the quality statement means for service providers, healthcare professionals and commissioners

Service providers (secondary care services) ensure that verbal and written information about neonatal infection (including what to look for and who to contact if they are concerned) is available before discharge for parents or carers of newborn babies in whom there have been concerns about early-onset neonatal infection.

Healthcare professionals discuss neonatal infection with parents or carers of newborn babies in whom there have been concerns about early-onset neonatal infection, and give them written information before discharge, including what to look for and who to contact if they are concerned.

Commissioners (clinical commissioning groups) specify that services have protocols in place to ensure that verbal and written information about neonatal infection is available for parents or carers of newborn babies in whom there have been concerns about early-onset neonatal infection. They also ensure that there is access to relevant healthcare professionals for parents or carers who are concerned about neonatal infection.

What the quality statement means for patients, service users and carers

Parents or carers of newborn babies who may be at risk of developing an infection have a healthcare professional discuss this with them and give them written information about infection in newborn babies before they leave hospital. The information should include how to check whether the baby might have an infection and who to contact if they are concerned.

Source guidance

- Antibiotics for early-onset neonatal infection (2012) NICE guideline CG149, recommendation 1.1.1.8 (key priority for implementation).

Definitions of terms used in this quality statement

Babies in whom early-onset neonatal infection is a concern

Babies with any of the risk factors or clinical indicators below, either before birth or during the first 72 hours after birth. Items marked **[red flag]** prompt a high level of concern.

Risk factors

- invasive group B streptococcal infection in a previous baby
- maternal group B streptococcal colonisation, bacteriuria or infection in the current pregnancy
- prelabour rupture of membranes
- preterm birth following spontaneous labour (before 37 weeks' gestation)
- suspected or confirmed rupture of membranes for more than 18 hours in a preterm birth
- intrapartum fever higher than 38°C, or confirmed or suspected chorioamnionitis
- 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) **[red flag]**
- suspected or confirmed infection in another baby in the case of a multiple pregnancy **[red flag]**.

Clinical indicators

- altered behaviour or responsiveness
- altered muscle tone (for example, floppiness)
- feeding difficulties (for example, feed refusal)
- feed intolerance, including vomiting, excessive gastric aspirates and abdominal distension
- abnormal heart rate (bradycardia or tachycardia)
- signs of respiratory distress
- respiratory distress starting more than 4 hours after birth **[red flag]**
- hypoxia (for example, central cyanosis or reduced oxygen saturation level)
- jaundice within 24 hours of birth
- apnoea
- signs of neonatal encephalopathy
- seizures **[red flag]**

- need for cardiopulmonary resuscitation
- need for mechanical ventilation in a preterm baby
- need for mechanical ventilation in a term baby **[red flag]**
- persistent fetal circulation (persistent pulmonary hypertension)
- temperature abnormality (lower than 36°C or higher than 38°C) unexplained by environmental factors
- signs of shock **[red flag]**
- unexplained excessive bleeding, thrombocytopenia, or abnormal coagulation (international normalised ratio greater than 2.0)
- oliguria persisting beyond 24 hours after birth
- altered glucose homeostasis (hypoglycaemia or hyperglycaemia)
- metabolic acidosis (base deficit of 10 mmol/litre or greater)
- local signs of infection (for example, affecting the skin or eye).

[Adapted from Antibiotics for early-onset neonatal infection (NICE guideline CG149) recommendation 1.1.1.1]

Discharge

When a baby is discharged from the hospital or midwifery-led unit or in the immediate postnatal period if the baby is born at home. [Adapted from Antibiotics for early-onset neonatal infection (NICE guideline CG149) recommendation 1.1.1.9].

Information about neonatal infection

Verbal and written information for parents and carers that they should seek medical advice (for example, from NHS Direct, their GP or an accident and emergency department) 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.

[Antibiotics for early-onset neonatal infection (NICE guideline CG149) recommendation 1.1.1.8]

Equality and diversity considerations

Information about neonatal infection should be accessible to parents or carers with additional needs such as physical, sensory or learning disabilities, and to parents or carers who do not speak or read English. Parents or carers of babies in whom early-onset neonatal infection has been a concern in any setting should have access to an interpreter or advocate if needed.

Quality statement 6 (placeholder): Antibiotic treatment for late-onset neonatal infection

What is a placeholder statement?

A placeholder statement is an area of care that has been prioritised by the Quality Standards Advisory Committee but for which no source guidance is currently available. A placeholder statement indicates the need for evidence-based guidance to be developed in this area.

Rationale

Late-onset neonatal infection (infection arising more than 72 hours after birth) has a higher incidence than early-onset neonatal infection (infection arising within 72 hours of birth) and the spectrum of causative microorganisms is broader than in early-onset infection. Guidance on the appropriate use of antibiotics in late-onset neonatal bacterial infection could help to improve clinical outcomes for babies and reduce the likelihood of antimicrobial resistance in babies and neonatal units.

Using the quality standard

Quality measures

The quality measures accompanying the quality statements aim to improve the structure, process and outcomes of care in areas identified as needing quality improvement. They are not a new set of targets or mandatory indicators for performance management.

We have indicated if current national indicators exist that could be used to measure the quality statements. These include indicators developed by the Health and Social Care Information Centre through its Indicators for Quality Improvement Programme. If there is no national indicator that could be used to measure a quality statement, the quality measure should form the basis for audit criteria developed and used locally.

See NICE's What makes up a NICE quality standard? for further information, including advice on using quality measures.

Levels of achievement

Expected levels of achievement for quality measures are not specified. Quality standards are intended to drive up the quality of care, and so achievement levels of 100% should be aspired to (or 0% if the quality statement states that something should not be done). However, NICE recognises that this may not always be appropriate in practice, taking account of safety, choice and professional judgement, and therefore desired levels of achievement should be defined locally.

Using other national guidance and policy documents

Other national guidance and current policy documents have been referenced during the development of this quality standard. It is important that the quality standard is considered alongside the documents listed in development sources.

Information for the public

NICE has produced information for the public about this quality standard. Patients, service users and carers can use it to find out about the quality of care they should expect to receive; as a basis for asking questions about their care, and to help make choices between providers of social care services.

Diversity, equality and language

During the development of this quality standard, equality issues have been considered and equality assessments are available.

Good communication between healthcare professionals and parents or carers of babies with neonatal infection is essential. Treatment, care and support, and the information given about it, should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English. Parents or carers of babies with neonatal infection in any setting should have access to an interpreter or advocate if needed.

Commissioners and providers should aim to achieve the quality standard in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this quality standard should be interpreted in a way that would be inconsistent with compliance with those duties.

Development sources

Further explanation of the methodology used can be found in the quality standards process guide.

Evidence sources

The documents below contain recommendations from NICE guidance or other NICE-accredited recommendations that were used by the Quality Standards Advisory Committee to develop the quality standard statements and measures.

- Antibiotics for early-onset neonatal infection (2012) NICE guideline CG149

Policy context

It is important that the quality standard is considered alongside current policy documents, including:

- Royal College of Paediatrics and Child Health (2013) National Neonatal Audit Programme – annual report 2012
- Centre for Maternal and Child Enquiries (2011) Perinatal mortality 2009
- British Association of Perinatal Medicine (2010) Service standards for hospitals providing neonatal care (3rd edition)

Definitions and data sources for the quality measures

- National Institute for Health and Care Excellence (2012) Empirical treatment of suspected infection clinical audit tool
- National Institute for Health and Care Excellence (2012) Intrapartum antibiotics clinical audit tool
- Royal College of Obstetricians and Gynaecologists (2012) Group B streptococcal disease, early-onset (green-top guideline no. 36)

Related NICE quality standards

Published

- Feverish illness in children under 5 years (2014) NICE quality standard 64
- Induction of labour (2014) NICE quality standard 60
- Multiple pregnancy (2013) NICE quality standard 46
- Postnatal care (2013) NICE quality standard 37
- Urinary tract infection in infants, children and young people under 16 (2013) NICE quality standard 36
- Caesarean section (2013) NICE quality standard 32
- Antenatal care (2012) NICE quality standard 22
- Bacterial meningitis and meningococcal septicaemia in children and young people (2012) NICE quality standard 19
- Patient experience in adult NHS services (2012) NICE quality standard 15
- Specialist neonatal care (2010) NICE quality standard 4

Future quality standards

This quality standard has been developed in the context of all quality standards referred to NICE, including the following topics scheduled for future development:

- Effective antimicrobial stewardship
- Intrapartum care
- Premature birth

The full list of quality standard topics referred to NICE is available from the quality standards topic library on the NICE website.

Quality Standards Advisory Committee and NICE project team

Quality Standards Advisory Committee

This quality standard has been developed by Quality Standards Advisory Committee 4. Membership of this committee is as follows:

Miss Alison Allam
Lay member

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Lead Nurse Specialist in Neurology, Norfolk Community Health and Care

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Mr John Walker
Head of Operations, Greater Manchester West Mental Health NHS Foundation Trust

The following specialist members joined the committee to develop this quality standard:

Mrs Phillipa Clark (from June 2014)
Midwife/Advanced Neonatal Nurse Practitioner, Poole NHS Trust

Dr Jim Gray
Consultant Microbiologist, Birmingham Children's Hospital

Professor Paul Heath
Professor of Paediatric Infectious Disease, St George's, University of London

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About this quality standard

NICE quality standards describe high-priority areas for quality improvement in a defined care or service area. Each standard consists of a prioritised set of specific, concise and measurable statements. NICE quality standards draw on existing NICE or NICE-accredited guidance that provides an underpinning, comprehensive set of recommendations, and are designed to support the measurement of improvement.

The methods and processes for developing NICE quality standards are described in the quality standards process guide.

This quality standard will be incorporated into the NICE pathway on antibiotics for early-onset neonatal infection.

NICE produces guidance, standards and information on commissioning and providing high-quality healthcare, social care, and public health services. We have agreements to provide certain NICE services to Wales, Scotland and Northern Ireland. Decisions on how NICE guidance and other products apply in those countries are made by ministers in the Welsh government, Scottish government, and Northern Ireland Executive. NICE guidance or other products may include references to organisations or people responsible for commissioning or providing care that may be relevant only to England.

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Endorsing organisation

This quality standard has been endorsed by NHS England, as required by the Health and Social Care Act (2012)

Supporting organisations

Many organisations share NICE's commitment to quality improvement using evidence-based guidance. The following supporting organisations have recognised the benefit of the quality standard in improving care for patients, carers, service users and members of the public. They have agreed to work with NICE to ensure that those commissioning or providing services are made aware of and encouraged to use the quality standard.

- Bliss
- Group B Strep Support
- Meningitis Research Foundation
- Royal College of General Practitioners
- Royal College of Obstetricians and Gynaecologists
- Royal College of Paediatrics and Child Health
- Royal College of Pathologists
- SANDS
- UK Clinical Pharmacy Association (UKCPA)
- UK Sepsis Trust