NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Antibiotics for neonatal infection

Date of Quality Standards Advisory Committee post-consultation meeting:
22 September 2014

2 Introduction

The draft quality standard for Antibiotics for neonatal infection was made available on the NICE website for a 4-week public consultation period between 1 July and 29 July 2014. 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 18 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.

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

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

1. For draft quality 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.

4 General comments

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

- Overall support was received for this quality standard and the good practice it promotes. The 5 draft quality statements and draft placeholder statement reflect key areas for quality improvement.

- Concerns were raised about the exclusion of any fetal/ antepartum risk assessments.
- The quality standard uses the terms newborn babies and neonates interchangeably; stakeholders felt only one term should be used.

Consultation comments on data collection

- Generally stakeholders felt that if the appropriate systems and structures were available, collection of data would be possible, with the clinical audit tool referred to in the quality standard being a useful method to collect this data.
- A stakeholder did query whether systems and structures would be available, which would therefore impact on data collection.
- Concerns were raised in terms of collecting data about previous pregnancies given that these may have taken place in a different care setting.

5 Summary of consultation feedback by draft statement

5.1 Draft 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.

Consultation comments

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

- Support was given for this statement and how it may reduce the incidence of early-onset neonatal infection.
- A stakeholder felt that a timescale should be placed on the “immediate clinical assessment”, similar to statement 3 which focuses upon treatment being given within 1 hour.
- Stakeholders felt that the process measures within the statement would be difficult to measure.
- Issues were raised with the clinical indicators and risk factors that are used within the statement definitions.

- Concerns were raised regarding risk factors in reference to group b streptococcal disease (such as colonisation) and stakeholders warned against opening the door to screening.

5.2 Draft 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.

Consultation comments

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

- Concerns were raised regarding risk factors in reference to group b streptococcal disease (such as colonisation) and stakeholders warned against this opening the door to screening. Stakeholders felt that we should be explicit within the rationale that screening is not recommended.
- Stakeholders felt that this statement would contribute to the prevention of group B streptococcal infections.
- A stakeholder felt that process measure b) would be unrealistic and difficult to collect. Its current wording could also count women who decline antibiotics and therefore have a negative impact.
- Several stakeholders commented on the “as soon as possible” aspect of the statement and that a timeframe is needed. The following was offered:
  - As soon as labour is established (a query was raised that this may not be practical as some women may be sent home after apparent establishment of labour)
  - More than 4 hours pre delivery
  - Minimum 2 hours before birth but ideally 4 hours
  - Organisations could develop local definitions

- Stakeholders highlighted that the wording of the audience descriptors as women “having a type of infection” is not the correct term and instead women should be referred to as carriers or being colonised.

- A stakeholder highlighted that there was no detail of how babies whose mothers had been given antibiotics prophylaxis should then be treated.

5.3 Draft statement 3

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

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- Stakeholders felt that this statement would contribute to the prevention of group B streptococcal infections.
- A stakeholder felt that “receiving antibiotics” requires definition as this could be prescribed or administered.
- A stakeholder highlighted that “decision to treat” is difficult to measure as this is a mental process made by a clinician. Clear documentation of this decision would be needed in order for the statement to be measurable.

5.4 Draft 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.

Consultation comments

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

- Support was received for this quality statement and that this could contribute to a reduction in antimicrobial resistance.
- Concern was raised about the viability of hospitals to establish systems which make the provision of blood cultures available 36 hours after starting antibiotic treatment, particularly at weekends due to staffing levels.
- A stakeholder felt that a timeframe on when to stop the antibiotic treatment, not just review antibiotic use is needed.

5.5 Draft 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.

Consultation comments

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

- This statement was supported by stakeholders and the need to improve communication with parents or carers was seen as important to identifying babies with infection and treating them as soon as possible.
- Stakeholders did feel that parents or carers can be overwhelmed with information and certain types should be prioritised.
- Stakeholders queried if a national information leaflet or letter can be recommended by NICE with other stakeholders suggesting this needs to be created.

5.6 Draft statement 6 (placeholder)

Use of antibiotics in late-onset neonatal infection.

Consultation comments

Stakeholders made the following comments in relation to draft statement 6:

- In general stakeholders agreed that no evidence-based guidance is currently available and that it is important that this is developed as babies with late onset neonatal infection are given unnecessary doses of antibiotics which can give rise to antimicrobial resistance.
- A stakeholder felt that any development within this area would need to differentiate between infection that is onset at home and at hospital.
- A stakeholder highlighted that work is being undertaken by Public Health England to produce a 5 year antimicrobial resistance strategy.

6 Suggestions for additional statements

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

- Prompt processing of laboratory investigations.
- Minimising antibiotic exposure to babies who do not have an infection.
- Discussing antibiotic use with parents or carers.
- Measurement of C-reactive protein (CRP) in blood tests (before and during antibiotic use).
- Care settings of babies.

Appendix 1: Quality standard consultation comments table

ID	Stakeholder	Statement No	Comments[1]
001	British Infection Association	General	The BIA is very supportive of this Quality Standard Draft.
002	Department of Health	General	Thank you for the opportunity to comment on the draft for the above quality standard. I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.
003	MRSA Action UK	General	MRSA Action UK welcomes this quality standard and particularly welcomes the focus on information being made available to parents and carers.
004	NHS England	General	Thank you for the opportunity to comment on the draft scope for the above Quality Standard. I wish to confirm that NHS England has no substantive comments to make regarding this consultation.
005	Public Health England	General	The focus appears to be on 'newborn' babies to the exclusion of any fetal / antepartum risk assessment. Some of this assessment will be undertaken at booking when revisiting previous pregnancy/childbirth issues and complications. It is assumed that this is included within other standards for GBS but this is an integral part of the risk assessment process so needs to be acknowledged. Generally, and particularly for the purposes of denominator data, there is a reliance on the provider holding comprehensive maternity records covering previous pregnancies whereas previous pregnancies/deliveries quite frequently may have taken place elsewhere. Newborn and neonatal appear to be used interchangeably. Suggest sticking to neonatal.
006	Royal College of Obstetricians and Gynaecologists	General	This document is clearly presented and easy-to-read
007	The Royal College of Midwives	General	The Royal College of Midwives welcomes the opportunity to comment on the draft scope of this quality standard.
008	Meningitis Research Foundation	Question 1	Yes
009	Public Health England	Question 1	It would appear that the real focus of these standards is Group B streptococcal infections. This needs to be expressed if that is the case or the scope widened to demonstrate coverage of other bacterial infections.

[1]PLEASE 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.

ID	Stakeholder	Statement No	Comments[1]
010	UK Clinical Pharmacy Association	Question 1	Question 1: Does this draft quality standard accurately reflect the key areas for quality improvement? Answer 1: Yes
011	Royal College of Obstetricians and Gynaecologists	Question 1	Does this draft quality standard accurately reflect the key areas for quality improvement? The 6 statements do reflect key areas for quality improvement – 4 of them are listed as 'Key priorities for implementation' in NICE clinical guideline 149. Other suggestions for quality standards would include: Measurement of CRP before starting antibiotics Measurement of CRP 18-24 hours after presentation Take in to account the baby's clinical needs, when deciding on the appropriate care setting for a baby
012	The Royal College of Midwives	Question 1	We consider that important areas for improvement that are missing in the standard are statements on Prompt processing of laboratory investigations - we know there is a wide variation in this The importance of minimalizing antibiotic exposure to babies who do not have an infection. This is clearly stated in NICE clinical guideline 149 on this subject, but this direction is not in the quality standard despite the discussion in the introduction. Highlighting the importance of discussion of the risks and benefits of the use of antibiotics with parents or carers.
013	Royal College of Paediatrics and Child Health	Question 1	Yes, the draft quality standard accurately reflects the key areas for quality improvement. However the statement "the baby receives an immediate clinical assessment if any are identified" needs to be firmed up and a time period placed around this as for quality statement 3 where babies receive antibiotics within 1 hour of the decision to treat.
014	Meningitis Research Foundation	Question 2	Yes
015	Public Health England	Question 2	Yes, however we would query whether it is realistic to assume that the systems and structures will be available. As mentioned in QS1, it is not certain that local data collection systems will be sufficiently sophisticated that this information will be collected in a robust way. Although electronic systems exist and the antenatal booking process is documented it would be worth checking with maternity services/informatics departments if this is/could be routinely collected/collated electronically in a format which can be analysed. This is also complicated by hand held maternity notes. It may be that this should be taken one step back (or as a separate standard) and the quality standard should be that commissioners require and providers ensure that electronic systems facilitate collection of this data in a format that can be analysed.

ID	Stakeholder	Statement No	Comments[1]
016	Royal College of Obstetricians and Gynaecologists	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? Yes - if the systems and structures were available, it would be possible to collect the data for the proposed quality measures
017	Royal College of Paediatrics and Child Health	Question 2	Yes, if the systems and structures were available, it would be possible to collect the data for the proposed quality measures
018	The Royal College of Midwives	Question 2	The clinical audit tools referred to in the quality standard are very useful for the collection of this data, if there are sufficient local resources to undertake the audits.
019	UK Clinical Pharmacy Association	Question 2	Question 2: If the systems and structure were available, do you think it would be possible to collect the data for the propose quality measures? Answer 2: Yes
020	Meningitis Research Foundation	Question 3	No. MRF is not aware of any evidence-based guidance that could be used to develop this placeholder statement. MRF would like to see new evidence-based guidance relating to the use of antibiotics in late-onset neonatal infection as there are currently no guidelines to cover cases of meningitis which occur on a neonatal unit after the 1st 72 hours of life. Neonates and young infants have the highest incidence of bacterial meningitis of any age group1 and the case fatality associated with neonatal meningitis has remained unchanged since the mid 1990's2. Evidence based guidelines could help with earlier recognition and diagnosis of neonatal meningitis beyond the first 72 hours of life in the hospital setting as well as optimise management and improve the consistency in the way cases are managed. Ensuring early use of appropriate antibiotics is important, in gram-negative meningitis for example, it is known that the time to sterilization of the CSF has an impact on outcome. Appropriate antibiotic use is also particularly important in the hospital setting where the spectrum of causative pathogens is likely to differ from babies with a community acquired infection.
021	Public Health England	Question 3	The predominant aetiological agents causing late onset septicaemia (LOS) are known. Antibiotics remain the mainstay of treatment, even though diagnostic processes may vary. Empirical therapy regimens are contentious and ever evolving. Several studies have evaluated the possible use of antimicrobials as preventative strategies for LOS. As there is

ID	Stakeholder	Statement No	Comments[1]
			significant cost resulting from inappropriate antimicrobial use, it is important to develop and implement antimicrobial stewardship programs. If new guidance is proposed, its focus should be on how institutions can establish epidemiologic surveillance programs and partner with their infectious disease colleagues to devise appropriate empiric antibiotic regimens specific to each NICU. Enhanced surveillance study (13 months) was launched by the British Paediatric Surveillance Unit (BPSU) and Public Health England (PHE) on 1 April 2014. Although this covers assessment of the incidence of group B streptococcal disease in infants up to 90 days of age in the UK and Ireland, it may provide useful information to inform the standards. It is hoped that the study will provide "data on the current burden of GBS disease (incidence, mortality, and short-term complication rate), current maternal risk factors, serotype distribution and antimicrobial susceptibility of isolates" It may be worth considering waiting until the completion of this work. Currently, work is being undertaken by the PHE-led English Surveillance Programme for Antimicrobial Utilisation and Resistance to improve surveillance of antibiotic prescribing and usage, this will include information on clinical indication. This work is being undertaken as part of the delivery programme for the UK 5 year Antimicrobial Resistance Strategy 2013-2018
022	Royal College of Obstetricians and Gynaecologists	Question 3	Regarding draft placeholder statement 6 – we are not aware of any evidence-based guidance that could be used to develop this placeholder statement
023	UK Clinical Pharmacy Association	Question 3	Question 3: For draft placeholder statement 6: Do you know of any evidence based guidance that could be used to develop this placeholder statement? Answer 3: Although we are not aware of any evidence based guidance, excluding late-onset babies from the same quality standards described in statements 3 and 4 implies that newborn babies must get prompt antibiotic treatment which is reviewed after 36 hours, but it doesn't matter how long it takes for a septic 3 day old baby to get their first dose of antibiotics and it doesn't matter how long it takes before doctors reassess their treatment. This should not be the case.
024	British Association of Perinatal Medicine	Quality Statement 1	Agree with quality statement, proposed structure and commissioner/ healthcare provider roles. All providers should be able to provide evidence of protocols and guidelines/arrangements. This is a realistic quality standard. The proposed quality measures are unrealistic: Numerator a), b) and c) are difficult enough data to collect within research studies and would distract from care delivery to the frontline.
025	British Medical Association	Quality Statement 1	With regard to the clinical indicator - the 'need for mechanical ventilation in a preterm baby (red flag)' – we would question why this is restricted to preterm babies. We would suggest that full term babies with no risk factor for respiratory distress syndrome (RDS) should also be included.
026	Cardiff & Vale University	Quality	More a comment on the risk factors list used in the guideline and now being replicated which includes

ID	Stakeholder	Statement No	Comments[1]
	Health Board	Statement 1	• prelabour rupture of membranes • suspected or confirmed rupture of membranes for more than 18 hours in a preterm birth We consider this an oversight. The 'prelabour rupture of the membranes' risk factor is lifted from the intrapartum guide where it is only considered a risk factor if prelabour ROM is >24 hours. As currently stated any pre-labour ROM, even if birth occurred with 18 hours (or much less) of ROM is classified as a risk factor in term births. This has the effect of greatly increasing the proportion of babies classified as being 'at risk' and requiring IV antibiotics. In Cardiff our neonatologists continue to consider ROM >18 hours as a risk factor in term as well as pre-term babies as they do not consider an argument for not doing so was presented in the original guideline. If it was the intention of the GDG to exclude ROM>18 hours as a risk factor in term babies, this would be a good opportunity to make this clear. It would be helpful if the quality standard gave some indication of the proportion of babies expected to receive IV antibiotics. The costing template provided by NICE uses 10%, so we have assumed this is the expected estimated proportion. If this 10% estimate is correct, is this of all births, births only at term and does it include babies admitted to the NNU. Clarification would be appreciated.
027	MRSA Action UK	Quality Statement 1	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.- Page 9 Risk factors and clinical indicators of possible early-onset neonatal infection should include change in skin colour. The guidance mentions jaundice, but if the infant looks considerably paler this may also be an area of concern for parents/carers to seek medical advice. (Change in skin colour is mentioned on page 23)
028	Public Health England	Quality Statement 1	It is not certain that local data collection systems will be sufficiently sophisticated that this information will be collected in a robust way. Although electronic systems exist and the antenatal booking process is documented it would be worth checking with maternity services/informatics departments if this is/could be routinely collected/collated electronically in a format which can be analysed. This is also complicated by hand held maternity notes. It may be that this should be taken one step back (or as a separate standard) and the quality standard should be that commissioners require and providers ensure that electronic systems facilitate collection of this data in a format that can be analysed.
029	Royal College of	Quality	Definition of pre-labour/premature ruptured membranes varies across national/international documents (18-24 hours).

ID	Stakeholder	Statement No	Comments[1]
	Paediatrics and Child Health	Statement 1	Definition of prematurity cut-off for risk assessment varies across national/international documents – a cut-off of 37 weeks might lead to excess healthy babies being investigated. Definition of abnormal temperature not reflective of standard neonatal practice – should be < 36.6 - > 37.2ºC. Needs to be re-phrased otherwise.
030	Royal College of Paediatrics and Child Health	Quality Statement 1	The clinical indicators for mechanical ventilation deviate from the NICE guideline. In this draft the clinical indicator is "need for mechanical ventilation in a preterm baby (red flag)" in the NICE guideline there are 2 clinical indicators- "need for mechanical ventilation in a preterm baby (NOT red flag)" and "need for mechanical ventilation in a term baby (red flag)". This is the same for all sections that use this list. This quality standard should be in line with NICE.
031	Royal College of Paediatrics and Child Health	Quality Statement 1	Hyperglycaemia is spelt incorrectly in the list of clinical indicators (spelt hyperflycaemia). This is the same for all sections that use this list.
032	The Royal College of Midwives	Quality Statement 1	The risk factors and clinical factors are oversimplified in this list and could lead to inappropriate use of antibiotics. It would be clearer if there was inclusion of the framework with discussion of the red flags and the use of clinical judgement, as in NICE clinical guideline 149.
033	The Royal College of Midwives	Quality Statement 1 & 2	RCM is very concerned that these statements on identification of risk factors in mother and baby and giving antibiotics to mothers with a previously affected baby or current colonisation may open the door to routine GBS screening. This should be qualified by referring to agreed protocols and current recommendations on screening.
034	St Mary's Hospital, CMFT	Quality statement 1	It would be difficult to accurately measure the number of infants assessed for clinical indicators of early onset neonatal infection. This should be included in every routine review by a midwife but how would one determine if all clinical indicators have been assessed? Does this require a "tick-box" proforma for routine midwifery review?
035	St Mary's Hospital, CMFT	Quality statement 1	A checklist would be helpful in ensuring risk factors were being assessed.
036	St Mary's Hospital, CMFT	Quality statement 1	If by clinical assessment what is meant is an examination and certain observations carried out by a midwife, this is achievable and measurable is a checklist or proforma are used
037	Group B Strep Support	Quality Statement 1, 2 and 3	Group B Strep Support welcomes Quality Statements 1-3, as they will ensure as many GBS infections are prevented as possible within the current guidelines. Checking for risk factors and offering the appropriate antibiotics will reduce GBS infections, and prompt intrapartum antibiotic prophylaxis for the pregnant woman and treatment of the baby with antibiotics will reduce mortality and morbidity in neonates.
038	British Association of Perinatal Medicine	Quality Statement 2	Agree with statement. Agree with quality measure for structure, which would be realistic. All providers should have evidence-based guidelines in place with stipulated arrangements for offering IAP. Process a) – This could be possibly achieved within maternity electronic data collecting systems which could use the intrapartum antibiotics clinical audit tool standards 1 & 2. Process b) is an unrealistic indicator to collect reliable information about. The rate of early-onset infection would also need clearer definition: would this be only blood culture positive infection or culture negative infection too?

ID	Stakeholder	Statement No	Comments[1]
039	Cardiff & Vale University Health Board	Quality Statement 2	Please consider amending to 'Pregnant women are offered intrapartum antibiotic prophylaxis as soon as labour is established if they have had a previous baby …
040	Department of Health expert advisory committee on Antimicrobial Resistance and Healthcare Associated Infection	Quality Statement 2	Intrapartum antibiotics need to be given >4 h pre delivery – this should be included
041	Group B Strep Support	Quality Statement 2	Group B Strep Support welcomes Quality Statements 2 stating that pregnant women are to be offered intrapartum antibiotic prophylaxis as soon as possible where one or more of the risk factors is identified. We would like to see a timeframe on this, in much the same way as there is one for giving the antibiotics to babies within one hour of the decision to treat. foll
042	MRSA Action UK	Quality Statement 2	MRSA Action UK agrees with this statement, but additionally would like to see routine screening for strep B carriage (not sure if this is in scope).
043	Public Health England	Quality Statement 2	Re: 'Pregnant women are offered intra-partum antibiotic prophylaxis as soon as possible'. We suggest that 'as soon as possible' needs to be defined for numerator purposes and to allow comparability. It is noted that the clinical audit tool suggests local definition of 'as soon as possible'. It is not clear how this is then setting a standard to improve mortality and length of stay if local differences exist. It is unclear at what point in the first stage of labour antibiotics should be started – when labour is established? There is a risk that a woman may not progress with apparent early first stage and be sent home, so repeated provision of antibiotics when she returns may occur. Re: 'streptococcal colonisation, bacteriuria or infection in the current pregnancy' - by referring to colonisation separately to bacteriuria and infection, it implies there is a separate process to detect GBS or way of 'incidentally' finding GBS in the absence of symptoms/bacteriuria/infection. This would then constitute screening which is not recommended in clinical practice as per Royal College of Obstetricians and Gynaecologists (RCOG)/UK National Screening Committee (NSC) guidelines. If a potential scenario could be demonstrated where GBS could be 'incidentally' picked up, this would be very useful to provide clarity in this area. Suggested text = "or group B streptococcus is detected in the current pregnancy, for example from high vaginal swabs or bacteriuria" It would be useful to reference RCOG/NSC and in relation to screening for GBS. Suggested text = The UK NSC recommended in 2012 that antenatal screening for group B streptococcus (GBS) carriage at 35 -37 weeks of pregnancy should not be offered in the UK. They concluded that screening for GBS is not to be recommended because there is insufficient evidence to demonstrate the benefits to be gained from screening

ID	Stakeholder	Statement No	Comments[1]
			all pregnant women and treating those carrying the organism with intravenous antibiotics during labour
044	Royal College of Nursing	Quality Statement 2	There is a need to develop a national protocol screening for group B streptococcal infection to be able to identify which infants would benefit from prophylaxis. An indication as to how to best manage positive results from self administered kits brought off the internet could be useful.
045	Royal College of Obstetricians and Gynaecologists	Quality Statement 2	Page 13 of 33. sentence at the top of the page says, “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” We try to avoid using the term ‘have this type of infection themselves’ – instead we say to the women that they are NOT infected but are carriers or are colonised. The RCOG GBS guideline (Greentop guideline 36) states that intrapartum antibiotic prophylaxis should be offered to women with: a previous affected child with GBS, GBS positive swab or bacteriuria in this pregnancy and prolonged SROM – prolonged SROM is missing from quality statement 2.
046	Royal College of Paediatrics and Child Health	Quality Statement 2	In order to truly assess the value of intrapartum antibiotic treatment and pick up the units that might not be achieving best practice standards it is important that a time cut-off is stipulated for the first intrapartum antibiotic dose (minimum 2 hours before birth, ideally 4 hours). Otherwise you might find that a high percentage of mothers receive antibiotics for the right indication, but too late before birth (without benefits for the baby).
047	Royal College of Paediatrics and Child Health	Quality Statement 2	Throughout Quality statement 2 it is stated antibiotic prophylaxis should be administered “as soon as possible” if women have had….. “As soon as possible” from when? From starting labour, from being admitted to hospital if being induced/having an elective C-section, from knowledge of being known to be GBS positive? This should be clarified.
048	Royal College of Paediatrics and Child Health	Quality Statement 2	Data on women who received prophylaxis that was not Benzylpenicillin would be useful (e.g. rates of women not receiving BenPen & reasons why- allergy/resistant organism in the woman/high levels of resistant organisms in the local area etc).
049	St Mary’s Hospital, CMFT	Quality statement 2	The quality standard is measuring whether an offer of intrapartum antibiotics is made. The data collected is whether antibiotics are given. The number of women declining prophylactic antibiotics is not taken into account. Patient choice in this example would lead to a measured decrease in quality!
050	St Mary’s Hospital, CMFT	Quality statement 2	How does one define “as soon as possible”?
051	Wrightington Wigan and Leigh NHS Foundation Trust	Quality Statement 2	Although we all recognise the importance of giving antepartum antibiotics, there is little guidance as to how we should then manage the babies from pregnancies where mother was given 1, 2, 3,etc doses of antibiotics. E.g. if mother received more than 2 dose of antepartum antibiotic, does that mean that the risk factor is then eliminated or decreases from red to amber? Should the newborn baby just be observed or should it be treated with antibiotics?
052	Royal College of	Quality	

ID	Stakeholder	Statement No	Comments[1]
	Obstetricians and Gynaecologists	Statement 2, 3 and 5	NICE Intrapartum Guideline states that a pyrexia as well as being a one off temp of 38C is also 2 temps of 37.5C 4 hours apart – this should be included
053	Royal College of Obstetricians and Gynaecologists	Quality Statement 2, 3 and 5	Typo – hyperglycemia – not 'hyperflycemia'
054	British Association of Perinatal Medicine	Quality Statement 3	Agree with statement The data would be difficult to collect as a routine; even within the context of a research study when there are dedicated research staff – such information is not easy to collect and subject to inaccuracies. Perhaps annual short term/ intermittent audits using the audit tool could be achievable
055	British Medical Association	Quality Statement 3	Under the 'Risk factors' (page 15) please could the duration of the prelabour rupture of the membrane be clarified?
056	MRSA Action UK	Quality Statement 3	MRSA Action UK agrees with this statement and would like to see rapid testing used to identify the micro-organism(s) involved to enable the correct antibiotic to target the infection.
057	Public Health England	Quality Statement 3	It is good to see this clearly defined timeframe, however in relation to 'antibiotic treatment to be started' – this could mean prescribed or administered so should be made clear
058	Royal College of Paediatrics and Child Health	Quality Statement 3	Not possible to measure when decision was made to treat as this is a mental process impossible to pin down in time. Doctors are not looking at the clock and say, "It is 21:34. I am now going to treat you….." Suggest to measure time delay from prescription to administration of antibiotics as this can vary a lot and is definitely amenable to improvement (and easily auditable).
059	St Mary's Hospital, CMFT	Quality statement 3	Agree wholeheartedly with this quality standard. There needs to be clear documentation of when the decision to treat is made which, if made antenataly, would set the standard limit at 1 hour of age.
060	British Association of Perinatal Medicine	Quality Statement 4	The statement concurs with the DH Antimicrobial stewardship initiative and could be linked accordingly to the NICE standard. The process could be audited eg by collaborations with pharmacists who routinely check prescription charts. Audit would be facilitated by electronic prescribing.
061	British Medical Association	Quality Statement 4	We hold some reservations surrounding the feasibility of hospitals to establish systems to provide blood culture results 36 hours after starting antibiotic treatment. Microbiology technicians may not be available on-site 24 hours a day. Achieving this target over the period of a weekend could be difficult.
062	Department of Health expert advisory committee on Antimicrobial Resistance and Healthcare Associated Infection	Quality Statement 4	Need to include when to stop. Patients stop empirical treatment at 48h but could stop at 36h – many laboratories cannot report blood culture negatives at 36h for staffing reasons
063	Group B Strep Support	Quality	Group B Strep Support welcomes Quality statement 4 as this will reduce the number of cases in which antibiotics are

ID	Stakeholder	Statement No	Comments[1]
		Statement 4	continued unnecessarily.
064	Public Health England	Quality Statement 4	No comment
065	Royal College of Paediatrics and Child Health	Quality Statement 4	There is insufficient scientific evidence to promote a blanket approach regarding blood culture results. The evidence quoted in the guidance is incomplete and could be biased by the experience of the advisory board for this guidance. Not all Trusts have the same microbiology systems in the UK (?). Processing and reporting is still dependent on staffing levels and availability in Microbiology Depts. Even if systems were the same across the UK and internal/external quality control was in place to determine performance of the systems, there is still a high risk for delay in reporting that needs to be addressed separately. This can be assessed by auditing the turnaround time of blood cultures using definite check points like (time blood culture taken, time blood culture logged, time culture read, time reporting system updated, etc.…). See also: http://www.hpa.org.uk/webc/hpawebfile/hpaweb_c/1317132857861
066	St Mary's Hospital, CMFT	Quality statement 4	Currently automated culture results become available at 36 hours. It will take a finite period of time for an adequate assessment to be made and for all the blood results to become available for a decision to be made regarding stopping antibiotic therapy. A more practical way of assessing quality standard compliance with this quality standard would be to ensure that no further antibiotics are given beyond 36 hours without the active decision to continue treatment.
067	The Royal College of Midwives	Quality Statement 4	We welcome this statement about reassessing babies on antibiotics after 36 hours and discontinuing if there is no infection. This is importantly addressing the issue of antimicrobial resistance and improving the experience of babies and their parents
068	British Association of Perinatal Medicine	Quality Statement 5	Structure is relevant and deliverable There is an opportunity to develop a consistent national parent information leaflet giving information about neonatal infection. This could be done through BAPM and the national Maternity .and Children's Strategic Clinical Networks (SCN), working together with parents and a charity such as BLISS Parents of babies admitted to neonatal units including this given antibiotics for early onset infection should be spoken to within 24 hours and though the content is not recorded, the fact that a discussion occurs is recorded on an electronic system (Badger.net mostly). This is audited by the NNAP. The suggested process regarding documentation of parents being given leaflets is unrealistic on an ongoing basis as would be very time consuming and subject to data collection issues. This could be audited on an intermittent basis by frontline workers undertaking specific audits
069	British Medical Association	Quality Statement 5	Parents and carers of newborn babies are often overwhelmed with information in the form of leaflets. We would suggest that information most useful in the short to medium term (i.e. days and weeks) is prioritised.
070	Group B Strep Support	Quality	Group B Strep Support welcomes and strongly supports Quality statement 5 – giving new parents information about

ID	Stakeholder	Statement No	Comments[1]
		Statement 5	what signs and symptoms of infection in their baby to be alert to, and what action to take, taking into account locally available facilities is key to ensuring sick babies are identified and treated early. We at GBSS have developed a brief information leaflet "Understanding your baby's GBS infection" (http://www.gbss.org.uk/filepool/2011_02_Understanding_your_babys_GBS_infection_FINAL.pdf) to provide key information for parents of babies who have suffered GBS infection, including the increased risk to subsequent babies. We strongly support improved communication with parents and carers about what to look for, what to do where a baby has symptoms consistent with neonatal infection, and why identifying and treating neonatal infection is so vital.
071	Public Health England	Quality Statement 5	We suggest defining what is meant by early-onset neonatal infection 'has been a concern' – does this mean early clinical signs or risk factors present? Whilst important to provide, it is unclear what 'access to relevant healthcare professionals for parents or carers who are concerned about neonatal infection' will mean. Does this mean open-access return? It may be that where risk factors exist the onus weighs too heavily on the parents. We suggest, for those identified as high risk, consider either: Change in discharge arrangements - consideration should be given as to whether those identified as high risk should have a longer stay in hospital (at least 72 hours) and are monitored more closely for infection by professional staff. OR On discharge more intensive visits by a professional should be advocated for the early days. Re: 'Including what to look for and who to contact if they are concerned'…this should include parental education about prevention of infection and should consider beyond intrapartum infection (as the focus in reality appears to be Group B Streptococcal). Transmission of E.coli and other organisms in the early postnatal period needs to be taken into account. As with Standard 1, it is not certain that local data collection systems will be so sophisticated that this information can be collected in a robust way. This may need to be included in the standard to be required by commissioners. We suggest that would be very difficult to implement and monitor, it is unlikely that information given to parents / carers will be recorded accurately in the case notes unless electronic records have a column that can be ticked. However, the validity and accuracy of this data will always be circumspect.
072	St Mary's Hospital, CMFT	Quality statement 5	A national parent information leaflet should be developed and made available.
073	Wrightington Wigan and Leigh NHS Foundation Trust	Quality Statement 5	Is there a standard leaflet/letter that NICE recommends adapting for local use?
074	British Association of Perinatal Medicine	Quality Statement 6	Use of antibiotics in late onset infection: the following guidance may assist with the placement statement: Anthony M, Bedford-Russell A, Cooper T, Fry C, Heath PT, Kennea N, McCartney M, Patel B, Pollard T, Sharland M,

ID	Stakeholder	Statement No	Comments[1]
			Wilson P. Managing and preventing outbreaks of Gram-negative infections in UK neonatal units. Arch Dis Child Fetal Neonatal Ed. 2013 Nov;98(6):F549-53. doi: 10.1136/archdischild-2012-303540. Epub 2013 Jun 21. Review. PubMed PMID: 23792354 Bedford Russell AR, Heath P, Sharland M. Improving antibiotic prescribing in neonatal units: time to act. Arch Dis Child, Fetal Neonatal Ed 2012;97(2):F141-6 Epub 2010 October 30. Quality standards could be targeted to support implementation of antimicrobial stewardship programmes, with DH guidance below modified for the neonatal setting. Department of Health's advisory committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI). Antimicrobial Stewardship: "Start Smart, - Then Focus'. 2011 There is currently inadequate sign-up to infection surveillance within UK neonatal units – which is aspirationally occurring via the electronic neonatal record system (largely Badger.net), and contributes to a national neonatal dashboard with catheter-associated infection as a domain. A NICE quality standard could support infection surveillance and would be a timely driver to support implementation of the PHE hosted Infections in Critical Care Quality Improvement Programme (ICCQIP) Oversight Group. Such collaboration would reduce confusion and lead to consistent management and data capture.
075	Department of Health expert advisory committee on Antimicrobial Resistance and Healthcare Associated Infection	Quality Statement 6	Evidence based guidelines for neonatal antibiotic treatments are lacking other than the guideline issued by NICE. There is excessive duration of antibiotic use for most courses of treatment and CRP is used as the main indicator to allow treatment to be stopped. As a result neonates are treated for much longer than adults where a five day course is usual.
076	Public Health England	Quality Statement 6	As general – see study information
077	Royal College of Paediatrics and Child Health	Quality Statement 6	Late onset sepsis needs to be divided into those where the onset is at home and those where the onset is in hospital. The causes and outcomes are very different.

Stakeholders who submitted comments at consultation

- British Association of Perinatal Medicine
- British Infection Association
- British Medical Association

- Cardiff & Vale University Health Board
- Department of Health
- Department of Health expert advisory committee on Antimicrobial Resistance and Healthcare Associated Infection
- Group B Strep Support
- Meningitis Research Foundation
- MRSA Action UK
- Newborn intensive care unit, St Mary’s Hospital, Central Manchester Foundation Trust
- NHS England
- Public Health England
- Royal College of Midwives
- Royal College of Nurses
- Royal College of Obstetricians and Gynaecologists
- Royal College of Paediatrics and Child Health
- UK Clinical Pharmacy Association
- Wrightington Wigan and Leigh NHS Foundation Trust