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CARE EXCELLENCE

Quality standards

Consultation summary report: Neonatal infection

Quality Standards Advisory Committee post-consultation meeting: 21 September 2023

1. Introduction

The draft quality standard for neonatal infection was made available on the NICE website for a 5-week public consultation period between 20 July and 24 August 2023. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 11 organisations, which included service providers, national organisations, professional bodies and others.

This report provides the quality standards advisory committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the committee as part of the final meeting where the committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the committee should read this summary alongside the full set of consultation comments, which are provided in appendix 1.

1. Questions for consultation

Stakeholders were invited to respond to the following general questions:

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

2. Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be to be for these to be put in place?

3. Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.

Stakeholders were also invited to respond to the following statement-specific questions:

4. For draft quality statement 1: For audit purposes, the quality statement supporting information states that the antibiotics should be given within 1 hour of the start of active labour, or within 1 hour of admission if the pregnant woman or pregnant person is already in active labour. Is this timescale appropriate and achievable?

5. For draft quality statements 2 and 3: The equality and diversity considerations for statement 2 and 3 note that central cyanosis may present differently depending on skin colour. Statement 3 also notes that other changes to skin colour can also be a symptom of neonatal infection, for example where the baby becomes very pale or dark yellow.

Are there resources or guides available for healthcare professionals that show how central cyanosis and other changes to skin colour related to neonatal infection may present on different skin colours? If so, could you please provide links to access them?

6. For draft quality statement 5: Babies in whom neonatal infection has been a concern has been defined based on expert opinion. Is this definition clear and useable?

1. General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

* Agreement that the quality standard reflects key areas for improvement.
* The quality standard does not mention viral or fungal infections, which can be serious in neonates. Suggestions to either note they are excluded or include them in the quality standard.
* Suggestion to define early- and late-onset neonatal infection in the introduction.
* Suggestion that neonatal morbidity, not just mortality, should be measured.
* Suggestion to ensure learning disability and autism are considered throughout the quality standard. This includes diagnostic overshadowing and reasonable adjustments.
* Comment that it is important for primary care to get a neonate with suspicion of infection to help quickly. Communication and access are key and these can be helped by digital means and reminders to frontline staff about the vulnerability of neonates and locality-specific signposting.

### Consultation comments on data collection (Consultation question 2)

* Stakeholder commented that for viral infections local systems and structures are in place to collect data for the proposed quality measures.
* Most relevant activity will occur outside primary care.
* Data for many of the proposed quality measures could be collected from electronic patient record systems. The main challenge is the workforce resource for data analysts and governance teams to facilitate data collection, analysis and drafting reports.

### Consultation comments on resource impact (Consultation question 3)

* The statements are achievable.
* It is unlikely that many of the statements are achievable because of limited governance team or data analysis capacity. Some measures, such as time to first antibiotics from decision to treat, are more easily achievable.

### Issues for consideration

#### For discussion:

* A suggestion has been made to include viral and fungal infections. The source guideline is NICE’s guideline on neonatal infection: antibiotics for prevention and treatment (NG195) which states that it covers bacterial infection. This can be added to the quality standard introduction.
1. Summary of consultation feedback by draft statement
	1. Draft statement 1

Pregnant women and pregnant people whose babies are at risk of early-onset neonatal infection are offered intrapartum antibiotics and given the first dose as soon as possible. **[2014, updated 2023]**

### Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

General

* Include a broader range of risk factors for neonatal infection such as maternal herpes simplex virus infection.
* Use ‘antimicrobials’ or ‘antibiotics or antivirals’ instead of antibiotics only.
* Note that not all at risk pregnant women and pregnant people would receive intrapartum antibiotics as this would depend on the risk factor.

Statement

* Include women and pregnant people in whom the need for antibiotic prophylaxis is only identified once labour is already well established.
* Suggestion to include ‘if the offer is accepted’ to the statement.

Rationale

* Suggestion to mention the significance, or not, of pre-labour rupture of membranes.
* Query on whether there is a common definition to define the start of active labour.

Measures

* Process a) denominator would be hard to accurately obtain (the number of pregnant women and pregnant people whose babies are at risk of early-onset neonatal infection.)
* Process b) reword to include those for whom the need for intrapartum antibiotics arises later than 1 hour of the start of active labour or 1 hour after admission if already in active labour.

Definitions

* Suggestions to amend definition of babies at risk of early-onset neonatal infection:
	+ add ‘has colonization with capsulated Escherichia coli in the birth canal’
	+ amend ‘rectovaginal swab samples’ to ‘rectal, vaginal, or rectovaginal swab samples’.
* Query on how the risk of early-onset neonatal infection is determined. Should the following additions be made to the definition:
	+ intrapartum fever higher than 38°C if there is suspected or confirmed bacterial infection
	+ confirmed rupture of membranes for more than 18 hours before a pre-term birth
	+ confirmed prelabour rupture of membranes at term for more than 24 hours before the onset of labour.
* Suggestion to amend definition of intrapartum antibiotics:
	+ change to ‘these are antibiotics given as soon as possible after labour starts and continued until the birth of the baby.’
	+ include the list of antibiotics that will be given, with a link to the guideline.

### Consultation question 4

For audit purposes, the quality statement supporting information states that the antibiotics should be given within 1 hour of the start of active labour, or within 1 hour of admission if the pregnant woman or pregnant person is already in active labour. Is this timescale appropriate and achievable?

Stakeholders made the following comments in relation to consultation question 4:

* The timeframe is appropriate and achievable.
* This depends on the antibiotics prescribed and if it is a stock item. If antibiotics need to be obtained from the pharmacy, 1 hour would not always be achievable.
* Suggestion to amend the statement to ‘as soon as possible and within one hour…’
* Suggestion to amend the statement to cover the timely administration of antibiotics for women who are identified as high risk at any time during labour.
* In primary care the achievement of this depends on how well the mother has been informed in terms of the onset of labour and the need to seek help. Access to shared care records or an electronic patient-held record would be helpful.

### Issues for consideration

#### For discussion:

* A suggestion has been made to include ‘within 1 hour’ in the quality statement. This is not in the guideline.

#### For decision:

* Suggestion for the statement and supporting information to include those whose need for intrapartum antibiotics is identified during labour. This population are already included. Should the supporting information state this more explicitly?
* Some amendments to the definitions have been suggested. The guideline recommendations have been used for these definitions. Should the suggested additions be made?
* We asked a consultation question about the 1 hour timescale for measurement purposes. Comments suggest this is achievable dependant on the antibiotics prescribed, as some may need to be obtained from pharmacy which would make this more difficult to achieve. Should the timescale be kept in the measure?
	1. Draft statement 2

Newborn babies are assessed for the risk factors and clinical indicators of early-onset neonatal infection. **[2014, updated 2023]**

### Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

General

* Use of the Kaiser Permanente calculator should be considered as this was introduced during COVID and many neonatal units use it, or a version of it.

Statement

* All babies are at risk of infection therefore the statement should state that an assessment should take place if the baby is at raised risk of infection.

Measures

* The numerator will be hard to ascertain and will also depend on the definition of ‘assessed for signs of infection’, eg NEWTT observations are done for a range of reasons so that could not be used as the numerator.
* From a quality of care view, it is more important to be aware of babies who should have been assessed and were not. It may be easier to look at cases where babies developed signs of infection and retrospectively review if there were risk factors that were overlooked.

Definitions

* Remove the different timescales for rupture of membranes from the risk factors definition to avoid confusion, as some people may not remember exact timings and units may have different definitions of prolonged rupture of membranes.
* Amend clinical indicators definition by adding the following to the other clinical indicators section: Laboratory evidence of abnormal level of CRP, procalcitonin and serum lactate.

Equality and diversity considerations (raised under statement 3 but apply to statements 2 and 3)

* Suggestion to add a line to highlight that pulse-oximeters are still more accurate for identifying low-oxygenation than a visual assessment alone.
* Query whether there are particular pulse-oximeters associated with overestimation of oxygen saturation levels in babies with dark skin.

### Consultation question 5

For draft quality statements 2 and 3: The equality and diversity considerations for statement 2 and 3 note that central cyanosis may present differently depending on skin colour. Statement 3 also notes that other changes to skin colour can also be a symptom of neonatal infection, for example where the baby becomes very pale or dark yellow.

Are there resources or guides available for healthcare professionals that show how central cyanosis and other changes to skin colour related to neonatal infection may present on different skin colours? If so, could you please provide links to access them?

Stakeholders suggested the following resources in response to consultation question 5:

* [Skin Deep](https://dftbskindeep.com/) by Don’t Forget the Bubbles website
* [Mind the Gap clinical handbook and web resource](https://www.blackandbrownskin.co.uk/mindthegap) written by M Mukwende, P Tamonv, M Turner from St Georges University of London
* [Symptom spotting on darker skin tones](https://www.bliss.org.uk/parents/about-your-baby/common-infectious-illnesses/symptom-spotting-darker-skin-tones.) by Bliss, produced with the Raham Project and Black Mums Upfront. This includes information and a visual for the detection of cyanosis, which uses images from Don’t Forget the Bubbles (above).
* [Meningitis and septicaemia symptoms](https://www.meningitis.org/meningitis/check-symptoms) by Meningitis Research Foundation has symptoms information detailing how to spot the characteristic non-blanching rash characteristic of meningococcal sepsis on darker skin tones. This notes that ‘The darker the skin, the harder it is to see a septicaemic rash, so check lighter areas like the palms of hands and soles of feet or look inside the eyelids and the roof of the mouth’.
* Joint Royal Colleges Ambulance Liaison Committee guidelines for ambulance crews have been [updated](https://aace.org.uk/jrcalc-updates-2019/medical-emergencies-in-adults-recognising-cyanosis-and-anaemia-in-darker-skin-tones/) to include recognition of cyanosis in darker skin in adults but not yet in children/babies.
* A stakeholder stated that they are not aware of a tool used in general practice but looking inside the mouth and comparing with a relative of the same skin colour would be reasonable for cyanosis, and comparing conjunctivae for anaemia or jaundice.

### Issues for consideration

#### For discussion:

* Use of the Kaiser Permanente calculator was discussed at the previous committee meeting. This was not included in the quality standard because the guideline states that this should only be used as part of a prospective audit.
* Stakeholder commented that the numerator is difficult to ascertain, suggesting retrospective review of cases where babies developed signs of infection and whether risk factors were overlooked.
* Some amendments to the definitions have been suggested. The guideline recommendations have been used for these definitions.

#### For decision:

* Note: consultation responses to question 5 relate to statements 2 and 3.
* Stakeholders have suggested some resources to signpost healthcare professionals in response to consultation question 5 regarding identification of changes to skin colour, including central cyanosis, and how this presents depending on the baby’s skin colour. Some wording has also been suggested regarding parts of the body to check for septicaemic rash.
* Stakeholders have suggested some additional information regarding pulse-oximeters to add to the equality and diversity considerations. Should this be added?
	1. Draft statement 3

Neonates who need antibiotic treatment for suspected neonatal infection receive it within 1 hour of the decision to treat. **[2014, updated 2023]**

### Consultation comments

General

* This was considered to be reasonable.
* For babies who become unwell outside an inpatient setting, this statement is less achievable, although the decision to treat is less likely to occur there as well.
* Primary care’s priority is recognition of the unwell baby and access to appropriate help which can be improved by parents having access and clinical sign information and timely, accurate discharge notes to primary care services.

Rationale

* Concern that the rationale wording may prevent antibiotics being administered in the community.

Measures

* Include morbidity to the outcome measures.

### Issues for consideration

#### For discussion:

* Note: consultation responses to question 5 relate to statements 2 and 3.
* A stakeholder asked if the 1 hour requirement will change in the updated NICE guideline on sepsis (NG51). This is not being changed.
* Whilst probably rare, is it possible that antibiotics for neonatal infection would be started outside secondary care? If so, some changes to the supporting information can be made to make this clearer.
	1. Draft statement 4

Neonates who start antibiotic treatment for suspected neonatal infection have their need for it reassessed at 36 hours for early-onset or at 48 hours for late-onset. **[2014, updated 2023]**

### Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

General

* Suggestion that the statement should give reassurance to clinicians on when antibiotic treatment can be safely stopped.

Statement

* Suggestion to simplify this to 36-48 hours for all neonatal infection.

Rationale

* Comment that early- and late-onset infections can be caused by the same bacteria. Suggestion to amend the wording to: The timescale for review is later for late-onset infection because these can be caused by bacteria that grow more slowly, and therefore it can take longer for a blood culture to become positive.

### Issues for consideration

#### For discussion:

* Supporting information for healthcare professionals states that if antibiotics are continued, the need for them is reassessed every 24 hours until they are stopped.
* Suggested amendment to rationale wording.
	1. Draft statement 5

Parents or carers of babies in whom neonatal infection has been a concern are given verbal and written information about neonatal infection before transfer to community care or before the midwife leaves after a home birth. **[2014, updated 2023]**

### Consultation comments

Stakeholders made the following comments in relation to draft statement 5:

General

* Confusion over use of ‘concern’ in statement and then ‘concerns’ in supporting information, suggesting there needs to have been more than one concern.
* National or regional information leaflets would be helpful as the lack of a standardised information leaflet for parents and carers on neonatal infection creates a challenge in implementing this statement.

Statement

* Suggestion that information should be provided to all parents and carers as all babies are at risk of developing an infection.

Audience descriptors

* Suggestion that the parents or carers section references that they are given information which includes information about skin-colour changes and how these might present on different skin colours.
* Suggestion to include health visitors in the healthcare professionals section.
* Suggestion that the service provider section states the information provided includes groups parents and carers can contact for information, as well as support.

Definitions

* Information about neonatal infection:
	+ more comprehensive written information should be provided to complement midwifery and neonatal advice
	+ suggestion include information on changes to skin colour in babies with non-white skin tones and to link to the [Bliss resource](https://www.bliss.org.uk/parents/about-your-baby/common-infectious-illnesses/symptom-spotting-darker-skin-tones.).

Equality and diversity considerations

* Written or verbal communication should be accessible for parents and carers, taking account of any reasonable adjustments that may be required, for example people with a sensory impairment who need information in BSL/braille and people with a learning disability who need an easy read format.

### Consultation question 6

Babies in whom neonatal infection has been a concern has been defined based on expert opinion. Is this definition clear and useable?

Stakeholders made the following comments in relation to consultation question 6:

* As it may not be clear what is meant by ‘’has been a concern’ the statement could read ‘Parents or carers of babies who are at increased risk of neonatal infection because of risk factors present before or after birth or where their baby has received antibiotics……’
* The definition states any clinical indicator of possible infection where the concern of risk of infection persisted following clinical review. Unclear why ‘where the concern persisted….’ is needed.
* The definition is clear if the person using it has the tables which identify the risk factors and clinical indicators of infection available. However, the scope is too narrow and misses babies that are unknowingly at risk (i.e, the mother carries GBS bacteria but is unaware).
* The definition is reasonable.

### Issues for consideration

#### For discussion:

* National or regional standardised information leaflets are outside the remit of quality standards.
* Suggestions to include all babies, not just those in whom neonatal infection has been a concern. This was discussed at the previous committee and was not included in the quality standard due to the existing quality statement in [NICE’s quality standard on postnatal care](https://www.nice.org.uk/Guidance/QS37) (QS37), statement 3: Parents are given information and advice, before transfer to community care or before the midwife leaves after a home birth, about symptoms and signs of serious illness in the baby that require them to contact emergency services. [2013, updated 2022]

#### For decision:

* Definition of babies in whom neonatal infection has been a concern. Based on stakeholder feedback, should the definition remain unchanged, be amended or should the quality statement be reworded?
* Suggestion to include additional detail about the information given to parents and carers regarding identification of skin-colour changes, dependant on the baby’s skin colour. Should this be added to the definition of information about neonatal infection?
1. Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

### Lumbar puncture

A suggestion was made to include quality statements on carrying out lumbar puncture for neonates that may have meningitis. This suggestion has not been progressed because it is within the remit of NICE’s quality standard on [meningitis (bacterial) and meningococcal septicaemia in children and young people](https://www.nice.org.uk/Guidance/QS19) (QS19). This quality standard will be undergoing a full update in 2023/24.

### Improved antibiotic prescribing and infection prevention in neonatal intensive care

A suggestion was made to include improved antibiotic prescribing and infection prevention in neonatal intensive care. These areas were considered during the Quality Standard Advisory Committee’s discussions when the quality standard was drafted. Quality statements 3 and 4 address some aspects of antibiotic prescribing. The committee noted the importance of the prevention of neonatal infection and that the majority of preventative factors are already in national guidance. The committee also recognised that there are no guideline recommendations specific to infection prevention and control for neonates. They did, however, note that areas such as catheter use are sufficiently covered by [NICE’s quality standard on infection prevention and control](https://www.nice.org.uk/guidance/qs61) (QS61).

### Access

A suggestion was made to include a broader statement about access. This has not been progressed as a specific area, however, equalities and health inequalities will continue to be considered by the Quality Standards Advisory Committee and by NICE during the development of the quality standard.

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# Appendix 1: Quality standard consultation comments table – registered stakeholders

| ID | Stakeholder | Section | Comments |
| --- | --- | --- | --- |
| General |
| 1 | Association of Paediatric Emergency Medicine  | General | We wondered whether neonatal morbidity should be measured, not just mortality? Important outcomes might be - antibiotic duration, length of stay, positive bacteriology in urine, CSF, blood etc, the need for critical care, and at least a 3 or 6 month follow up status |
| 2 | Bliss | General – briefing paper | On page 3 of the briefing paper – to be aware, the way neonatal services are commissioned are changing. They are moving from being commissioned directly by NHSE to being commissioned via ICBs. |
| 3 | Bliss | General – Equality Impact Assessment | It is welcome that further detail regarding skin-colour changes has been included & reflected in this document from the topic engagement stage. Since the topic engagement stage, the Race Health Observatory has published a [Review of neonatal assessment and practice in Black, Asian and minority ethnic newborns: Exploring the Apgar score, the detection of cyanosis, and jaundice](https://www.nhsrho.org/wp-content/uploads/2023/07/RHO-Neonatal-Assessment-Report.pdf)While they similarly highlight that medical devices like bilirubinometers or pulse-ox may not be as effective when used on babies with darker skin tones, their review does identify strongly that the use of these medical devices is much more accurate than a clinician making a visual assessment for skin colour changes. As such they recommend:1. Given poor visual detection of jaundice and cyanosis, particularly in Black and darker skin toned neonates, the following recommendations are made: * Cyanosis: Healthcare organisations should strongly consider use of pulse oximetry screening if there is any indication of concern over oxygenation. For this reason, the UK National Screening Committee should also strongly consider including routine pulse oximetry screening as a requirement within NIPE (the Newborn and Infant Physical Examination) to mitigate the health disadvantages experienced by those with darker skin tones.

It might be helpful to consider referencing this review and its recommendations in the Equality Impact Assessment, and within relevant sections of the Quality Standard? |
| 4 | British Infection Association  | General | The title of this standard is ‘infection’ yet there is no mention of viral or fungal infections, which can be serious in neonates. I suggest either mentioning these are excluded, including them, or adjusting the title. |
| 5 | Group B Strep Support  | General | In the Data Source sections for both a) and b) of the Quality Measures, we would ask why it states “Data can be collected from information recorded locally” rather than “Data must be collected from information recorded locally” (our emphasis)? Without collecting these data, audits won’t be possible. Please can this be amended to show that the Trust should or must collect these data? |
| 6 | Group B Strep Support  | General –Update information – page 26 | In About this quality standard, we’d like to see the language amended from “Taking account of safety, shared decision-making, choice and professional judgement, desired levels of achievement should be defined locally.” to “Taking account of safety, informed decision-making, choice and professional judgement, desired levels of achievement should be defined locally.”This better reflects current thinking and language used about decision-making and patient consent / informed choice. |
| 7 | NHS England | General | This quality standard is clear and concise. From a primary care perspective, getting a neonate with suspicion of infection to help rapidly enough is a prime consideration. This relies on many factors, but communication and access are key and both can be helped by digital means and well as reminders to all at the frontline about the vulnerability of the neonate and locality-specific signposting. (I suspect that we are better at signposting pregnant women but the same does apply). |
| 8 | NHS England Learning Disability and Autism Programme | General | We recommend including reference to the importance of Communication: Communicate with and try to understand the person you are caring for. Check with the person themselves, their family member or carer or their hospital or communication passport for the best way to achieve this. Use simple, clear language, avoiding medical terms and ‘jargon’ wherever possible. Some people may be non-verbal and unable to tell you how they feel. Pictures may be a useful way of communicating with some people, but not all. |
| 9 | NHS England Learning Disability and Autism Programme | General | A person with a learning disability and some autistic people may not be able to articulate their response to pain in the expected way: for example, they may say that they have a pain in their stomach when the pain is not there; may say the pain is less acute than you would anticipate; or not say they are in pain when they are. Some may feel pain in a different way or respond to it differently: for example, by displaying challenging behaviour; laughing or crying; trying to hurt themselves; or equally may become withdrawn or quiet. People who use a wheelchair may have chronic pain. Understanding what is ‘normal’ for that person by talking to |
| 10 | NHS England Learning Disability and Autism Programme | General | Be aware of diagnostic overshadowing: This occurs when the symptoms of physical ill health are mistakenly either attributed to a mental health or behavioural problem or considered inherent to the person’s learning disability or autism diagnosis. People with a learning disability or autism have the same illnesses as everyone else, but the way they respond to or communicate their symptoms may be different and not obvious.  |
| 11 | NHS England Learning Disability and Autism Programme | General | Pay attention to healthcare passports: Some people with a learning disability and some autistic people may have a healthcare passport giving information about the person and their health needs, preferred method of communication and other preferences. Ask the person or their accompanying carer if they have one of these. |
| 12 | NHS England Learning Disability and Autism Programme | General | We strongly suggest reference to making reasonable adjustments: This is a legal requirement as stated in the Equality Act 2010 and is important to help you make the right diagnostic and treatment decisions for an individual. You can ask the person and their carer or family member what reasonable adjustments should be made. Adjustments aim to remove barriers, do things in a different way, or to provide something additional to enable a person to receive the assessment and treatment they need. Possible examples include; allocating a clinician by gender, taking blood samples by thumb prick rather than needle, providing a quiet space to see the patient away from excess noise and activity.**We suggest that the quality statements refer to the importance of the Oliver McGowan Mandatory Training on learning disability and autism for staff.** The Oliver McGowan Mandatory Training on Learning Disability and Autism is the government’s preferred and recommended training for health and social care staff. Access the e:learning on: [The Oliver McGowan Mandatory Training on Learning Disability and Autism](https://portal.e-lfh.org.uk/Component/Details/781480). |
| 13 | St. George’s and UKHSA | General | Comprehensive document |
| 14 | UK National Screening Committee  | General | Could the document's box in pg 1 include definitions for early-onset and late-onset neonatal infections? |
| Question 1 |
| 15 | Association of Paediatric Emergency Medicine  | Question 1 | APEM members felt that the standards were reasonable and acceptable and follow current practice in our paediatric urgent and emergency care units. |
| 16 | Bliss | Question 1 | Yes, we agree this quality standards document does reflect key areas for quality improvement. |
| 17 | British Infection Association  | Question 1 | Virologists (CVN – Clinical Virology Network) partner’s comments:The standard has focused only on bacterial infections as causes of neonatal sepsis. Viral causes, for example herpes simplex virus infection and CMV, have been omitted. Mother to baby transmission of viral infections, for example adenovirus and enterovirus infections, should also be considered in unwell or septic neonates if there is a relevant maternal clinical history, in particular a woman with meningitis preceding labour for enterovirus infection. Disseminating a quality standard that focuses only on bacterial aetiologies risks under-diagnosis of these conditions, which has significant implications for neonatal morbidity and mortality. |
| 18 | Group B Strep Support  | Question 1 | This can only be answered by those responsible for local services. The draft quality standard reflects some key areas for quality improvement |
| 19 | Meningitis Research Foundation | Question 1 | We agree that all of the quality statements within this quality standard are important areas for quality improvement, but we would also like to see a statement in place which reflects the need for clinicians to carry out a lumbar puncture (LP) in neonates that may have meningitis. We are also of the opinion that the focus of quality statement 5 is far too narrow and should be expanded to all parents of newborns (see comment number 9) |
| 20 | Sheffield Teaching Hospitals NHS Foundation Trust | Question 1 | It would be clinically relevant and a useful QI project to review babies who receive “treatment” courses of antibiotics and if these meet the NICE guideline. If this could be shortened that would reduce length of stay and improve antimicrobial stewardship-both useful quality improvements. Alternatively looking that the antibiotic course has been considered every day (as per NICE guideline)-rather than sticking to a fixed course length irrespective of clinical status. Again this could reduce length of stay, antimicrobial stewardship and likely family experience. |
| Question 2 |
| 21 | Bliss | Question 2 | There are some mechanisms for reporting. The National Neonatal Audit Programme (NNAP) collects data on bloodstream infection after 72-hours of age. How this measure will be defined for 2023 data collection can be found here: <https://www.rcpch.ac.uk/sites/default/files/2023-06/2023_nnap_audit_measures_guide_v1.1_jun_23.pdf>  |
| 22 | British Infection Association  | Question 2 | Virologists (CVN – Clinical Virology Network) partner’s comments:We are only commenting on the virological aspects and local systems and structures are in place to collect data for the proposed quality measure involving considering and managing those viral infections. |
| 23 | Group B Strep Support  | Question 2 | This can only be answered by those responsible for local services. Data for many of the proposed quality measures could be collected from most of the various electronic patient record systems in use (e.g. Clevermed / BadgerNet, K2, Meditech, Cerner). The main challenge is the workforce resource: for data analysts and governance teams to facilitate data collection, analysis and drafting reports.  |
| 24 | NHS England | Question 2 | It is unlikely that primary care is the best source of this data since most relevant activity will occur outside that environment.  |
| Question 3 |
| 25 | Group B Strep Support  | Question 3 | This can only be answered by those responsible for local services. It is unlikely that many of the statements are achievable because of limited governance team / data analysis capacity. Some measures, e.g. time to first antibiotics from decision to treat, are more easily achievable. Data for such measures may be collected by clinicians conducting audits. As above, workforce resource would be required specifically for governance teams to facilitate data collection, and data analysts to support analysis to draft reports. |
| 26 | Sheffield Teaching Hospitals NHS Foundation Trust | Question 3 | Yes, they are achievable. Some national (or regional) parent information regarding suspected/confirmed neonatal sepsis would be useful and reduce multiple units producing documents. This would need to be available in multiple language formats and ideally electronically. |
| Question 7  |
| 27 | Group B Strep Support  | Question 7 | A challenge to implementing the NICE guidance may be the current lack of a standardised Patient Information leaflet given to parents/carers on early and late-onset neonatal infection, covering signs of infection in babies and when to escalate. The introduction of a leaflet would help facilitate the implementation of Quality Standard 5. An example of a Trust’s own leaflet can be found here:<https://www.liverpoolwomens.nhs.uk/media/4600/leaflet-my-baby-has-an-infection.pdf>  |
| 28 | Meningitis Research Foundation | Question 7 | There is a recommendation for clinicians to carry out an LP in neonates that may have meningitis, and we know that success rates on LP in neonates can be lower than for other age groups. A recent study found that holding babies in the sitting position was associated with higher success rates than when the procedure was performed with them lying down[[1]](#footnote-1). Having a quality standard on auditing rates of appropriate LPs in this age group with accompanying guidance on how best to perform the procedure could drive improved meningitis diagnosis in neonates. The importance of this is outlined in comment 1.In comment 9 we have outlined some of the challenges associated with implementing the guidance in terms of providing information and support to parents. We do not believe that quality statement 5 as it is currently worded addresses the recommendations in the guidance around information provision to parents (1.1.2, 1.1.5 and 1.1.12). To rectify this, we believe the scope of quality statement 5 should be expanded to reflect that all parents should be informed about the signs of neonatal infection. For this reason, it would be useful for there to be a universally available resource which alerts parents to the factors that puts their baby at increased risk, the clinical signs to look out for and contains advice on when and where to get help if they are worried about their baby. This resource could also have space within it for the treating clinician to specify why they believe this baby is at particularly increased risk in order to fully address the different level of information provision required in recommendations 1.1.5 and 1.1.12. It could also signpost out to the relevant charities for more information as they are well resourced to answer queries from the public. |
| 29 | NHS England | Question 7 | This quality standard highlights the importance of recognition and prioritisation of the unwell baby. I don’t know how well the new care navigation systems in General Practice do this but certainly, as we increasingly rely on these, neonatal age must be within the prioritisation/divert criteria for first contact services. Secondly the importance of suitable readily accessible information in terms of risk. Shared electronic records are particularly helpful given that first contact is usually now remote and so to look in a patient held paper record is not practical. Lastly public health messages tend to focus on adult emergencies, promoting use of apps for parents such as “healthier together” is useful in ensuring that parents have access to information quickly at all times.  |
| 30 | Sheffield Teaching Hospitals NHS Foundation Trust | Question 7 | No major issues in implementing the NICE guidance |
| Statement 1 |
| 31 | British Infection Association  | Quality statement 1 | Page 7:Babies who are at risk of early-onset neonatal infectionBabies are at risk of early-onset neonatal infection if the pregnant woman or pregnant person:* is in preterm labour, or
* has group B streptococcal colonisation, bacteriuria or infection during the current pregnancy, or
* has colonization with capsulated Escherichia coli in the birth canal, (to add)

Virologists (CVN – Clinical Virology Network) partner’s comments:* Pregnant women and pregnant people whose babies are at risk of early-onset neonatal infection are offered intrapartum antibiotics and given the first dose as soon as possible.
* Please consider the importance of viral neonatal infections: we would recommend to include a broader range of risk factors for neonatal infection such as maternal herpes simplex virus infection. In addition we would advise the use of the term “antimicrobials” or “antibiotics or antivirals” instead of antibiotics only.
 |
| 32 | Group B Strep Support  | Quality statement 1 – page 5 | “b) Proportion of pregnant women and pregnant people receiving intrapartum antibiotics who are given them within 1 hour of the start of active labour or 1 hour of admission if already in active labour.”We recognise this does not include people for whom the need for IAP arises later than 1 hour of start or labour or admission following identification of a clinical indicator (e.g. pyrexia). Suggest: “Proportion of pregnant women and pregnant people receiving intrapartum antibiotics who are given them within 1 hour of:* the start of active labour or
* admission if already in active labour or
* decision to treat following identification of clinical indicator if already in active labour and in hospital/birthing centre”

If this amend is accepted, this should also amend the definition used in the Data source and the Numerator, as well as the Definition of ‘As soon as possible’ for this QS. |
| 33 | Group B Strep Support  | Quality statement 1 – page 7 | In the Definitions section listed under Babies who are at risk of early-onset neonatal infection, we’d recommend amending “…rectovaginal swab samples…” to “rectal, vaginal, or rectovaginal swab samples” to make clear that this isn’t exclusively rectovaginal swab samples. |
| 34 | Group B Strep Support  | Quality statement 1– page 8 | In the Definitions section listed under Intrapartum antibiotics, we’d suggest mirroring the language used in NICE’s Guideline on Neonatal Infection in the Intrapartum Antibiotics definition to instead read “These are antibiotics given as soon as possible after labour starts and continued until the birth of the baby.”As it stands, it could be read as being attached to a drip throughout labour. |
| 35 | Group B Strep Support  | Quality statement 1 – page 8 | In the Definitions section under As soon as possible, we suggest listing the antibiotics that will be given, so Benzylpenicillin, Cephalosporin, Vancomycin (or one of these in combination with gentamicin plus metronidazole) as well as a link to the NICE guideline. |
| 36 | Meningitis Research Foundation | Quality statement 1 | As mentioned in comment number 4, we would like to see this statement also cover women in whom it has been identified would benefit from antibiotic prophylaxis once their labour is already well established. We would also like the statement to express more urgency by stating that antibiotics should be given as soon as possible and at least within 1 hour of the start of active labour, or within an hour of admission to hospital. Additionally, we would like the statement to cover the timely administration of antibiotics for women who are identified as high risk at any time during their labour. For example, women who develop fever during labour should also receive antibiotics as soon as possible and within an hour if they are identified as in need of these beyond 1 hour into their active labour. |
| 37 | Sheffield Teaching Hospitals NHS Foundation Trust | Quality statement 1 | Statement 1-not all at risk pregnant women would receive intrapartum antibiotics-it would depend on the risk factor (e.g. PROM) |
| 38 | Sheffield Teaching Hospitals NHS Foundation Trust | Quality statement 1 | The denominator for 1 would be difficult to be certain to have accurately obtained (depending on different unit’s EPR systems) |
| 39 | UK National Screening Committee  | Quality statement 1 | In Pg 5 ‘Quality statement’ please see suggestion in red Quality statementPregnant women and pregnant people whose babies are at risk of early-onset neonatal infection are offered intrapartum antibiotics and if the offer is accepted, given the first dose as soon as possible. [2014, updated 2023] Pg 5 Rationale section How is the risk of early-onset neonatal infection determined? Is this referring to the recommendation in Section 1.3 of the Neonatal infection: antibiotics for prevention and treatment NICE guideline [NG195] Published: 20 April 2021 or other guidance such as RCOG Green-top Guideline No. 36? Pg 5 b) Is there a common definition that will be used to define the start of active labour? Does there need to be a mention of the significance (or not) of pre-labour rupture of membranes specifically in this section’? |
| Question 4 |
| 40 | Group B Strep Support  | Question 4 | “…the antibiotics should be given within 1 hour of the start of active labour, or within 1 hour of admission if the pregnant woman or pregnant person is already in active labour”We would like to see this statement adjusted to include as soon as possible and within one hour in the definition. That sense of urgency is currently missed from the statement. The current wording inadvertently appears to suggest that up to an hour’s delay is acceptable.­We would also like to see this statement include that antibiotics should be given as soon as possible after the decision to treat when that decision to treat is made more than 1 hour after labour has started or admission to hospital, e.g. if the woman or birthing person develops a fever in labour. This situation is missed out of the statement as it stands. Just a comment – we are concerned that, what a woman may understand as being in “active labour” and the medical definition of active labour, are not always the same. Members of our Medical Advisory Panel have seen this in their practice, which has resulted in IAP being administered <4 hours before birth, which has been particularly upsetting for parents when their baby develops infection. We suggest: “the antibiotics should be given as soon as possible after (and within a maximum of 1 hour of) * the start of active labour
* admission if the pregnant woman or pregnant person is already in active labour
* the decision to treat if the pregnant woman or pregnant person is already admitted or in active labour”

We think this better reflects the guideline and will help ensure more people are given IAP for at least 4 hours before birth, which is beneficial in preventing early-onset GBS infection. We would like to see these adjustments in all the places in the QS where the previous version is used. |
| 41 | Meningitis Research Foundation | Question 4 | Yes, MRF are of the opinion that the statement antibiotics should be given within 1 hour of the start of active labour, or within 1 hour of admission is both appropriate and achievable. We are also of the opinion that the statement could go further by stating that antibiotics should be given as soon as possible and at least within 1 hour of the start of active labour or within 1 hour of admission.Additionally we would like the statement to cover the timely administration of antibiotics for women who are identified as high risk at any time during their labour. For example, women who develop fever during labour should also receive antibiotics as soon as possible and within an hour if they are identified as in need of these beyond 1 hour into their active labour. |
| 42 | NHS England | Question 4 | In primary care the achievement of this depends on how well the mother has been informed in terms of the onset of labour and the need to seek help. It is likely that a healthcare professional in primary care will refer/signpost to intrapartum services, but they will not necessarily appreciate the risk or urgency without additional information that may lie in the patient-held record but is unlikely to be held/accessible in General Practice or urgent care records. Access to shared care records or an electronic “patient-held” record would be helpful.  |
| 43 | Sheffield Teaching Hospitals NHS Foundation Trust | Question 4 | Yes - assuming it is clinically appropriate to start the antibiotics |
| 44 | UK National Screening Committee  | Question 4 | Pg 8 Question for consultationIt would depend on the antibiotics prescribed and whether it is a stock item or not. If the antibiotics need to be obtained from the pharmacy, then 1 hour would not be achievable in all cases. Also, does there need to be consideration of the time taken for babies who are at home and need to be transferred in for treatment/should/expectation of treatment starting in the community/availability of drugs? |
| Statement 2 |
| 45 | Association of Paediatric Emergency Medicine  | Quality statement 2 | The source material states separate risk factors being 'confirmed prelabour rupture of membranes at term for over 24hrs before start of labour' and ‘confirmed rupture of membranes for more than 18 hours before a preterm birth’.1. We feel that individual units may have different definitions of prolonged rupture of membranes (PROM), such as the more simple for the emergency department situation: ‘rupture of membranes > 24 hours’. We wondered that many parents may not recall when labour started which could lead to confusion. We note that guidance on PROM seems variable.
2. We wondered if the difference between 18 and 24 hours of ROM depending on the gestation may overcomplicate a time-critical situation in the emergency department environment, especially as stated before that parents may not be able to recall exact timings, particularly under stress.
3. We wondered at the difference between the definitions, one being ‘before the start of labour’, and the other ‘before a (preterm) birth’. Is this intentional and based on national / international criteria?

Is there a reason why this could not be clarified or simplified for the non-neonatal unit acute hospital setting? |
| 46 | Bliss | Quality statement 2 | It is welcome to see the additions to the ‘Equality and diversity considerations’ regarding identification of cyanosis in babies with darker skin tones. The section notes that it’s important for HCPs to understand how to identify skin-colour changes and where on the body to look for these. We’d suggest including a brief description and sign-posting to resources from here. For example, cyanosis might be more obvious on the lips, tongue and gums, under the nails and around the eyes. If a specific HCP-facing resource is not available, we’d suggest sign-posting to the information produced by Bliss referenced in the comments above, and the Don’t Forget the Bubbles website. |
| 47 | British Infection Association  | Quality statement 2 | Page 12:Other 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 (including grunting, recession, tachypnoea)
* hypoxia (for example, central cyanosis or reduced oxygen saturation level)
* persistent pulmonary hypertension of newborn babies
* jaundice within 24 hours of birth
* signs of neonatal encephalopathy
* temperature abnormality (less than 36°C or more than 38°C) unexplained by environmental factors
* unexplained excessive bleeding, thrombocytopenia, or abnormal coagulation
* altered glucose homeostasis (hypoglycaemia or hyperglycaemia)
* metabolic acidosis (base deficit of 10 mmol/litre or more).

Laboratory evidence of abnormal level of CRP, procalcitonin and serum lactate (to add) |
| 48 | Group B Strep Support  | Quality statement 2 – page 9 | In the Quality statement section: all babies are at risk of infection, so we suggest amending “Newborn babies have an assessment to check if they are at risk of infection.” to “Newborn babies have an assessment to check if they are at raised risk of infection.” |
| 49 | Group B Strep Support  | Quality statement 2 – page 12 | In the Equality and diversity considerations section, we recommend signposting to additional resources here. Suggest Bliss resource: <https://www.bliss.org.uk/parents/about-your-baby/common-infectious-illnesses/symptom-spotting-darker-skin-tones>  |
| 50 | Sheffield Teaching Hospitals NHS Foundation Trust | Quality statement 2 | The numerator here will be hard to ascertain. It will also depend on the definition of “assessed for signs of infection”. For example NEWTT obs are done for a range of reasons, not just suspected infection so that could not be used as the numerator.From a quality of care viewpoint, it is more important to be aware of babies who should have been assessed and were not – i.e. those who subsequently had or were suspected to have sepsis and if they should have been assessed earlier due to risk factors (see comment for Q2) |
| 51 | Sheffield Teaching Hospitals NHS Foundation Trust | Quality statement 2 | Statement 2 is vague -“assessed for signs of infection”- does this mean NEWTT obs, or a medical review? It would be hard to audit-it might be easier to look at cases where babies developed signs of infection and retrospectively review if there were antenatal risk factors that had been overlooked. |
| 52 | St. George’s and UKHSA | Quality statement 2 | The use of the Kaiser Permanente calculator should be considered as this was introduced during COVID and many neonatal units have since either adopted or adapted it. |
| Question 5 |
| 53 | Association of Paediatric Emergency Medicine  | Question 5 | We know of two excellent resources for healthcare professionals to help them recognise skin changes related to neonatal infection on different skin colours. * Skin Deep by Don’t Forget the Bubbles website. Additional resources provided within the website. Available from: <https://dftbskindeep.com/>
* Mind the Gap clinical handbook and web resource written by M Mukwende, P Tamonv, M Turner from St Georges University of London. Available from: <https://www.blackandbrownskin.co.uk/mindthegap>
 |
| 54 | Bliss | Question 5 | In terms of resources for how cyanosis and other infections present on darker skin-tones, we are aware of:* Bliss information produced with the Raham Project and Black Mums Upfront. This includes information and a visual for the detection of cyanosis: <https://www.bliss.org.uk/parents/about-your-baby/common-infectious-illnesses/symptom-spotting-darker-skin-tones> This is aimed primarily at parents, but the images may be useful for HCPs, and this could be a useful resource for HCPs to share with parents.
* Don’t Forget the Bubbles Skin Deep Project has compiled a library of various conditions, demonstrating how they present on different skin-tones: <https://dftbskindeep.com/> The images from this website were also used in the information produced by Bliss, the Raham Project and Black Mums Upfront.
 |
| 55 | Group B Strep Support  | Question 5 | Regarding additional resources available for healthcare professionals showing how changes to skin colours related to neonatal infection may present on different skin colours, Bliss have partnered with Black Mums Upfront and the Raham Project to create a guide for spotting symptoms of common infectious illnesses on babies and children with Black, Brown and darker skin tone. This includes cyanosis and rashes and can be found here: <https://www.bliss.org.uk/parents/about-your-baby/common-infectious-illnesses/symptom-spotting-darker-skin-tones>. |
| 56 | Meningitis Research Foundation | Question 5 | The charity Bliss have recently produced a helpful resource helping people to identify infectious symptoms such as cyanosis and certain rash types on darker skin tones which can help spot symptoms from a range of infections <https://www.bliss.org.uk/parents/about-your-baby/common-infectious-illnesses/symptom-spotting-darker-skin-tones>. MRF also produce symptoms information detailing how to spot the characteristic non-blanching rash characteristic of meningococcal sepsis on darker skin tones. In our symptoms information we point out that “The darker the skin, the harder it is to see a septicaemic rash, so check lighter areas like the palms of hands and soles of feet or look inside the eyelids and the roof of the mouth” <https://www.meningitis.org/meningitis/check-symptoms>  |
| 57 | NHS England | Question 5 | JRCALC (see link) guidelines for ambulance crews have been [updated](https://aace.org.uk/jrcalc-updates-2019/medical-emergencies-in-adults-recognising-cyanosis-and-anaemia-in-darker-skin-tones/) to include recognition of cyanosis in darker skin in adults but not yet in children/babies. I don’t know of any tool in General Practice although the general principles of looking inside the mouth and comparing with relative/friend of the same skin colour if in doubt would be reasonable to expect for cyanosis (and comparing conjunctivae with regard to anaemia/jaundice).  |
| 58 | Sheffield Teaching Hospitals NHS Foundation Trust | Question 5 | Unaware of any resources. |
| Statement 3 |
| 59 | Association of Paediatric Emergency Medicine  | Quality statement 3 | We feel that this is a reasonable expectation. Is this recommendation likely to change in the updated version of NG51: Sepsis: recognition, diagnosis and early management? |
| 60 | Bliss | Quality statement 3 | Please see comments in Statement 2 regarding signposting which are applicable here.In addition: ‘’It is also important that healthcare professionals are aware that some pulse oximeters can overestimate oxygen saturation levels in babies with dark skin, especially if the saturation level is borderline. ‘’In line with the findings and recommendations from the RHO report referenced in comment 1, we’d recommend including an additional line after this sentence to highlight that pulse-oximeters are still more accurate for identifying low-oxygenation than a visual assessment alone and so should be used if there are any concerns about oxygenation.  |
| 61 | Group B Strep Support  | Quality statement 3 – page 13 | In the Rationale section, we are concerned that this description may prevent antibiotics being adminstered in the community if someone qualified can make the decision to do that and can administer them. We appreciate this may be an unusual situation but would like to see this addressed.  |
| 62 | Group B Strep Support  | Quality statement 3 – page 13 | In Outcome, we recommend including morbidity, so this becomes “Neonatal mortality and morbidity because of neonatal infection.” |
| 63 | Group B Strep Support  | Quality statement 3 – page 17 | Under Equality and diversity considerations – it’s great to see a reference to pulse oximeters and darker skin tones, as this will raise important awareness among health professionals. Are there further resources or protocols to signpost health professionals to for more information or support and, if so, can links be added please?? |
| 64 | Group B Strep Support  | Quality statement 3 – page 18 | Under Question for consultation, consider linking to Bliss resource for spotting symptoms of common infectious illnesses on babies and children with Black, Brown and darker skin tone. <https://www.bliss.org.uk/parents/about-your-baby/common-infectious-illnesses/symptom-spotting-darker-skin-tones> |
| 65 | NHS England | Quality statement 3 | We have noted the statement, “It is also important that healthcare professionals are aware that some pulse oximeters can overestimate oxygen saturation levels in babies with dark skin, especially if the saturation level is borderline.”Could this be expanded i.e. are there particular pulse oximeters associated with these findings. We have reviewed the citation in the fuller briefing paper which is as follows: “Be aware that some pulse oximeters can underestimate or overestimate oxygen saturation levels, especially if the saturation level is borderline. Overestimation has been reported in people with dark skin. See also the [NHS England Patient Safety Alert on the risk of harm from inappropriate placement of pulse oximeter probes](https://gbr01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.england.nhs.uk%2F2018%2F12%2Frisk-of-harm-from-inappropriate-placement-of-pulse-oximeter-probes%2F&data=05%7C01%7Cfreddie.drew%40nhs.net%7C3f3ae840d80b482e9c2608db9febd073%7C37c354b285b047f5b22207b48d774ee3%7C0%7C0%7C638279607376260357%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=TGb70PTuvfMiPjJBvjW2HbowI%2Fw6XwSOtHTIWh%2BtnXM%3D&reserved=0).” – however the patient safety alert doesn’t mention the use of pulse oximeters on different skin tones at all, but rather focuses on the risk of misplacement of finger probes on ears, and vice versa. Could a citation be provided which links to the statement relating to overestimate of oxygen levels.” |
| 66 | NHS England | Quality statement 3 | For babies who become unwell outside an inpatient setting Statement 3 is less achievable, although the decision to treat is less likely to occur there as well. The priority in primary care is recognition of the unwell baby and access to appropriate help. This can be improved by ensuring that all parents have relevant access and clinical sign information, the discharge note to primary care services is timely, accurate and highlights all points of note including risk factors for infection and first point of contact healthcare staff know to prioritise assessment of neonates.  |
| 67 | UK National Screening Committee  | Quality statement 3 | Pg 13 Outcomes please see suggestion in red: Reduction in Neonatal mortality because of neonatal infection.  |
| 68 | UK National Screening Committee  | Quality statement 3 | Also, does there need to be consideration of the time taken for babies who are at home and need to be transferred in for treatment/should/expectation of treatment starting in the community/availability of drugs? |
| Statement 4 |
| 69 | Association of Paediatric Emergency Medicine  | Quality statement 4 | We wondered if there was a reason why the timing for reassessing antibiotic therapy couldn’t be simplified to ‘36-48 hours’ for all? The British Society for Antimicrobial Chemotherapy Paediatric Pathways advises this in their ‘Febrile Infant Aged < 90 Days’ pathway available at <https://bsac.org.uk/paediatricpathways/>Is there evidence for separating the two out, other than anecdotal for the likely infecting bacteria?  |
| 70 | Group B Strep Support  | Quality statement 4 – page 19 | In Rationale, early and late-onset infections can be caused by the same bacteria (eg GBS). We therefore recommend amending “The timescale for review is later for late-onset infection because it is caused by different bacteria” to read “The timescale for review is later for late-onset infection because these can be caused by bacteria that grow more slowly, and therefore it can take longer for a blood culture to become positive.”  |
| 71 | Group B Strep Support  | Quality statement 4 | We would like to see more emphasis on when antibiotic treatment can be safely stopped, for example, QS 4 should give considerable reassurance to clinicians. |
| Statement 5 |
| 72 | Bliss | Quality statement 5 | ‘’What the quality standard means for different audiences’’ - could the parents or carers section of this specifically reference that they are given information which includes information about skin-colour changes and how these might present on babies with Black, Brown or darker skin tones?Please see comments in Statement 2 regarding additional information and signposting which are applicable here. We’d recommend that signposting to the parent information resource created by Bliss, the Raham Project and Black Mums Upfront is listed as a resource HCPs can share with parents and carers as part of these discussions.  |
| 73 | Group B Strep Support  | Quality statement 5 – page 22 | We are very pleased to see that providing information to parents and carers of babies at transfer/as a midwife leaves after home birth is included here. We know from calls to our helpline that families are unclear what the potential signs of serious infection in babies are, and what action to take. Providing such information to parents and carers of babies will help them by empowering them to escalate their concerns if the baby is showing signs of infection. Early identification and treatment improves outcomes – saving lives and preventing disability.  |
| 74 | Group B Strep Support  | Quality statement 5 – page 22 | In Quality statement - we would like to see this information provided to all parents and carers of babies on transfer/ discharge/ before a midwife leaves after a home birth since all babies are at risk of developing infection. For example, GBS carriage in pregnancy is a risk factor for a baby developing early and late-onset GBS infection, However, many birthing people unknowingly carry GBS (it is not routinely tested for in pregnancy in the UK) and their babies will be at raised risk of developing infection. Providing this information to all parents and carers will contribute to the prompt escalation and treatment of all babies who develop neonatal infection. Providing this information to all parents and carers would, we think, be easier than just to a subsection – it's less likely to be missed if everyone should receive it. We would recommend this is amended to "Ensure that all parents and carers of all babies are provided with verbal and written information about neonatal infection before transfer to community care or before the midwife leaves after a home birth.”This would then need to be reflected throughout QS 5 and its subsections. |
| 75 | Group B Strep Support  | Quality statement 5 – page 22 | In Quality statement - If it is to be included, we would like to see more clarity over what defines ‘concern’ in “babies in whom neonatal infection has been a concern” – this would be in the Quality Statement, the Quality measures ‘Process’ section, in the ‘What the quality statement means for different audiences’ section. We note that the language changes later in this QS from concern to “where there have been concerns about neonatal infection," suggesting there needs to be multiple concerns for a parent/carer to receive information about neonatal infection. |
| 76 | Group B Strep Support  | Quality statement 5 – page 23 | In the Service providers section, we would like to see health visitors included in the audience list for healthcare professionals. |
| 77 | Group B Strep Support  | Quality statement 5 – page 23 | In the Service providers section, we recommend amending the final sentence to “The information should also include information on organisations and groups they can contact if they need information or support.” |
| 78 | Group B Strep Support  | Quality statement 5– page 24 | In Information about neonatal infection we are concerned that more comprehensive written information should be provided to complement midwifery and neonatal advice. GBSS has a number of leaflets and information sheets that are available to use for both health professionals and for families. We suggest this paragraph is added:Parents and carers should be provided with information about neonatal infection that they can easily read and understand themselves, or with support, so they can communicate effectively with health care services. Information should be in a format that suits their needs and preferences. It should be accessible to people who do not speak or read English, and it should be culturally appropriate. People should have access to an interpreter or advocate if needed. |
| 79 | Group B Strep Support  | Quality statement 5 – page 24 | In Definitions of terms used in this quality statement, in the Information about neonatal infection section, we recommend amending the penultimate bullet point to include information on changes in skin colour in babies with non-white skin tones <https://www.bliss.org.uk/parents/about-your-baby/common-infectious-illnesses/symptom-spotting-darker-skin-tones>. |
| 80 | Group B Strep Support  | Quality statement 5 | A challenge to implementing the NICE guidance may be the current lack of a standardised Patient Information leaflet given to parents/carers on early and late-onset neonatal infection, covering signs of infection in babies and when to escalate. The introduction of a leaflet would help facilitate the implementation of Quality Standard 5. An example of a Trust’s own leaflet can be found here: <https://www.liverpoolwomens.nhs.uk/media/4600/leaflet-my-baby-has-an-infection.pdf>  |
| 81 | Meningitis Research Foundation | Quality statement 5 | Within the guidance there are recommendations for parents to receive different levels of information about neonatal infection depending on their circumstances. For example:* point 1.1.2 recommends talking to parents about concerns as soon as they arise and explaining what neonatal infection is,
* point 1.1.5 recommends informing parents and the GP if babies are considered to be at increased risk of infection,
* point 1.1.12 recommends that before any baby is transferred home from the hospital, midwifery led unit (or in the immediate post-natal period in the case of babies born at home) parents and carers should be advised to seek urgent medical help if certain symptoms arise.

The way that quality statement 5 is currently worded means that it doesn’t fully address any of the above recommendations in their entirety. It most closely audits recommendation 1.1.5, but does not address informing the GP and seems to stand outside of the current recommendations in the guidance. For example, the definition of “babies in whom neonatal infection has been a concern” does not exist in the guidance, only in the quality standard which implies that the quality statement lies outside of the guidance as it currently stands. Due to this lack of consistency between the guidance and quality statement 5, we believe that it will be very hard to measure both the numerator and the denominator for this quality statement.MRF strongly believe that it is vital for all parents of newborns to be aware of the signs and symptoms of neonatal infection and know when to seek help. Time and again we hear from bereaved parents saying they wish that a medical professional would have told them at some point during their pregnancy, labour or subsequent delivery about the risk of neonatal infection, the signs to look for in their baby and when to seek help.All neonates are at a considerably higher risk of infection than other age groups. Analysis of UK surveillance network data from 2005 to 2014 indicated the incidence of infection to be 6.1/1000 live births[[2]](#footnote-2). These are much higher rates than for diseases we immunise against, so whilst no vaccine is currently available that prevents the bulk of these infections and considering the extremely low cost associated with simply providing parents with life saving symptoms information, it seems logical to simply provide this information to every parent of a newborn and for this to be the focus of quality statement 5. Whilst we agree with the sentiment that for parents of babies whom are deemed to be of concern these messages should be particularly emphasised, we should also remember that it is simply not possible to identify every baby that is at increased risk, so in order to catch everyone, the quality statement should ensure that information is provided to all. For example, we know that GBS colonisation increases the risk to the newborn, but seeing as no routine screening is carried out it is impossible to identify these carriers. It will be important for the parents of these unborn babies who are at increased risk to be able to know the signs of neonatal infection the same as it would for parents of babies who have identifiable risk factors. Development of a universal resource to provide to all parents with a section that can be filled in by the treating clinician indicating why they believe a particular baby to be at particular risk would be helpful for informing all parents and those with babies deemed to be of particular concern. (see comment number 6).A secondary benefit of increasing awareness of the risks of neonatal infections in new parents could also be increased acceptability among pregnant people for new vaccines or screening interventions that can help prevent infections such as GBS.The guidance itself points out that “parents and carers have the right to be involved in planning and making decisions about their baby's health and care, and to be given information and support to enable them to do this”. Providing information to everyone about the risks of neonatal infection, what to look for, and where to get help and support alongside auditing whether this has been done is key to better outcomes in these and future babies and increasing awareness in the population as a whole. |
| 82 | Meningitis Research Foundation | Quality statement 5 | Meningitis Research Foundation (MRF) believe that if quality statement 5 was broadened to all parents rather than just parents with babies deemed to be at higher risk, then less resource would be required to both monitor and achieve high compliance with the quality statement. It is easier to simply provide information to and empower all parents by educating them on the risk factors, signs and symptoms of infection in babies rather than trying to identify babies deemed to be at higher risk and only providing information to those parents. There is also a strong rational which aligns with the current guideline for providing information to all parents (see comment 9)  |
| 83 | Meningitis Research Foundation | Quality statement 5 | We are pleased to see that quality statement 5 has been expanded to consider providing information to parents of babies born outside of the hospital setting. |
| 84 | NHS England | Quality statement 5 | In general, yes although given current concerns about access, condition urgency and that any neonate is theoretically at risk, I wonder whether all parents of neonates should be given verbal and written information before leaving the birthing centre/the midwife leaves from a home birth.  |
| 85 | NHS England Learning Disability and Autism Programme | Quality statement 5 | Quality Statement 5- consideration should be made to ensure any written or verbal communication is accessible for parents. This should take account of any translation or reasonable adjustments that may be required for parents where English is not a first language, and for disabled parents, such as those who have a sensory impairment and may need information in BSL/braille, or those parents with a learning disability and require an easy read format. |
| 86 | Sheffield Teaching Hospitals NHS Foundation Trust | Quality statement 5 | Yes, they are achievable. Some national (or regional) parent information regarding suspected/confirmed neonatal sepsis would be useful and reduce multiple units producing documents. This would need to be available in multiple language formats and ideally electronically. |
| 87 | UK National Screening Committee  | Quality statement 5 | Pg 22 ProcessDenominator – the number of neonates in whom neonatal infection has been a concern. Should this refer to all babies? Not sure how consistency can be achieved by 'has been a concern'. Also if the target is to reduce late onset as well- then the denominator needs to be all newborn babies. |
| Question 6 |
| 88 | Bliss | Question 6 | The wording of this statement could be amended for clarity. It may not be clear what is meant by ‘'has been a concern’’. An amended version could read:‘’Parents or carers of babies who are at increased risk of neonatal infection because of risk factors present before or after birth or where their baby has received antibiotics, are given verbal and written information about neonatal infection before transfer to community care or before the midwife leaves after a home birth.’’ |
| 89 | Group B Strep Support  | Question 6 | * Babies in whom neonatal infection has been a concern has been defined based on expert opinion
* By definition (page 24), this includes any baby who has had:

any clinical indicator of possible infection “where the concern of risk of infection persisted following clinical review” We feel the definition is clear and useable, though we are unclear why the qualification of ‘where the concern of risk of infection persisted following clinical review” is necessary. We have concerns that, while most parents may be given verbal advice, very few parents are given written advice. |
| 90 | Meningitis Research Foundation | Question 6 | Babies in whom neonatal infection has been a concern are identified as “any baby who has had:* any of the risk factors for neonatal infection or
* any clinical indicator of possible infection where the concern of risk of infection persisted following clinical review or
* antibiotics for suspected or confirmed infection.”

Whilst this definition is clear if you have all the tables to hand which identify the risk factors and clinical indicators of infection, we argue that the scope is too narrow and misses babies that are unknowingly at risk (i.e, the mother carries GBS bacteria but is unaware). The need for identifying “babies of concern” in order to provide parents with information about neonatal infection also seems to contradict the current guidance point 1.1.12 which recommends that before any baby is transferred home from the hospital, midwifery led unit (or in the immediate post-natal period in the case of babies born at home) parents and carers should be advised to seek urgent medical help if certain symptoms arise (therefore implying that all parents should be given information about neonatal infection) Please see comment 9 for more details. |
| 91 | NHS England | Question 6 | This is clear and useable, for primary care, communication of risk is important.  |
| 92 | Sheffield Teaching Hospitals NHS Foundation Trust | Question 6 | This is reasonable- interpreting this as any baby who has clinical signs of sepsis or there have been antenatal risk factors |
| 93 | UK National Screening Committee  | Question 6 | Pg 25 Question for consultationBabies in whom neonatal infection has been a concern has been defined based on expert opinion. Is this definition clear and useable?Our opinion is that ‘Has been a concern’ is unclear but it can be made clearer by ‘has been a concern as defines as……...’ |
| Additional areas |
| 94 | Meningitis Research Foundation | Additional areas | We would also like to see a statement in place which reflects the need for clinicians to carry out a lumbar puncture (LP) in neonates that may have meningitis. Page 60 of the guidance recommends that if it is safe to do so, a lumbar puncture should be performed when there is a strong clinical suspicion of early-onset neonatal infection or when there are clinical symptoms or signs suggesting meningitis. Obtaining a sample of cerebrospinal fluid (CSF) by performing an LP is essential for diagnosing a case of meningitis and treating with the correct antibiotics for the appropriate timeframe. Additionally, being able to rule out a case of meningitis by performing LP can reduce the amount of time that an infant is given antibiotics and therefore improve antimicrobial stewardship. A meningitis diagnosis is associated with severe long term after effects in as many as 29% of survivors[[3]](#footnote-3), with higher rates of long term neurological after-effects compared to neonatal sepsis[[4]](#footnote-4),[[5]](#footnote-5). A confirmed diagnosis is also important for improved access to support, ongoing follow up and aftercare for any potential future problems the child may go on to develop.Measurement of both the numerator and the denominator if such a quality standard were to be included would be very achievable. Data can be collected from information recorded locally by healthcare professionals and provider organisations, such as from patient records. |
| 95 | Meningitis Research Foundation | Additional areas | In response to consultation question 7:There is a recommendation for clinicians to carry out an LP in neonates that may have meningitis, and we know that success rates on LP in neonates can be lower than for other age groups. A recent study found that holding babies in the sitting position was associated with higher success rates than when the procedure was performed with them lying down[[6]](#footnote-6). Having a quality standard on auditing rates of appropriate LPs in this age group with accompanying guidance on how best to perform the procedure could drive improved meningitis diagnosis in neonates. The importance of this is outlined in comment 1. |
| 96 | NHS England | Additional areas | In general, yes although given current concerns about access, condition urgency and that any neonate is theoretically at risk, I wonder whether all parents of neonates should be given verbal and written information before leaving the birthing centre/the midwife leaves from a home birth. I also wonder whether a broader quality standard about access would be reasonable?  |
| 97 | UK Health Security Agency | Additional areas | A key area for quality improvement in neonatal infections is that of improved antibiotic prescribing and infection prevention in neonatal intensive care. Antibiotic exposure in early life is associated with poor health outcomes such as obesity and atopy (PMID: 33208243) and neonatal units carry a high burden of antimicrobial resistant bacteria, contributing to the already high morbidity and mortality in this age group. |
| No comments |
| 98 | British Society for Antimicrobial Chemotherapy | N/A | Thank you for your invitation to comment on the above update.Members of The British Society for Antimicrobial Chemotherapy (BSAC) have no comments for this NICE quality standard on Neonatal infection update. |
| 99 | Royal College of Nursing | N/A | Thank you for the opportunity to contribute to the above consultation, we received no member comments this time. |

## Registered stakeholders who submitted comments at consultation

* Association of Paediatric Emergency Medicine, an RCPCH Speciality Group
* Bliss
* British Infection Association
* Group B Strep Support
* Meningitis Research Foundation
* NHS England
* NHS England Learning Disability and Autism Programme
* St. George’s and UKHSA
* Sheffield Teaching Hospitals NHS Foundation Trust
* UK Health Security Agency
* UK National Screening Committee

## Registered stakeholders who advised they had no comments at consultation

* British Society for Antimicrobial Chemotherapy
* Royal College of Nursing

Note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees.

1. Marshall, Andrew SJ, et al. "Assessment of infant position and timing of stylet removal to improve lumbar puncture success in neonates (NeoCLEAR): an open-label, 2× 2 factorial, randomised, controlled trial." *The Lancet Child & Adolescent Health* 7.2 (2023): 91-100. [↑](#footnote-ref-1)
2. Cailes, Benjamin, et al. "Epidemiology of UK neonatal infections: the neonIN infection surveillance network." *Archives of Disease in Childhood-Fetal and Neonatal Edition* 103.6 (2018): F547-F553. [↑](#footnote-ref-2)
3. Stevens, J. P., et al. "Long term outcome of neonatal meningitis." *Archives of Disease in Childhood-Fetal and Neonatal Edition* 88.3 (2003): F179-F184. [↑](#footnote-ref-3)
4. Horváth-Puhó, Erzsébet, et al. "Mortality, neurodevelopmental impairments, and economic outcomes after invasive group B streptococcal disease in early infancy in Denmark and the Netherlands: a national matched cohort study." *The Lancet Child & Adolescent Health* 5.6 (2021): 398-407. [↑](#footnote-ref-4)
5. Lykke, Malene Risager, et al. "Long-term Risk of Epilepsy Following Invasive Group B Streptococcus Disease in Neonates in Denmark." *JAMA Network Open* 6.4 (2023): e239507-e239507. [↑](#footnote-ref-5)
6. Marshall, Andrew SJ, et al. "Assessment of infant position and timing of stylet removal to improve lumbar puncture success in neonates (NeoCLEAR): an open-label, 2× 2 factorial, randomised, controlled trial." *The Lancet Child & Adolescent Health* 7.2 (2023): 91-100. [↑](#footnote-ref-6)