Antibiotics for neonatal infection

NICE quality standard

Draft for consultation

July 2014

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% occurred 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. It has been suggested that 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
- overall 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, Part 1 and Part 1A.

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 areas*** **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 areas*** **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 indicator*** 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 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 ***Indicators*** *4.3 Mortality rate from causes considered preventable ** (NHSOF 1a)*
Alignment across the health and social care system ** Complementary to indicators in the NHS Outcomes Framework	

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 infection care pathway. A person-centred, integrated approach to providing services is fundamental to delivering high-quality care to 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 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.

Role of parents and carers

Quality standards recognise the important role parents and carers have in 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. Newborn babies and their mothers are assessed for risk factors and clinical indicators of early-onset neonatal infection and the baby receives an immediate clinical assessment if any are identified.

Statement 2. Pregnant women are offered intrapartum antibiotic prophylaxis as soon as possible if they have had a previous baby with an invasive group B streptococcal infection, or group B streptococcal colonisation, bacteriuria or infection in the current pregnancy.

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

Statement 4. Newborn babies receiving antibiotic treatment based on risk factors and clinical indicators of early-onset neonatal infection have their antibiotic treatment reassessed 36 hours after starting treatment.

Statement 5. Parents or carers of newborn babies in whom early-onset neonatal infection has been a concern before discharge are given verbal and written information about neonatal infection, including what to look for and who to contact if they are concerned.

Statement 6 (placeholder). Use of antibiotics in late-onset neonatal infection.

Questions for consultation

Questions about the quality standard

Question 1 Does this draft quality standard accurately reflect the key areas for quality improvement?

Question 2 If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

Questions about the individual quality statements

Question 3 For draft placeholder statement 6: Do you know of any evidence-based guidance that could be used to develop this placeholder statement? If so, please

provide details. If not, would new evidence-based guidance relating to the use of antibiotics in late-onset neonatal infection have the potential to improve practice? If so, please provide details.

Quality statement 1: Risk factors and clinical indicators of early-onset neonatal infection

Quality statement

Newborn babies and their mothers are assessed for risk factors and clinical indicators of early-onset neonatal infection and the baby receives an immediate clinical assessment if any are identified.

Rationale

Using risk factors or clinical indicators to identify babies who are at increased risk or showing signs of possible early-onset neonatal infection enables healthcare professionals to make decisions about further investigations and antibiotic treatment.

Quality measures

Structure

Evidence of local arrangements and written protocols to ensure that newborn babies and their mothers are assessed for risk factors and clinical indicators of early-onset neonatal infection and the baby receives an immediate clinical assessment if these are identified.

Data source: Local data collection.

Process

a) 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.

b) Proportion of newborn babies' mothers who are assessed for risk factors of early-onset neonatal infection.

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

Denominator – the number of newborn babies.

Data source: Local data collection.

c) Proportion of newborn babies identified with risk factors or clinical indicators of early-onset neonatal infection who receive an immediate clinical assessment.

Numerator – the number in the denominator who receive an immediate clinical assessment.

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 (secondary care services) ensure that healthcare professionals are trained to identify the risk factors and clinical indicators of early-onset neonatal infection and perform an immediate clinical assessment if any have been identified, and that systems and protocols are in place to support this.

Healthcare professionals (including midwives and doctors) monitor for risk factors and clinical indicators of early-onset neonatal infection and perform an immediate clinical assessment if any have been identified.

Commissioners (clinical commissioning groups for secondary care) ensure that secondary 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 clinical assessments if any have been identified.

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

Babies born within the past 72 hours are cared for by healthcare professionals who are able recognise signs and symptoms of infection in newborn babies.

Source guidance

- Antibiotics for early-onset neonatal infection (NICE clinical guideline 149), recommendations 1.2.1.1, 1.2.1.2, 1.2.2.1 and 1.2.2.2.

Definitions of terms used in this quality statement

Newborn babies

All babies under 72 hours of age.

Risk factors and clinical indicators of possible early-onset neonatal infection

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

[NICE clinical guideline 149, recommendation 1.2.1.1]

Quality statement 2: Intrapartum antibiotics

Quality statement

Pregnant women are offered intrapartum antibiotic prophylaxis as soon as possible if they have had a previous baby with an invasive group B streptococcal infection, or group B streptococcal colonisation, bacteriuria or infection in the current pregnancy.

Rationale

Intrapartum antibiotic prophylaxis for women who have had a previous baby with an invasive group B streptococcal infection, or group B streptococcal colonisation, bacteriuria or infection in the current pregnancy can prevent their newborn babies having an early-onset neonatal infection.

Quality measures

Structure

Evidence of local arrangements to ensure that pregnant women are offered intrapartum antibiotic prophylaxis as soon as possible if they have had a previous baby with an invasive group B streptococcal infection or group B streptococcal colonisation, bacteriuria or infection in the current pregnancy.

Process

a) Proportion of pregnant women offered intrapartum antibiotic prophylaxis if they have had a previous baby with an invasive group B streptococcal infection, or group B streptococcal colonisation, bacteriuria or infection in the current pregnancy.

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

Denominator – the number of pregnant women who have had a previous baby with an invasive group B streptococcal infection, or group B streptococcal colonisation, bacteriuria or infection in the current pregnancy.

Data source: Local data collection. Data can be collected using intrapartum antibiotics clinical audit tool audit standards 1 and2.

b) Proportion of pregnant women offered intrapartum antibiotic prophylaxis who receive it as soon as possible.

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

Denominator – the number of pregnant women offered intrapartum antibiotic prophylaxis.

Data source: Local data collection. Data can be collected using intrapartum antibiotics clinical audit tool audit standards 3a and 3b.

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 (secondary care services) ensure that systems and protocols are in place to enable intrapartum antibiotic prophylaxis to be offered as soon as possible to pregnant women who have had a previous baby with an invasive group B streptococcal infection, or group B streptococcal colonisation, bacteriuria or infection in the current pregnancy.

Healthcare professionals (including midwives and doctors) adhere to protocols and offer intrapartum antibiotic prophylaxis as soon as possible to pregnant women who have had a previous baby with an invasive group B streptococcal infection, or group B streptococcal colonisation, bacteriuria or infection in the current pregnancy.

Commissioners (clinical commissioning groups for secondary care) ensure that secondary care providers have systems and protocols in place for healthcare professionals to offer intrapartum antibiotic prophylaxis as soon as possible to pregnant women who have had a previous baby with an invasive group B streptococcal infection, or group B streptococcal colonisation, bacteriuria or infection in the current pregnancy.

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

Pregnant women who have had a previous baby with a type of infection known as group B streptococcal or who have this type of infection themselves are offered antibiotics as soon as possible.

Source guidance

- Antibiotics for early-onset neonatal infection (NICE clinical guideline 149), recommendation 1.3.1.1 (key priority for implementation).

Definitions of terms used in this quality statement

Intrapartum antibiotic prophylaxis

Intravenous benzylpenicillin is offered for intrapartum antibiotic prophylaxis, with the first dose given as soon as possible and continued until the birth of the baby.

If the woman is allergic to penicillin, clindamycin is offered unless individual group B streptococcus sensitivity results or local microbiological surveillance data indicate a different antibiotic. [Adapted from NICE clinical guideline 149, recommendations 1.3.1.2 and 1.3.1.5]

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

Quality statement

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

Process

Proportion of newborn babies who need antibiotic treatment who receive antibiotics 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 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 (secondary care services) ensure that systems and protocols are in place for antibiotic treatment to be started within 1 hour of the decision to treat.

Healthcare professionals (including midwives and doctors) adhere to protocols for antibiotic treatment to be started within 1 hour of the decision to treat.

Commissioners (clinical commissioning groups for secondary care) ensure that secondary care providers can demonstrate that systems and protocols are in place for antibiotic treatment to start within 1 hour of the decision to treat.

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

Babies who need antibiotic treatment receive it within 1 hour.

Source guidance

- Antibiotics for early-onset neonatal infection (NICE clinical guideline 149), recommendation 1.2.3.2 and 1.2.3.4 (key priorities for implementation).

Definitions of terms used in this quality statement

Newborn babies who need antibiotic treatment

In babes with any red flags, or with two or more ‘non-red flag’ risk factors or clinical indicators, perform investigations and start antibiotic treatment. Do not delay starting antibiotics pending test results.

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

[NICE clinical guideline 149, recommendation 1.2.3.2]

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

Quality statement

Newborn babies receiving antibiotic treatment based on risk factors and clinical indicators of early-onset neonatal infection have their antibiotic treatment reassessed 36 hours after starting treatment.

Rationale

Newborn babies should have their antibiotic treatment reassessed 36 hours after starting treatment to ensure that they are not receiving antibiotics unnecessarily. Reassessment (which will include the consideration of blood test results) will allow antibiotic treatment to be stopped if the clinical indications are that a baby does not have an infection. This will help to reduce the likelihood of antimicrobial resistance and improve the experience of the postnatal period for babies and their parents or carers.

Quality measures

Structure

Evidence of local arrangements to ensure that newborn babies receiving antibiotic treatment based on risk factors and clinical indicators of early-onset neonatal infection have their antibiotic treatment reassessed 36 hours after starting treatment.

Process

Proportion of newborn babies receiving antibiotic treatment based on risk factors and clinical indicators of early-onset neonatal infection who have their antibiotic treatment reassessed 36 hours after starting treatment.

Numerator – the number in the denominator who have their antibiotic treatment reassessed 36 hours after starting treatment.

Denominator – the number of newborn babies receiving antibiotic treatment based on risk factors and clinical indicators for early-onset neonatal infection.

Data source: Local data collection.

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

Service providers (secondary care services) ensure that healthcare professionals reassess antibiotic treatment 36 hours after treatment has started and ensure that systems and protocols are in place for blood culture results to be returned within 36 hours.

Healthcare professionals (including midwives and doctors) adhere to protocols and reassess antibiotic treatment 36 hours after starting treatment to determine whether it should be continued.

Commissioners (clinical commissioning groups for secondary care) ensure that secondary care providers can demonstrate that systems and protocols are in place that includes the availability of blood culture results within 36 hours so that antibiotic treatment can be reassessed 36 hours after treatment has started.

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

Babies being given antibiotic treatment are checked after 36 hours to see whether they need to continue having the treatment.

Source guidance

- Antibiotics for early-onset neonatal infection (NICE clinical guideline 149), recommendation 1.7.2.1 (key priority for implementation).

Definitions of terms used in this quality statement

Reassessing antibiotic treatment

In babies given antibiotics because of risk factors for infection or clinical indicators of possible infection, consider stopping antibiotics at 36 hours if:

- the blood culture is negative, and
- the initial clinical 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 trends of C-reactive protein concentration are reassuring. [NICE clinical guideline 149, 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 NICE clinical guideline 149, 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 before discharge are given verbal and written information about neonatal infection, including what to look for and who to contact if they are concerned.

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 to ensure rapid treatment if needed.

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 before discharge are given verbal and written information about neonatal infection, including what to look for and who to contact if they are concerned.

Data source: Local data collection.

Process

Proportion of parents or carers in whom early-onset neonatal infection has been a concern before discharge are given verbal and written information about neonatal infection, including what to look for and who to contact if they are concerned.

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

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

Data source: Local data collection.

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

Service providers (secondary care services) ensure verbal and written information about neonatal infection (including what to look for and who parents or carers can contact if they are concerned) is available and that healthcare professionals understand and act on the need to discuss neonatal infection with parents or carers of newborn babies for whom there have been concerns.

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

Commissioners (clinical commissioning groups for secondary care) specify that services have protocols in place to ensure that verbal and written information about neonatal infection is available. 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 soon after birth 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 (NICE clinical guideline 149), 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 who have any of the following risk factors or clinical indicators either before birth or during the first 72 hours after birth (items marked (red flag) should 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 (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 hyperflycaemia)
- metabolic acidosis (base deficit of 10 mmol/litre or greater)
- local signs of infection (for example, affecting the skin or eye).

[NICE clinical guideline 149, recommendation 1.1.1.1]

Information about neonatal infection

Verbal and written advice 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.

  [NICE clinical guideline 149, 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 about 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): Use of antibiotics in 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) is more prevalent 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. The appropriate use of antibiotics in late-onset neonatal bacterial infection will improve clinical outcomes for babies and reduce the likelihood of antimicrobial resistance in babies and neonatal units.

Question for consultation

Do you know of any relevant evidence-based guidance that could be used to develop this placeholder statement? If so, please provide details. If not, would new evidence-based guidance relating to use of antibiotics in late-onset neonatal infection have the potential to improve practice? If so, please provide details.

Status of this quality standard

This is the draft quality standard released for consultation from 1 July to 29 July 2014. It is not NICE's final quality standard on antibiotics for neonatal infection. The statements and measures presented in this document are provisional and may change after consultation with stakeholders.

Comments on the content of the draft standard must be submitted by 5pm on 29 July 2014. All eligible comments received during consultation will be reviewed by the Quality Standards Advisory Committee and the quality statements and measures will be refined in line with the Quality Standards Advisory Committee's considerations. The final quality standard will be available on the NICE website from December 2014.

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'.

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 on the NICE website.

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. NICE clinical guideline 149 (2012).

Policy context

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

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

Related NICE quality standards

Published

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

In development

- Feverish illness in children. Publication expected July 2014.

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:

- Intrapartum care
- Premature birth.

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

Dr Harry Allen
Consultant Old Age Psychiatrist, Manchester Mental Health and Social Care Trust

Mrs Claire Beynon
Head of Threshold Management and Individual Funding Requests, NHS South West Commissioning Support Unit

Dr Jo Bibby
Director of Strategy, The Health Foundation

Mrs Jane Bradshaw
Lead Nurse Specialist in Neurology, Norfolk Community Health and Care

Dr Allison Duggal
Consultant in Public Health, Public Health England

Mr Tim Fielding

Consultant in Public Health, North Lincolnshire Council

Mrs Frances Garraghan

Lead Pharmacist for Women's Health, Central Manchester Foundation Trust

Mrs Zoe Goodacre

Network Manager, South Wales Critical Care Network

Mr Malcolm Griffiths

Consultant Obstetrician and Gynaecologist, Luton & Dunstable University Hospital NHS Foundation Trust

Dr Jane Hanson

Head of Cancer National Specialist Advisory Group Core Team, Cancer National Specialist Advisory Group, NHS Wales

Ms Nicola Hobbs

Head of Contracts and Assurance Adult Social Care and Public Health Divisions, Leicester City Council

Mr Roger Hughes

Lay member

Mr John Jolly

Chief Executive Officer, Blenheim Community Drug Project, London

Dr Damien Longson (Chair)

Consultant Liaison Psychiatrist, Manchester Mental Health and Social Care Trust

Dr Rubin Minhas

GP Principal, Oakfield Health Centre, Kent

Mrs Julie Rigby

Quality Improvement Programme Lead, Strategic Clinical Networks, NHS England

Mr Alaster Rutherford

Primary Care Pharmacist, NHS Bath and North East Somerset

Mr Michael Varrow

Information and Intelligence Business Partner, Essex County Council

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:

Dr Jim Gray

Consultant Microbiologist, Birmingham Children's Hospital

Professor Paul Heath

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

Mrs Jane Plumb

Lay member

Dr Aung Soe

Consultant Neonatologist, Medway NHS Foundation Trust

Dr Mark Turner

Consultant Neonatologist, Liverpool Women's NHS Foundation Trust

NICE project team

Dr Dylan Jones

Associate Director

Dr Shirley Crashaw

Consultant Clinical Adviser

Mr Shaun Rowark

Lead Technical Analyst

Mr Tony Smith

Technical Adviser

Mrs Rachel Neary-Jones
Programme Manager

Mr Anthony Gildea
Project Manager

Mrs Jenny Mills
Co-ordinator

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 has been incorporated into the NICE pathway for [topic] [link to pathway(s)].

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.

Copyright

ISBN: