NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Preterm labour and birth

Date of Quality Standards Advisory Committee post-consultation meeting:
07 July 2016

2 Introduction

The draft quality standard for Preterm labour and birth was made available on the NICE website for a 4-week public consultation period between 26 April and 24 May 2016. 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 15 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. 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 have an example from practice of implementing the NICE guideline(s) that underpins this quality standard? If so, please submit your example to the NICE local practice collection on the NICE website. Examples of using NICE quality standards can also be submitted.

4. 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 treatment. Please describe any potential cost savings or opportunities for disinvestment.

Stakeholders were also invited to respond to the following general question:

5. For this draft quality standard: When developing quality standards and prioritising key areas for quality improvement, current variation in practice is a key consideration. Section 1.2 in the NICE guideline on preterm labour and birth makes recommendations on prophylactic vaginal progesterone and prophylactic cervical cerclage for women who have had a transvaginal ultrasound between 16^{+0} and 24^{+0} weeks of pregnancy. Are transvaginal ultrasound scans routinely offered to all pregnant women between 16^{+0} and 24^{+0} weeks of pregnancy, or is there variation in practice? Please detail your answer.

4 General comments

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

- Good support on the focus on detailed information in this quality standard as lack of access to this information was reported as being significant long term issue. Consistent information will however require that all staff must be up to date with current evidence and local policy.
- A number of editorial comments were received on a number of statements and underpinning information.

Consultation comments on data collection

- For all of the statements data collection is dependent on local practice with no routine data collection currently implemented. Retrospective audits and notes review will be required.

Consultation comments on resource impact

- Statement 1-Accurate measurement could not be achieved without dedicated data collection mechanisms, staff and additional costs.
- Statement 4- Appropriate use of antenatal corticosteroids may have cost saving NHS implications through reductions in neonatal morbidity and mortality but additional resources may be required for data collection.
- Question 5-Variation in practice was reported in relation to the routine offer of transvaginal ultrasound scans to all pregnant women between 16- 24 weeks of

pregnancy. Many units currently cannot provide 24/7 cervical length scanning. This would require a significant amount of resource in terms of equipment need, maintenance and education or training and maintenance of these skills.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

Women at increased risk of preterm labour are given information about the potential signs and symptoms.

Consultation comments

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

- General support for information as being important and should be documented in clinical notes to measure if it is being done. Quality of information is also important but more difficult to measure.
- Concern raised on some vague symptoms within the list of 'potential symptoms of preterm labour' which is supported by 'expert opinion'. Due to its vague content it was felt that having this current list may cause anxiety to the woman or cause unnecessary resource implications to the obstetric unit.
- Suggestion to define the 'at increased risk' population to enable comparisons between different units.
- Concern raised that this statement does not take into account information on tocolysis medication and the associated risks.
- Concern raised that this statement is unlikely to produce a significant improvement in outcomes as the majority of women at preterm birth risk will already be aware of preterm labour symptoms as these are the same as labour at term.
- It was reported that a discussion with women at preterm labour risk is standard practice for the Obstetric Team but still relevant if this is not being generally met. It will potentially contribute to a decrease in fetal and neonatal morbidity, maternal morbidity and may improve the mother's experience of childbirth and baby care.

5.2 Draft statement 2

Women who are having a planned preterm birth are given information about the risks and outcomes including the likelihood of the baby surviving.

Consultation comments

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

- Support for this statement list which should be included in the implementation tools.
- Suggestion to define this statement's upper gestation focus.
- Suggestion to highlight that healthcare professionals can share uncertain prognosis as each individual infant and child is unique. There should be emphasis that long term developmental difficulties and impairments can be supported.
- Suggestion to include fathers and wider family in this information support.
- Suggestion to include outcome information on morbidity and disability and information on utero transfers and the newborn network system.
- Request for nationally agreed information on this for parents with regular updates.

5.3 Draft statement 3

Women in suspected preterm labour who are 29^{+6} weeks pregnant or less are offered tocolysis, maternal corticosteroids and magnesium sulfate.

Consultation comments

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

- Support for this statement's potential benefit for prevention of neurodevelopmental disability.
- Concern raised on the routine offer of tocolysis due to a number of contraindications to tocolysis reported. Suggestion to therefore state that these should be offered only if there are no contraindications to this therapy.
- Concern raised on offering magnesium sulfate to women in suspected preterm labour rather than in established preterm labour as stated in NG25 guideline.

- Concern raised that this population is focused on women less than 29 weeks pregnant which doesn't reflect NG25 guideline.

5.4 Draft statement 4

Women between 30 and 33^{+6} weeks of pregnancy are offered maternal corticosteroids if they are in diagnosed preterm labour, are having a planned preterm birth, or have preterm prelabour rupture of membranes (P-PROM).

Consultation comments

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

- Supported as being important and easy to measure with outcomes relating to neonatal morbidity and mortality.
- Concern raised that both a hospital guideline for preterm delivery and Royal College Of Gynaecologists (RCOG) antenatal corticosteroid guidelines includes up to 34^{+6} weeks of gestation in preterm labour i.e. more mature foetuses than this draft statement.
- Suggestion to include tocolysis in this statement or alternatively give a reason why tocolysis is not appropriate.
- Suggestion to include women who have not previously had steroids during pregnancy to the denominator.

6 Suggestions for additional statements

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

- Early antenatal care and continuity of care from the same midwife.
- Appropriate monitoring.
- Delayed cord clamping.
- Information on cervical length assessments
- Administration of progesterone
- Use of cervical cerclage.

Appendix 1: Quality standard consultation comments table – registered stakeholders

ID	Stakeholder	Statement number	Comments[1]
1	NHS England	General	Thank you for the opportunity to comment on the above Quality Standard. I wish to confirm that NHS England has no substantive comments to make regarding this consultation.
2	Royal College of Nursing	General	This is to inform you that the RCN has no comments to submit to inform on the above standards consultation at this time
3	the 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.
4	Buckinghamshire Healthcare NHS Trust	General	Section 1.2 in the NICE guideline on preterm labour and birth makes recommendations on prophylactic vaginal progesterone and prophylactic cervical cerclage for women who have had a transvaginal ultrasound between 16+0 and 24+0 weeks of pregnancy. I think there is a variation in practice but would consider that if there is a recommendation for one particular practice then this should be the standard that is set. I don't believe the standard should reflect what is considered best practice.
5	The Royal College of Midwives	General	The RCM agrees that this draft quality standard reflects some key areas for quality improvement.
6	RCGP	General	The RCGP welcomes this document but feels that GPs do not deal with this other than by signposting to midwifery and obstetric services as an emergency. The RCGP would like to highlight that in 'Saving Mothers' Lives 2014', page 35 there is a section called "communication" and a vignette where a GP was involved in giving inappropriate advice to a woman. The GP should never have been put in that position. (JS)
7	Joint Royal Colleges Ambulance Liaison Committee	Introduction	The Joint Royal Colleges Ambulance Liaison Committee (JRCALC) has reviewed the proposed Quality Standards in terms of relevance to pre-hospital ambulance services and personnel. Many women with preterm labour will use the ambulance services for transfer to secondary care.

[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 number	Comments[1]
			The introduction states: “All healthcare professionals involved in assessing, caring for and treating women who are considered to be at risk of preterm labour and birth should have sufficient and appropriate training and competencies to deliver the actions and interventions described in the quality standard”. Although the proposed Quality Standards cannot be actioned by pre-hospital emergency care practitioners, it is vitally important that they are aware of how preterm labour presents, what situations lead to an increased risk of preterm labour (road traffic trauma is pertinent) and how to manage threatened or actual preterm labour presenting in the ‘out of hospital’ situation. Management of preterm labour in the prehospital situation is already included in JRCALC national obstetric guidance and this will be revised in June 2016. Urgency of transfer will be reviewed as part of the process. Ambulance services can facilitate use of the proposed quality standards by ensuring timely transfer to secondary care, which is where the standards will be actioned clinically by obstetric teams.
8	RCOG	Introduction	The term ‘growth retardation’ should be replaced with ‘growth restriction’ (‘fetal growth restriction’ is given in the section ‘glossary of terms’ in the full guideline)
9	RCOG	Question 2	We believe that local systems and structures are in place to collect the data for the proposed quality measures.
10	The Royal College of Midwives	Question 2	If the systems and structures were available, it would be possible to collect the data for the proposed quality measures.
11	BMFMS	Question 2	The general opinion was that most Trusts are not set up to record electronically what verbal or written information is given to women either for statement 1 or 2. Most Trusts probably do have electronic records for medications on discharge records/labour notes BUT probably do not record if they were offered and declined – general opinion was that most maternity IT units are not set up to collect the data required.
12	RCOG	Question 4	We believe that each of the statements in this draft quality standard would be achievable by local services – the use of tocolytic agents, corticosteroids and magnesium sulfate is established in routine NHS clinical practice. The full Preterm birth and labour guideline recommends tocolysis for PTB between 26-34 weeks. It did not divide into <29 weeks and 30-34. In the QS statement 3 focuses specifically on <29 weeks but there is no mention on tocolysis in statement 4 between 30-34 weeks. We believe statement 4 should

ID	Stakeholder	Statement number	Comments[1]
			also include tocolysis or give a reason why tocolysis is not appropriate. We also believe it should be stated that tocolysis should be offered only if there are no contraindications to such therapy.
13	BMFMS	Question 4	Many units cannot provide 24/7 cervical length scanning – this would require a significant amount of resource with regard to equipment need, maintenance and then education/training and maintenance of skills
14	BMFMS	Question 4	The general feeling is fetal fibronectin significantly reduces ante-natal admissions and IUT – hence treating and admitting all suspected PTL feels like a very backward step
15	RCOG	Question 5	This question asks whether transvaginal ultrasound scans are routinely offered to all pregnant women between 16+0 and 24+0 weeks of pregnancy, or is there variation in practice. All women are offered a transabdominal fetal anatomy scan at approximately 20 weeks' gestation but NOT a transvaginal scan. I am not aware of any units/hospitals/Trusts that offer a transvaginal scan routinely. At present there are insufficient trained sonographers and scan machines available to perform transvaginal assessment of cervical length routinely in women.
16	University Hospitals Southampton NHS Trust	Question 5	Cervical length measurement is not routinely offered at present in the majority of hospitals. There are insufficient trained sonographers nationally at present to complete the current standard ultrasound examinations in pregnancy. To introduce routine cervical length measurement would require a large training programme to ensure this was being completed to an appropriate standard and a significant increase in scan time and staff numbers to achieve this. There is little evidence of benefit or routine screening in improving outcomes. Although routine screening was not an indication for progesterone in the recently published OPPTIMUM study, this showed no evidence of benefit in longer term outcomes.
17	Society and College of Radiographers	Question 5	A question is asked on page 6 about whether cervical length measurement by ultrasound is offered routinely. This is not currently the case as far as low risk women are concerned and would have a major impact on service delivery if it were to be introduced. Some departments do routinely assess the cervix transabdominally at the booked Fetal Anomaly Screening Programme (FASP) screening scans as part of local placental site assessment protocols and to exclude vasa praevia, some also have

ID	Stakeholder	Statement number	Comments[1]
			cervical length assessment referral criteria for high risk women. Assessment of the cervix is not a FASP requirement and adding a transvaginal scan would extend examination times and have a significant impact on workload. There would also be specific consent required. There is a nationwide shortage of sonographers that Health Education England are currently leading a project on, the SCoR is a stakeholder. Specific points raised by our Ultrasound Advisory Group were: Additional time required asking women to empty bladder and then undertaking the transvaginal scan Some women do not like having family in the room for a transvaginal scan, so swapping around who is/is not in the room takes time. An internal scan is an intimate examination. RCR and SCoR intimate examination and chaperone policies apply. A family member is not regarded as a formal chaperone. https://www.rcr.ac.uk/sites/default/files/bfcr154_intimateexams.pdf http://www.sor.org/learning/document-library/intimate-examinations-and-chaperone-policy-0 There are large variations in accuracy and consistency when measuring cervical length, even with experienced staff who have been given a standardised protocol. If introduced training and quality assurance/consistency checking would be required. The impact on sonographer workload and how this might affect waiting times of other examinations (obstetric and non-obstetric) would need to be considered.
18	BMFMS	Question 5	TV US is not routinely offered to all pregnant women between 16-24 weeks - it varies significantly dependent on type of obstetric unit, availability of research clinics and preterm labour clinics and level of risk in each unit. For that to be achieved there would be huge issues in many units – with regard to capacity in offering such scans, skill and resource issues, equipment and training issues.

ID	Stakeholder	Statement number	Comments[1]
19	Ferring Pharmaceuticals Ltd	1	Question 1 Does this draft quality standard accurately reflect the key areas for quality improvement? We are of the opinion that this statement does not cover the complete scope of provision of information to patients, as it does not take into account and measure the adequacy of information provided to patients regarding the use of off -label medication for tocolysis and the associated risks, as well as potential for adverse events when considering the choice of this therapy against licensed, albeit more expensive, alternatives, as per the General Medical Council's Prescribing guidance: prescribing unlicensed medicines (http://www.gmc-uk.org/Prescribing_guidance.pdf_59055247.pdf). Thus the Outcome measured (Patient satisfaction with the information provided) will be biased if it does not also document that the patient has been provided the required necessary information about unlicensed medication.
20	Ferring Pharmaceuticals Ltd	1	Please note that individual healthcare trusts' policies sometimes demand that informed consent is obtained for off-label or unlicensed prescribing, to comply with their clinical governance and risk management policies. Thus the Outcome measured (Patient satisfaction with the information provided) will be biased if it does not also document that the patient has been provided the required necessary information about unlicensed medication.
21	University Hospitals Southampton NHS Trust	1	The rationale for this statement is untested, and it is unlikely to produce a significant improvement in outcomes. The majority of women at risk of preterm birth will already be aware of the symptoms of preterm labour, since these are the same as labour at term, so a great effort to document this standard is unlikely to produce a proportionate health gain. In our experience few women with significant symptoms of preterm birth fail to attend hospital in a timely manner
22	University Hospitals Southampton NHS Trust	1	It is likely to be exceptionally difficult to measure this accurately so that proper comparisons can be made between different units. There is no clear definition of who is at increased risk (does this include only women where a risk can be identified at booking, or those who develop problems in pregnancy? If those later, what problems qualify? Would a UTI be a risk factor? If so, how severe? Would APH be a

ID	Stakeholder	Statement number	Comments[1]
			risk factor? If so, how severe, etc. More importantly, few hospitals would have mechanisms to collect this data routinely, even if there were clear definitions: the only mechanism would be by retrospective audit, with a high chance that data would be collected inaccurately and inconsistently. Accurate measurement could not be achieved without dedicated data collection mechanisms, staff and additional costs.
23	Royal College of Paediatrics and Child Health	1	Question 1: This is primarily a statement that relates to Obstetric rather than Paediatric care but in our experience it is standard practice for the Obstetric Team to have this discussion with women at risk of preterm labour. If through this discussion preterm labour can be identified early facilitating the administration of tocolysis, antenatal corticosteroids, magnesium or antibiotics as appropriate to each individual, it will likely contribute to a decrease in fetal and neonatal morbidity, maternal morbidity and may improve the mothers experience of childbirth. It is therefore a relevant quality standard and it is concerning if this standard is not being met. Question 2: Dependent upon local practice, this information should be recorded in either the mothers' hand-held records or in an electronic database such as 'Maternity Medway'. This data is not routinely audited locally. Feasibility of collecting the data would be limited by the need to review antenatal hand-held or electronic records and whether all conversations are accurately documented. Question 3: No Question 4: This quality standard should be being achieved as part of routine practice. The resource implications are likely to be only in the time costs of an individual demonstrating it is being achieved through audit/monitoring. Question 5: Transvaginal ultrasounds at this gestation at the Whittington are offered only to those with a history of previous preterm delivery, and not routinely. Members of the local Obstetric team are not aware of other Trusts at which all women have a transvaginal in addition to transabdominal ultrasound but there may be variation in practice elsewhere.
24	BAPM	1	Important and should be documented in clinical notes so should be easy to measure if done or not. Quality of info would be more difficult to measure, but is very important.

ID	Stakeholder	Statement number	Comments[1]
25	RCGP	1	The RCGP feels this is a sensible statement. However the list of 'potential symptoms of preterm labour' includes some that seem vague; that GPs were not previously aware of as being symptoms of preterm labour; and that are indeed listed here as 'Expert opinion', it should include some quality evidence instead of 'expert opinion'. The RCGP is concerned that having this list of 'potential symptoms of preterm labour' may cause anxiety to the women or excessive visits to the obstetric unit to check if they are in preterm labour. (DJ)
26	The Royal College of Midwives	1	There must be consistency in the information given which will mean that all staff giving it must be up to date with current evidence and local policy. This will present a challenge in the context of the lack of evidence in the key areas as outlined in the research recommendations in the source guideline.
27	BAPM	Statement 1 and 2	Important and should be documented in clinical notes so should be easy to measure if done or not. Quality of info would be more difficult to measure, but is very important.
28	The Royal College of Midwives	Statement 1 and 2	We are very pleased to see the high focus in the standard on detailed information giving to women and their families at all stages of pregnancy with the risk of prematurity, as lack of access to this information has remained an important and disturbing issue for a long time.
29	RCOG	2	The following sentence is an important one, and yet needs tweaking. Consider editing as follows: Rationale Women who are having a planned preterm birth need information to be given as early as possible in the antenatal period regarding the level and nature of the risks involved. This can help them to understand what neonatal care their baby might need, to discuss this with their neonatologist or paediatrician, and to tour the neonatal unit. This may also help them to decide the circumstances under which they would like their baby to be resuscitated.
30	University Hospitals Southampton NHS Trust	2	There is an opportunity to improve advice given to parents before planned premature delivery but this should include information about morbidity and handicap and not just mortality, since this may be at least as important to parents.
31	University Hospitals Southampton NHS Trust	2	A difficulty with this quality standard is having generalisable and agreed information to provide. Although we have parent information leaflets, there is considerable debate about whether to use published national data (e.g. EPICURE) or local data. Local data may not have been as rigorously collected, particularly in relation to handicap and neurodevelopmental issues. If this standard was introduced NICE should consider providing nationally agreed information for parents which would need

ID	Stakeholder	Statement number	Comments[1]
			regular updating.
32	University Hospitals Southampton NHS Trust	2	The upper gestation at which this standard would apply has not been defined. Preterm birth includes all those up to 36+6 weeks: depending on the upper gestation chosen an increasing number or mothers would have to be counselled and this counselling becomes less valuable as the risks of PTB fall significantly at later gestations.
33	University Hospitals Southampton NHS Trust	2	Collecting this data would rely on retrospective notes review: this would require a considerable amount of work if being carried out regularly: it would require A. Identification of all premature deliveries. B. Within these identification of all deliveries that were planned rather than spontaneous. C. Within these, investigation of all mothers notes to identify if there was a documented discussion about neonatal outcome. D. Clear definitions of what standards should be met to consider an appropriate discussion had occurred.
34	Royal College of Paediatrics and Child Health	2	Question 1: This statement has relevance for both the Obstetric and Paediatric teams. It is unlikely to significantly affect outcomes relating to morbidity and mortality, but is likely to have an impact upon the parental experience of the birth and care of the baby. The local guidance at the Whittington Hospital is that all mothers at risk of delivering between 23 and 35 weeks of gestation are seen by a member of the Paediatric team, with those at earlier gestations being seen by a Registrar or Consultant and those in whom there is a balance of risks in determining optimal timing for planned preterm delivery often being seen jointly by Obstetric and Neonatal Consultants. There is a local guideline that includes gestation specific data on outcomes, and written information leaflets for parents. The guideline specifies points of discussion that are very similar to those outlined in the quality standard and it is standard to offer the parents a tour of the Neonatal Unit antenatally. Question 2: The consultations between mother and medical professional should be routinely documented in the antenatal hand-held records which would need to be manually searched. There is variation in practice about how much of this conversation is documented, based on whether the mother was seen in a formal joint obstetric and neonatal perinatal clinic or if it took place in a more informal setting on the ante-natal in-patient wards. There is also variation based upon the gestation of the baby (e.g. likely to be documented in more detail if baby at threshold of viability) and individual clinician's practice.

ID	Stakeholder	Statement number	Comments[1]
			Local audit standards at the Whittington Hospital (which should be measured annually) specify that all mothers at risk of preterm delivery are counselled by Neonatal staff and this is accurately documented in maternal notes. In our experience, auditing it is likely to be time consuming due to the need to manually search notes and the limitations in information documented. Question 3: No Question 4: This standard should already be being achieved locally. The cost implication is likely to be determined by the time taken demonstrating that it is being achieved, but may also include the cost of adding a specific highlighted section to maternal hand-held records where these discussions should be documented. Education – This statement provides an opportunity for trainees to observe senior colleagues or to be observed counselling parents and demonstrating appropriate documentation. Development of such skills would be considered an important part of standard Paediatric/Neonatal training rather than an additional competency that needs to be met. Attendance at specific joint perinatal clinics may provide additional training opportunities for neonatal trainees. It will be essential to ensure trainees have access to appropriate local resources and data in order to be able to adequately counsel mothers.
35	Royal College of Paediatrics and Child Health	2	The guidance on information sharing regarding potential outcomes for the baby contains all the key information required. Attention however must be highlighted that professionals can share uncertain prognosis; and despite there being population based data; each individual infant and child is unique. There should be emphasis that long term developmental difficulties and impairments can be supported; and that focus should be on participation and activity not necessarily impairment. Alongside communication support e.g. interpreters for language barriers; information sharing (with

ID	Stakeholder	Statement number	Comments[1]
			consent) should also be with fathers and wider family.
36	BMFMS	2	Does there need to be a mention of in utero transfers and the newborn network system to ensure the right baby is in the right unit
37	Buckinghamshire Healthcare NHS Trust	2	This statement is worded quite colloquially ie “surviving”. I would suggest stating “ including perinatal morbidity and mortality rates”
38	The Royal College of Midwives	2	As above there must be consistency in the information given which will mean that all staff giving it must be up to date with current evidence and local policy. This will mean ensuring that midwives and neonatal nurses are kept aware of the information that is being given by other members of the team.
39	The Royal College of Midwives	2	The list here is very useful and should be highlighted through implementation tools.
40	RCOG	3	Page 15 - Should the following sentence be moved to page 5 – in other words, the first reference to tocolysis, steroid injections and magnesium sulfate? “Women in suspected preterm labour who are less than 30 weeks pregnant are offered tocolytics (medicines that slow down or stop labour), steroid injections and magnesium sulfate (medicine that helps protect a baby’s brain).”
41	RCOG	3	While steroids and magnesium are sensible standards to consider, I am very uncomfortable that we are advocating tocolysis as routine here. The evidence that tocolysis improves outcomes is minimal, and there is an argument that (especially when the PTL may be associated with infection) tocolysis may in fact result in overall harm. It is reasonable to consider it, but also entirely reasonable not to give it.
42	University Hospitals Southampton NHS Trust	3	This statement would need greater clarity before being introduced, particularly in relation to tocolysis. There are a number of relative and absolute contraindications to tocolysis, and the statement would need to include these before implementation and measurement.
43	University Hospitals Southampton NHS Trust	3	There is no current mechanism in many hospitals that captures all cases of threatened PTB. It is also very difficult to clearly define who is in threatened preterm labour and comparisons between hospitals would need a much clearer specification of who should and should not be included in this standard. Would this include women with positive FFN, change in cervical length or some other definition?

ID	Stakeholder	Statement number	Comments[1]
			It would be much easier to identify whether women who delivered preterm had received any or all of these treatments, subject to clear agreement about when these are inappropriate or contraindicated.
44	Royal College of Paediatrics and Child Health	3	Question 1: This quality statement is likely to have significant impact on the outcomes identified for improvement in the draft quality standard. Tocolysis, while only likely to delay preterm delivery for 48 hours to 7 days, may provide the opportunity for an in-utero transfer of care to a centre with specialised neonatal facilities or the administration of a complete course of ante-natal corticosteroids. Administration of maternal antenatal corticosteroids is well established best practice for babies at these gestations, and their benefits relating to neonatal morbidity and mortality well documented. The use of magnesium sulfate for neuroprotection has historically been more controversial, but is reported to be of potential benefit for prevention of neurodevelopmental disability. However, the statement primarily relates to Obstetric rather than Paediatric care. The Whittington Hospital guideline for preterm delivery is currently being updated in light of the new NICE guideline. The current guideline states that all those in preterm labour at 24 - 29+6 weeks of gestation (defined as either 4cm dilated or have PPROM and delivery is clinically indicated) should be given magnesium sulfate and antenatal corticosteroids. A discussion about the benefits and risks of tocolysis should also be conducted by the obstetric team, and guidance on choice of tocolytic is given in the guideline. Question 2: This data is not routinely collected for all those in suspected preterm labour. For those whose babies who are born prematurely and admitted to a neonatal unit, it would be reasonably straightforward to collect data on use of tocolytics, magnesium sulfate and steroids as these are recorded electronically (on the Badgernet system) but this is reliant on high quality data entry. Due to the difficulty in accurately identifying those women at risk of preterm delivery, it is likely that not all women counselled and offered tocolysis, maternal corticosteroids and magnesium sulfate will go on to deliver a pre-term infant. Creating a structure to identify these women may be possible for those hospitals which use a solely electronic ante-natal medical record, but is likely to be extremely difficult for those which still rely on paper records alone. It may also be complicated by the possibility of women receiving care at more than one hospital. Question 3: No

ID	Stakeholder	Statement number	Comments[1]
			Question 4: This statement should be achievable for tocolysis, magnesium sulfate and antenatal corticosteroids. Appropriate use of these agents may have cost saving implications for the NHS through reductions in neonatal morbidity and mortality along with reductions in long-term neurodevelopmental disability, but it is likely to be difficult to demonstrate this in the short-term and may require additional investment in outcome studies such as Epicure.
45	BMFMS	3	The guideline says to give MgSO4 to women in ESTABLISHED PTl, the quality standard to women with SUSPECTED PTL – they need to match
46	BAPM	3	Important and should be easy to measure. I think “tocolysis” should be “tocolysis when not contraindicated”
47	Buckinghamshire Healthcare NHS Trust	3	Is the American spelling of Sulfate intended?
48	RCOG	4	I think the denominator here should be women who are between 30 and 33+6 weeks of pregnancy and are in diagnosed preterm labour and who have not previously had steroids in this pregnancy. The guideline highlights that there are risks as well as benefits to women from multiple courses of steroids, so those who have previously had steroids in this pregnancy would not routinely be expected to be given more.
49	University Hospitals Southampton NHS Trust	4	The same difficulties of measurement apply to this as to Statement 3: It would be much easier to identify whether women who delivered preterm at this gestation had received steroids, subject to clear agreement about when these are inappropriate or contraindicated. For instance, if a mother has received steroids earlier in pregnancy, and presents with a new problem between 30 and 33+6 weeks, is repeat steroids indicated, or not.
50	Royal College of Paediatrics and Child Health	4	Question 1: This quality statement is also likely to have a significant impact on the outcomes identifiedfor improvement in the draft quality standard. Administration of maternal antenatal corticosteroids is well established best practice for babies at these gestations, and their benefits relating to neonatal morbidity and mortality well documented. However, the statement primarily relates to Obstetric rather than Paediatric care. The Whittington Hospital guideline for preterm delivery is currently being updated in light of the 2015 NICE guideline. The current local guideline states that all those up to 34+6 weeks of gestation in preterm labour or with a fetal fibronectin greater than 50 mg/mL should be given antenatal corticosteroids. It therefore

ID	Stakeholder	Statement number	Comments[1]
			includes more mature foetuses than the quality standard specifies. Question 2: As with Statement 3, this data is not routinely collected for all those in suspected preterm labour. For those whose babies who are born prematurely and admitted to a neonatal unit, it would be reasonably straightforward to collect data on use of steroids as these are recorded electronically (on the Badgernet system) but this is reliant on high quality data entry. Due to the difficulty in accurately identifying those women at risk of preterm delivery, it is likely that not all women counselled and offered maternal corticosteroids will go on to deliver a pre-term infant. Creating a structure to identify these women may be possible for those hospitals which use a solely electronic ante-natal medical record, but is likely to be extremely difficult for those which still rely on paper records alone. It may also be complicated by the possibility of women receiving care at more than one hospital. Question 3: No Question 4: This should already be being achieved. Appropriate use of antenatal corticosteroids may have cost saving implications for the NHS through reductions in neonatal morbidity and mortality. However, additional resources may be necessary in order to collect the data in order to prove adherence to the quality standard.
51	BMFMS	4	RCOG antenatal corticosteroid guidelines advise to give such to 34+6 weeks not 33+6 as in this document
52	BAPM	4	Important and should be easy to measure.
53	RCOG	Additional area	Yes – the draft quality standard does accurately reflect the key areas for quality improvement However while it monitors the implementation of the recommendations in the guideline, what is really required is information about how the incidence of preterm delivery can be reduced in clinical practice based on cervical length assessments, administration of progesterone and use of cervical cerclage. In reality assessment of the quality of care provided for women has to start at this early stage when we have the opportunity to make a difference to the clinical outcome and reduce neonatal morbidity and mortality.

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54	RCGP	Additional area	There are potential interventions that can reduce the risk of preterm labour including early antenatal care and continuity of care from the same midwife. However these are not included in these Quality standards.(MH) . Fernandez Turienzo C, Sandall J , Peacock J. Health services research Models of antenatal care to reduce and prevent preterm birth: a systematic review and meta analysis BMJ Open 2016;6:e009044 doi:10.1136/bmjopen-2015-009044 http://bmjopen.bmj.com/content/6/1/e009044.short (MH)
55	The Royal College of Midwives	Additional area	However , we think the standard should address some other areas that need improvement and include statements on : Discussion about appropriate monitoring – offering women in established preterm labour but with no other risk factors a choice of fetal heart rate monitoring using either: cardiotocography using external ultrasound or intermittent auscultation. Delayed cord clamping- Waiting at least 30 seconds, but no longer than 3 minutes, before clamping the cord Of preterm babies if the mother and baby are stable. Positioning the baby at or below the level of the placenta before clamping the cord.
56	Clinical Innovations	Appendix 3 p 39	We take issue with ID 026 submitted by Advance Global Health LTD, found on page 23 and 39-40. Firstly, human IGFBP-1 is a well characterized protein since more than 25 years. Its synthesis by the liver and decidua, and levels in amniotic fluid and other body fluids have been thoroughly examined in all stages of pregnancy and the data have been published in peer-reviewed journals. Meanwhile, the data available on PAMG-1 is more limited and partly confusing. Most importantly PAMG-1 is found in more bodily fluids than just amniotic fluid, made evident by the marketing by the company to use the same protein to detect preterm labor in patients with intact membranes. PAMG-1 is also routinely found in blood, although at lower concentrations than in amniotic fluid. Thus, the claim that it is the only protein marker unique to amniotic fluid is simply false. IGFBP-1 has been used as a marker of ROM since the mid-90s. Since then, several studies

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			have consistently shown that this test identifies membrane rupture with high degree of accuracy. Even more recently, a diagnostic test that utilizes the presence of IGFBP-1 and AFP has been introduced to the market. This provides a unique advantage because it identifies both proteins found in high concentrations in the amniotic fluid, in fact, the AFP levels are highest late in the second trimester and early third trimester when diagnosis of rupture of membranes is most pertinent (the very premature). The other claim made by Advance Global Health is that PAMG-1 is superior to IGFBP-1 also cannot be backed up by the worldwide literature. Albayrak et al., 2011 and Palacio et al., 2014 are two head to head trials in which the two proteins (PAMG-1 and IGFBP-1) were used to diagnose ROM and neither trial showed a significant difference between the two proteins' ability to detect ROM. Considering all the points above, the currently available data does not unequivocally support the superiority of the PAMG-1 test as compared with any IGFBP-1 test. Albayrak, M, Ozdemir I, Koc O, Ankarali H, Ozen O. Comparison of the diagnostic efficacy of two rapid bedside immunoassays and combined clinical conventional diagnosis in prelabor rupture of membranes. European J Obstet Gynecol Reprod Bio 2011; 158: 179-182 Montse Palacio, Maritta Kühnert, Richard Berger, Cindy L Larios and Louis Marcellin. RESEARCH ARTICLE Open Access Meta-analysis of studies on biochemical marker tests for the diagnosis of premature rupture of membranes. BMC Pregnancy and Childbirth 2014, 14:183
57	BMFMS	EQIA	It is frequently noted that interpreters should be used if necessary – increasingly Trusts will not fund face to face interpreters – does it need to be explicit the interpreter may be overthe telephone on language line

Registered stakeholders who submitted comments at consultation

- British Association of Perinatal Medicine
- British Maternal and Fetal Medicine Society
- Buckinghamshire Healthcare NHS Trust
- Clinical Innovation
- Department of Health
- Ferring Pharmaceuticals Ltd
- Joint Royal Colleges Ambulance Liaison Committee
- NHS England
- Royal College of General Practitioners
- Royal College of Gynaecologists and Obstetricians
- Royal College of Midwives
- Royal College of Nursing
- Royal College of Paediatrics and Child Health
- Society and College of Radiographers
- University Hospitals Southampton NHS Trust