

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health and social care directorate

Quality standards and indicators

Briefing paper

Quality standard topic: Preterm labour and birth

Output: Prioritised quality improvement areas for development.

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Contents

1	Introduction	2
2	Overview	2
3	Summary of suggestions	5
4	Suggested improvement areas	7
	Appendix 1: Review flowchart	25
	Appendix 2: Glossary	26
	Appendix 3: Suggestions from stakeholder engagement exercise – registered stakeholders.....	27

1 Introduction

This briefing paper presents a structured overview of potential quality improvement areas for preterm labour and birth. It provides the Committee with a basis for discussing and prioritising quality improvement areas for development into draft quality statements and measures for public consultation.

1.1 Structure

This briefing paper includes a brief description of the topic, a summary of each of the suggested quality improvement areas and supporting information.

If relevant, recommendations selected from the key development source below are included to help the Committee in considering potential statements and measures.

1.2 Development source

The key development source referenced in this briefing paper is:

[Preterm labour and birth](#) (2015) NICE guideline NG25

2 Overview

2.1 Focus of quality standard

This quality standard will cover care for women who are considered to be at risk of preterm labour and birth including diagnosing preterm labour. It will not include women with a multiple pregnancy.

2.2 Definition

Preterm labour and birth is before 37⁺⁰ weeks of pregnancy.

2.3 Incidence and prevalence

Preterm birth is the single biggest cause of neonatal mortality and morbidity in the UK. Over 52,000 babies (around 7.3% of live births) in England and Wales in 2012 were born preterm – that is, before 37⁺⁰ weeks of pregnancy. There has been no decline in the preterm birth rate in the UK over the last 10 years.

Babies born preterm have high rates of early, late and post neonatal mortality, and the risk of mortality increases as gestational age at birth decreases. Babies who survive have increased rates of disability. Recent UK studies comparing cohorts born in 1995 and 2006 have shown improved rates of survival (from 40% to 53%) for

extreme preterm births (born between 22 and 26 weeks). Rates of disability in survivors were largely unchanged over this time period.

The major long-term consequence of prematurity is neurodevelopmental disability. Although the risk for the individual child is greatest for those born at the earliest gestational ages, the global burden of neurodevelopmental disabilities depends on the number of babies born at each of these gestations, and so is greatest for babies born between 32 and 36 weeks, less for those born between 28 and 31 weeks, and least for those born at less than 28 weeks gestation.

Around 75% of women delivering preterm do so after preterm labour, which may or may not be preceded by preterm prelabour rupture of membranes (P-PPROM). The remaining women delivering preterm have an elective preterm birth when this is thought to be in the fetal or maternal interest (for example, because of extreme growth retardation in the baby or maternal conditions such as pre-eclampsia).

2.4 *Management*

Optimal diagnosis can facilitate transfer to a place where appropriate neonatal intensive care can be provided, a strategy known to improve rates of survival for the baby.

2.5 *National Outcome Frameworks*

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

Table 1 [NHS Outcomes Framework 2015–16](#)

Domain	Overarching indicators and improvement areas
1 Preventing people from dying prematurely	<p>Overarching indicators</p> <p>1a Potential Years of Life Lost (PYLL) from causes considered amenable to healthcare</p> <p>i Adults ii Children and young people</p> <p>1c Neonatal mortality and stillbirths</p> <p>Reducing mortality in children</p> <p>1.6 i Infant mortality*</p> <p>ii Neonatal mortality and stillbirths</p>
4 Ensuring that people have a positive experience of care	<p>Overarching indicators</p> <p>4c <i>Friends and family test</i></p> <p>4d <i>Patient experience characterised as poor or worse</i></p> <p>ii <i>Hospital care</i></p> <p>Improvement areas</p> <p>Improving women and their families' experience of maternity services</p> <p>4.5 Women's experience of maternity services</p>
5 Treating and caring for people in a safe environment and protecting them from avoidable harm	<p>Overarching indicators</p> <p>5a <i>Deaths attributable to problems in healthcare</i></p> <p>5b <i>Severe harm attributable to problems in healthcare</i></p> <p>Improvement areas</p> <p>Improving the culture of safety reporting</p> <p>5.6 Patient safety incidents reported</p>
<p>Alignment with Public Health Outcomes Framework</p> <p>* Indicator is shared</p> <p>Indicators in italics in development</p>	

Table 2 [Public health outcomes framework for England, 2013–2016](#)

Domain	Objectives and indicators
4 Healthcare public health and preventing premature mortality	<p>Objective</p> <p>Reduced numbers of people living with preventable ill health and people dying prematurely, whilst reducing the gap between communities</p> <p>Indicators</p> <p>4.1 Infant mortality*</p> <p>4.3 Mortality rate from causes considered preventable**</p>
<p>Alignment with Adult Social Care Outcomes Framework and/or NHS Outcomes Framework</p> <p>* Indicator is shared</p> <p>** Indicator is complementary</p>	

3 Summary of suggestions

3.1 Responses

In total 11 stakeholders responded to the 2-week engagement exercise 09/10/15-23/10/15

Stakeholders were asked to suggest up to 5 areas for quality improvement. Specialist committee members were also invited to provide suggestions. The responses have been merged and summarised in table 3 for further consideration by the Committee.

Full details of all the suggestions provided are given in appendix 3 for information.

Table 3 Summary of suggested quality improvement areas

Suggested area for improvement	Stakeholders
Information and support	BLISS, RCPCH, SCM
Prophylactic vaginal progesterone and prophylactic cervical cerclage	KCLDWH, RCPCH, SCM,
Identifying infection in women with P-PROM	RCPCH
Diagnosing preterm labour for women with intact membranes	HEYNHSTRUST, KCLDWH, RCPCH, SCM
Tocolysis	RCPCH
Maternal corticosteroids	KCLDWH
Magnesium sulfate for neuroprotection	KCLDWH, RCPCH, SCM, WEAHSN,
Timing of cord clamping for preterm babies (born vaginally or by caesarean section)	BLISS, RCPCH
AGHLtd, Advanced Global Health Ltd – UK Distributors of AmniSure (PAMG-1) & PartoSure (PAMG-1) BLISS HEYNHSTRUST, Hull & East Yorkshire Hospitals NHS Trust KCLDWH, King's College London (Division of Women's Health) NHSE, NHS England RCGP, Royal College of Paediatrics and Child Health RCPCH, Royal College of Nursing SCM, Specialist Committee Member WEAHSN, West of England Academic Health Science	

3.2 *Identification of current practice evidence*

Bibliographic databases were searched to identify examples of current practice in UK health and social care settings; 1231 studies were identified for QS topic. In addition, current practice examples were suggested by stakeholders at topic engagement (3 studies) and internally at project scoping (3 studies).

Of these studies, 3 were assessed as having potential relevance to this topic and the suggested areas for quality improvement identified by stakeholders (see appendix 1). A summary of relevant studies is included in the current practice sections for each suggested area of improvement.

4 Suggested improvement areas

4.1 Information and support

4.1.1 Summary of suggestions

Information and support

Significant variation in information in both factual content and therapeutic approach was reported by a stakeholder. Stakeholders supported the provision of a standardised package of written and oral information and support for women at high risk of preterm birth including meeting with a neonatologist and having a neonatal unit tour.

A stakeholder also highlighted the importance of information provision by trained staff using an approved patient information leaflet. This could potentially minimise variable information and parental distress on why specific procedures may happen. Healthcare professionals working with parents before delivery was reported as key.

4.1.2 Selected recommendations from development source

Table 4 below highlights recommendations that have been provisionally selected from the development source that may support potential statement development. These are presented in full after table 4 to help inform the Committee's discussion.

Table 4 Specific areas for quality improvement

Suggested quality improvement area	Suggested source guidance recommendations
Information and support	NICE NG25 Recommendations 1.1.1 and 1.1.2

NICE NG25 – Recommendation 1.1.1

When giving information and support to women at increased risk of preterm labour, with suspected, diagnosed or established preterm labour, or having a planned preterm birth (and their family members or carers as appropriate):

- give this information and support as early as possible, taking into account the likelihood of preterm birth and the status of labour
- follow the principles in the NICE guideline on patient experience in adult NHS services
- bear in mind that the woman (and her family members or carers) may be particularly anxious

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- give both oral and written information
- describe the symptoms and signs of preterm labour
- explain to the woman about the care she may be offered.

NICE NG25 – Recommendation 1.1.2

For women who are having a planned preterm birth or are offered treatment for preterm labour in line with sections 1.8–1.10 (and their family members or carers as appropriate), provide information and support that includes:

- information about the likelihood of the baby surviving and other outcomes (including long-term outcomes) and risks for the baby, giving values as natural frequencies (for example, 1 in 100)
- explaining about the neonatal care of preterm babies, including location of care
- explaining about the immediate problems that can arise when a baby is born preterm
- explaining about the possible long-term consequences of prematurity for the baby (how premature babies grow and develop)
- ongoing opportunities to talk about and state their wishes about resuscitation of the baby
- an opportunity to tour the neonatal unit
- an opportunity to speak to a neonatologist or paediatrician.

4.1.3 Current UK practice

No published studies on current practice data were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience.

4.1.4 Resource impact assessment

This area was not included in the resource impact report for NG25. It was not identified as an area that would have a significant resource impact (>£1m in England each year).

4.2 *Prophylactic vaginal progesterone and prophylactic cervical cerclage*

4.2.1 Summary of suggestions

Stakeholders supported offering either prophylactic vaginal progesterone or prophylactic cervical cerclage only to women who are at specific high risk for example women who have had previous preterm birth or late miscarriage, short cervical length or a history of cervical trauma.

A stakeholder highlighted that incorrect cervical length measurement may lead to false positives and unnecessary intervention or false negatives and risk of poor outcome associated with preterm birth.

4.2.2 Selected recommendations from development source

Table 5 below highlights recommendations that have been provisionally selected from the development source that may support potential statement development. These are presented in full after table 5 to help inform the Committee's discussion.

Table 5 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Prophylactic vaginal progesterone and prophylactic cervical cerclage	NICE NG25 Recommendations 1.2.1-1.2.3

NICE NG25 Recommendation 1.2.1

Offer a choice of either prophylactic vaginal progesterone or prophylactic cervical cerclage to women:

- with a history of spontaneous preterm birth or mid-trimester loss between 16⁺⁰ and 34⁺⁰ weeks of pregnancy **and**
- in whom a transvaginal ultrasound scan has been carried out between 16⁺⁰ and 24⁺⁰ weeks of pregnancy that reveals a cervical length of less than 25 mm.

Discuss the benefits and risks of prophylactic progesterone and cervical cerclage with the woman and take her preferences into account.

NICE NG25 Recommendation 1.2.2

Offer prophylactic vaginal progesterone to women with no history of spontaneous preterm birth or mid-trimester loss in whom a transvaginal ultrasound scan has been

carried out between 16⁺⁰ and 24⁺⁰ weeks of pregnancy that reveals a cervical length of less than 25 mm.

NICE NG25 Recommendation 1.2.3

Consider prophylactic cervical cerclage for women in whom a transvaginal ultrasound scan has been carried out between 16⁺⁰ and 24⁺⁰ weeks of pregnancy that reveals a cervical length of less than 25 mm and who have either:

- had preterm prelabour rupture of membranes (P-PROM) in a previous pregnancy **or**
- a history of cervical trauma.

4.2.3 Current UK practice

Sharp and Alfirevic¹ (2013) reported unit variation in cervical length to necessitate treatment.

4.2.4 Resource impact assessment

This area was not included in the resource impact report for NG25. It was not identified as an area that would have a significant resource impact (>£1m in England each year).

¹ Sharp and Alfirevic (2013) [Provision and practice of specialist preterm labour clinics: a UK survey of practice](#)

4.3 Identifying infection in women with P-PROM

4.3.1 Summary of suggestions

Preterm prelabour rupture of membranes (P-PROM) exposes both the fetus and the mother to infection risk. Infection identification in women with P-PROM was supported by a stakeholder as an important neonatal outcome.

4.3.2 Selected recommendations from development source

Table 6 below highlights recommendations that have been provisionally selected from the development source that may support potential statement development. These are presented in full after table 6 to help inform the Committee’s discussion.

Table 6 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Identifying infection in women with P-PROM	NICE NG25 Recommendations 1.5.1 and 1.5.2

NICE NG25 Recommendation 1.5.1

Use a combination of clinical assessment and tests (C-reactive protein, white blood cell count and measurement of fetal heart rate using cardiotocography) to diagnose intrauterine infection in women with P-PROM.

NICE NG25 Recommendation 1.5.2

Do not use any one of the following in isolation to confirm or exclude intrauterine infection in women with P-PROM:

- a single test of C-reactive protein
- white blood cell count
- measurement of fetal heart rate using cardiotocography.

4.3.3 Current UK practice

No published studies on current practice data were highlighted for this suggested area for quality improvement; this area is based on stakeholder’s knowledge and experience.

4.3.4 Resource impact assessment

This area was not included in the resource impact report for NG25. It was not identified as an area that would have a significant resource impact (>£1m in England each year).

4.4 *Diagnosing preterm labour for women with intact membranes*

4.4.1 Summary of suggestions

A stakeholder reported variation in access to prompt fetal fibronectin or transvaginal ultrasound services. Fetal fibronectin testing and transvaginal ultrasound measurement of cervical length was highlighted as being beneficial in assessing high risk women with symptoms where the diagnosis of labour is uncertain. This provides clinicians with additional information on delivery risk so that interventions are appropriately offered such as in-utero transfer.

4.4.2 Selected recommendations from development source

Table 7 below highlights recommendations that have been provisionally selected from the development source that may support potential statement development. These are presented in full after table 7 to help inform the Committee's discussion.

Table 7 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Diagnosing preterm labour for women with intact membranes	NICE NG25 Recommendations 1.7.5-1.7.7

NICE NG25 Recommendation 1.7.5

Consider fetal fibronectin testing as a diagnostic test to determine likelihood of birth within 48 hours for women who are 30⁺⁰ weeks pregnant or more if transvaginal ultrasound measurement of cervical length is indicated but is not available or not acceptable. Act on the results as follows:

- if fetal fibronectin testing is negative (concentration 50 ng/ml or less), explain to the woman that it is unlikely that she is in preterm labour and:
 - think about alternative diagnoses
 - discuss with her the benefits and risks of going home compared with continued monitoring and treatment in hospital
 - advise her that if she does decide to go home, she should return if symptoms suggestive of preterm labour persist or recur
- if fetal fibronectin testing is positive (concentration more than 50 ng/ml), view the woman as being in diagnosed preterm labour and offer treatment as described in sections 1.8 and 1.9.

NICE NG25 Recommendation 1.7.6

If a woman in suspected preterm labour who is 30+⁰ weeks pregnant or more does not have transvaginal ultrasound measurement of cervical length or fetal fibronectin testing to exclude preterm labour, offer treatment consistent with her being in diagnosed preterm labour (see sections 1.8 and 1.9).

NICE NG25 Recommendation 1.7.7

Do not use transvaginal ultrasound measurement of cervical length and fetal fibronectin testing in combination to diagnose preterm labour.

4.4.3 Current UK practice

Stock et al² (2015) concluded that 45 (35%) out of 198 UK maternity units undertake transvaginal ultrasound of cervical length with 18 (13.5%) units reporting sequential use of cervical length scan followed by a biochemical test. Two units (2%) used cervical length in isolation.

Also Sharp and Alfirevic³ (2013) reported unit variation in fetal fibronectin testing.

4.4.4 Resource impact assessment

The [resource impact report](#) for NG25 states that there may be increased costs to ensure that maternity services can provide cervical length scans outside normal working hours for women who are 30+⁰ weeks pregnant or more with intact membranes who are in suspected preterm labour. This may be provided by on-call imaging services and/or by training healthcare professionals on obstetrics units to ensure that sufficient expertise is available at all times. Additional ultrasound equipment may need to be bought by provider organisations to increase scanning capacity.

However, it was not identified as an area that would have a significant resource impact (>£1m in England each year).

² Stock et al (2015) [Variation in management of women with threatened preterm labour](#)

³ Sharp and Alfirevic (2013) [Provision and practice of specialist preterm labour clinics: a UK survey of practice](#)

4.5 *Tocolysis*

4.5.1 Summary of suggestions

A stakeholder supported the use of tocolysis to determine in-utero transfers between care units.

4.5.2 Selected recommendations from development source

Table 8 below highlights recommendations that have been provisionally selected from the development source that may support potential statement development. These are presented in full after table 8 to help inform the Committee’s discussion.

Table 8 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Tocolysis	NICE NG25 Recommendation 1.8.1

NICE NG25 Recommendation 1.8.1

Take the following factors into account when making a decision about whether to start tocolysis:

- whether the woman is in suspected or diagnosed preterm labour
- other clinical features (for example, bleeding or infection) which may suggest that stopping labour is contraindicated
- gestational age at presentation
- likely benefit of maternal corticosteroids (see section 1.9)
- availability of neonatal care (need for transfer to another unit)
- the preference of the woman.

4.5.3 Current UK practice

Stock et al⁴ (2015) concluded overall 130 (98%) UK units use tocolysis for women with threatened preterm labour. However significant current variation in in-utero transfers both within and between UK regions was also reported.

⁴ Stock et al (2015) [Variation in management of women with threatened preterm labour](#)

4.5.4 Resource impact assessment

The [resource impact report](#) for NG25 discussed offering oxytocin receptor antagonists for tocolysis only if the calcium channel blocker nifedipine is contraindicated. The cost of nifedipine is around £1 for a 48-hour treatment period compared with around £547 for a 48-hour treatment period for oxytocin receptor antagonists. There is considerable variation in practice for tocolysis medication, and using nifedipine as first-line treatment may result in savings for provider organisations.

However, it was not identified as an area that would have a significant resource impact (>£1m in England each year).

4.6 *Maternal corticosteroids*

4.6.1 Summary of suggestions

A stakeholder supported administration timing of this intervention as being critical for a significant reduction in death and serious morbidities in preterm babies.

4.6.2 Selected recommendations from development source

Table 9 below highlights recommendations that have been provisionally selected from the development source that may support potential statement development. These are presented in full after table 9 to help inform the Committee's discussion.

Table 9 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Maternal corticosteroids	NICE NG25 Recommendations 1.9.1-1.9.6

NICE NG25 Recommendation 1.9.1

For women between 23⁺⁰ and 23⁺⁶ weeks of pregnancy who are in suspected or established preterm labour, are having a planned preterm birth or have P-PROM (see section 1.3), discuss with the woman (and her family members or carers as appropriate) the use of maternal corticosteroids in the context of her individual circumstances.

NICE NG25 Recommendation 1.9.2

Consider maternal corticosteroids for women between 24⁺⁰ and 25⁺⁶ weeks of pregnancy who are in suspected or established preterm labour, are having a planned preterm birth or have P-PROM.

NICE NG25 Recommendation 1.9.3

Offer maternal corticosteroids to women between 26⁺⁰ and 33⁺⁶ weeks of pregnancy who are in suspected, diagnosed or established preterm labour, are having a planned preterm birth or have P-PROM.

NICE NG25 Recommendation 1.9.4

Consider maternal corticosteroids for women between 34⁺⁰ and 35⁺⁶ weeks of pregnancy who are in suspected, diagnosed or established preterm labour, are having a planned preterm birth or have P-PROM.

NICE NG25 Recommendation 1.9.5

When offering or considering maternal corticosteroids, discuss with the woman (and her family members or carers as appropriate):

- how corticosteroids may help
- the potential risks associated with them.

NICE NG25 Recommendation 1.9.6

Do not routinely offer repeat courses of maternal corticosteroids, but take into account:

- the interval since the end of last course
- gestational age
- the likelihood of birth within 48 hours.

4.6.1 Current UK practice

Adams et al (2015)⁵ concluded only 48% of patients with an indication for preterm birth received corticosteroids within 7 days of administration.

4.6.2 Resource impact assessment

This area was not included in the resource impact report for NG25. It was not identified as an area that would have a significant resource impact (>£1m in England each year).

⁵ Adams et al (2015) [The timing of administration of antenatal corticosteroids in women with indicated preterm birth](#)

4.7 *Magnesium sulfate for neuroprotection*

4.7.1 Summary of suggestions

A stakeholder highlighted that neurological effects of preterm birth are common and may cause severe disability. The use of neuroprotective agents may reduce long-term disability and health needs and minimise adverse outcomes such as cerebral palsy.

A stakeholder supported the use of magnesium sulfate for fetus neuroprotection for preterm labour before 30 weeks gestation. Also giving this to the mother in appropriate time ahead of delivery was reported as beneficial to the neonate, in terms of improved neurodevelopmental outcome.

4.7.2 Selected recommendations from development source

Table 10 below highlights recommendations that have been provisionally selected from the development source that may support potential statement development. These are presented in full after table 10 to help inform the Committee's discussion.

Table 10 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Magnesium sulfate for neuroprotection	NICE NG25 Recommendations 1.10.1-1.10.5

NICE NG25 Recommendation 1.10.1

Offer intravenous magnesium sulfate for neuroprotection of the baby to women between 24⁺⁰ and 29⁺⁶ weeks of pregnancy who are:

- in established preterm labour **or**
- having a planned preterm birth within 24 hours.

NICE NG25 Recommendation 1.10.2

Consider intravenous magnesium sulfate for neuroprotection of the baby for women between 30⁺⁰ and 33⁺⁶ weeks of pregnancy who are:

- in established preterm labour **or**
- having a planned preterm birth within 24 hours.

NICE NG25 Recommendation 1.10.3

Give a 4g intravenous bolus of magnesium sulfate over 15 minutes, followed by an intravenous infusion of 1g per hour until the birth or for 24 hours (whichever is sooner).

NICE NG25 Recommendation 1.10.4

For women on magnesium sulfate, monitor for clinical signs of magnesium toxicity at least every 4 hours by recording pulse, blood pressure, respiratory rate and deep tendon (for example, patellar) reflexes.

NICE NG25 Recommendation 1.10.5

If a woman has or develops oliguria or other signs of renal failure:

- monitor more frequently for magnesium toxicity
- think about reducing the dose of magnesium sulfate.

4.7.3 Current UK practice

Stock et al⁶ (2015) concluded that magnesium sulfate is used in 82 of 133 units (62%) with another 6 units (5%) reporting an intention to start using it.

4.7.4 Resource impact assessment

The [resource impact report](#) for NG25 discussed that it is not standard practice in all units to offer intravenous magnesium sulfate for neuroprotection of the baby to women between 24+0 and 33+6 weeks of pregnancy if they are in established preterm labour or are having a planned preterm birth within 24 hours.

The additional cost to providers for magnesium sulfate is unlikely to be significant (around £45 per 24-hour period; see appendix, table 1) but additional midwife time may be needed to monitor the woman throughout the 24-hour treatment period. However, it was not identified as an area that would have a significant resource impact (>£1m in England each year).

More use of magnesium sulfate for neuroprotection may avoid adverse events such as cerebral palsy and intracranial haemorrhage. The impact of this could not be quantified however any savings would benefit the wider health, social care and education economies.

⁶ Stock et al (2015) [Variation in management of women with threatened preterm labour](#)

4.8 *Timing of cord clamping for preterm babies (both vaginally or by caesarean section)*

4.8.1 Summary of suggestions

Stakeholders supported cord milking and delayed cord clamping practices to beneficially enhance the amount of placental transfusion which has many benefits such as improving systemic blood pressure and increases cerebral oxygen perfusion.

A stakeholder reported that there is now evidence that cord milking is superior to delayed clamping in terms of neonatal cardiovascular status.

4.8.2 Selected recommendations from development source

Table 11 below highlights recommendations that have been provisionally selected from the development source that may support potential statement development. These are presented in full after table 11 to help inform the Committee’s discussion.

Table 11 Specific areas for quality improvement

Suggested quality improvement area	Selected source guidance recommendations
Timing of cord clamping for preterm babies (both vaginally or by caesarean section)	NICE NG25 Recommendations 1.13.1 and 1.13.2

NICE NG25 Recommendation 1.13.1

If a preterm baby needs to be moved away from the mother for resuscitation, or there is significant maternal bleeding:

- consider milking the cord **and**
- clamp the cord as soon as possible.

NICE NG25 Recommendation 1.13.2

Wait at least 30 seconds, but no longer than 3 minutes, before clamping the cord of preterm babies if the mother and baby are stable.

4.8.3 Current UK practice

No published studies on current practice data were highlighted for this suggested area for quality improvement; this area is based on stakeholder's knowledge and experience.

4.8.4 Resource impact assessment

This area was not included in the resource impact report for NG25. It was not identified as an area that would have a significant resource impact (>£1m in England each year).

4.9 Additional areas

Summary of suggestions

The improvement areas below were suggested as part of the stakeholder engagement exercise. However they were felt to be either unsuitable for development as quality statements, outside the remit of this particular quality standard referral or require further discussion by the Committee to establish potential for statement development.

There will be an opportunity for the QSAC to discuss these areas at the end of the session on 4 February 2016.

Additional areas

PAMG-1 protein test

A stakeholder highlighted PAMG-1 protein as the most reliable protein to aid diagnosis of rupture of membranes (ROM).

Psychological parental support

Maternity unit affiliated to NICU level 3 facilities

A stakeholder supported affiliation between maternity units and NICU level 3 facilities as being associated with better outcomes.

Implementation of specialist preterm birth clinics

A stakeholder highlighted the need for this service as this is inconsistent within those specialist clinics which do exist with variation in management.

Centres equipped to provide full neonatal intensive care

A stakeholder highlighted the importance of centres being equipped to provide full neonatal intensive care.

Practical information

A stakeholder raised the significant financial burden on parents of babies needing neonatal care. Each hospital has a different support package for families to help with everyday costs and practicalities such as parking permits, food discounts, onsite accommodation which is important.

A stakeholder highlighted that is vital that parents are informed of available psychological support. When this is not available information and signposting on this must be provided to parents.

Post-natal ward layout

A stakeholder reported that effective layout of the post-natal ward is vital for mental health and wellbeing.

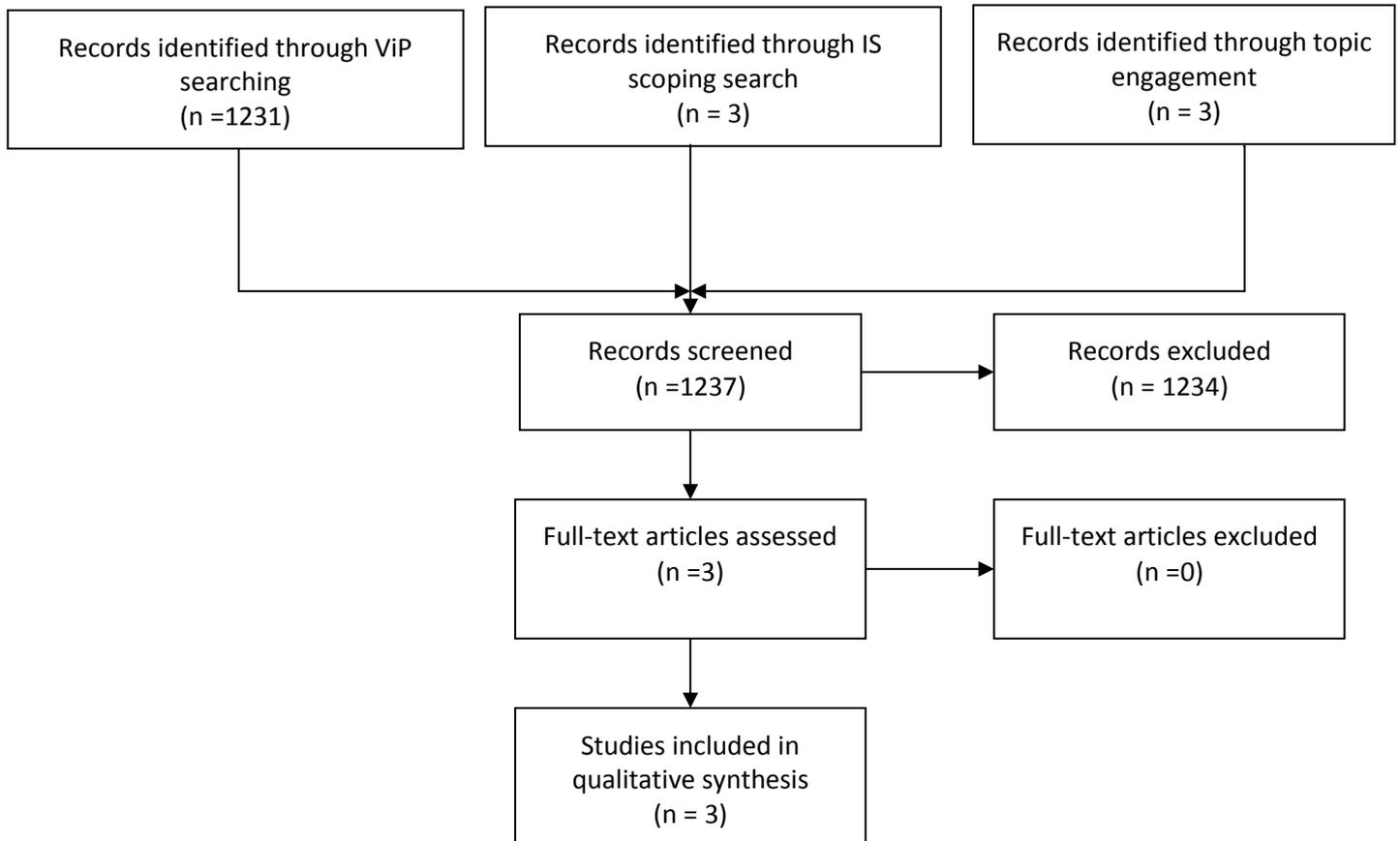
Multidisciplinary team care

A stakeholder highlighted the need for access to a co-ordinated multi-disciplinary team (MDT) obstetric and medical clinic, to avoid multiple appointments and poor communication between senior specialists.

Experiences of neonatal care

A stakeholder highlighted experience of care as being a key requirement of the National Outcomes Frameworks with a positive experience of care improving outcomes.

Appendix 1: Review flowchart



Appendix 2: Glossary

Cervical cerclage A surgical treatment for cervical incompetence or insufficiency.

Cord milking After delivery, the caregiver holds the umbilical cord and squeezes blood down the cord into the baby.

Diagnosed preterm labour A woman is in diagnosed preterm labour if she is in suspected preterm labour and has had a positive diagnostic test for preterm labour.

Established preterm labour A woman is in established preterm labour if she has progressive cervical dilatation from 4 cm with regular contractions.

Fetal fibronectin A fibronectin protein produced by fetal cells.

Magnesium sulfate An inorganic salt containing magnesium, sulfur and oxygen, with the formula MgSO₄.

Prophylactic cervical cerclage A treatment for cervical weakness (also termed cervical incompetence or insufficiency) to prevent preterm birth and miscarriage.

Prophylactic progesterone Progesterone by vaginal suppository to reduce the incidence of spontaneous preterm birth.

Preterm prelabour rupture of membranes (P-PROM) A woman is described as having P-PROM if she has ruptured membranes before 37⁺⁰ weeks of pregnancy but is not in established labour.

Symptoms of preterm labour A woman has presented before 37⁺⁰ weeks of pregnancy reporting symptoms that might be indicative of preterm labour (such as abdominal pain), but no clinical assessment (including speculum or digital vaginal examination) has taken place.

Suspected preterm labour A woman is in suspected preterm labour if she has reported symptoms of preterm labour and has had a clinical assessment (including a speculum or digital vaginal examination) that confirms the possibility of preterm labour but rules out established labour.

Tocolysis A drug which stops or delays the progress of labour once it is believed to have started is a 'tocolytic'. Drugs which are used to 'prevent' preterm labour are not considered tocolytics for example progesterone.

Appendix 3: Suggestions from stakeholder engagement exercise – registered stakeholders

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
Information and support					
001	Bliss	Provision of information and communication to families about neonatal care.	<p>As the NICE Preterm Labour and Birth guidelines rightly establish, going into preterm labour can happen suddenly and is likely to cause a great deal of anxiety for both parents.</p> <p>While the Guidelines highlight the importance of explaining information taking into account the mother’s anxiety, the quality standard should set out clearly how units can improve the accessibility and clarity of their communications</p>	<p>Taking in information during a high stress situation can be difficult. Research is currently being undertaken by the Neonatal Decisions Study to assess and improve how conversations can be conducted so parents feel they have options and are involved in the decision making about their own and their baby’s care.</p> <p>Asking encouraging questions and stressing that it is alright for parents to ask further questions at another point in time also helps to open up communication between professionals and parents.</p> <p>Other techniques, recommended by the Bliss family friendly accreditation scheme includes providing written information, as well as verbal, so parents can remind themselves about why certain procedures may happen, for example.</p>	Bliss, ‘Bliss family friendly accreditation scheme: helping to make family-centred care a reality on your neonatal unit,’ (2015)
002	Royal College of Paediatrics and Child Health	Information available to the parents	Partnership working with the parents before delivery	Partnership working with the parents before delivery	NICE NG25
003	SCM1	Provision of a standardised “package”	NICE Preterm labour guideline recommends that both women at	Qualitative data review (NICE preterm labour guideline) suggests that these themes are	https://www.rcog.org.uk/globalassets/documents/pati

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
		of information and support for for women at high risk of preterm birth which includes written and oral information, meeting with neonatologist/tour of NICU etc	increased risk of preterm labour or having a planned preterm birth are provided with both oral and written information which details of survival/neonatal care etc	identified as being important to women who have experienced a preterm birth RCOG has an existing patient information leaflet specifically on preterm labour only	ents/patient-information-leaflets/pregnancy/pi-premature-labour.pdf
004	SCM2	Delivery of good quality oral and written information to women at high risk of preterm delivery.	Delivering preterm is extremely stressful for families, and is known to be associated with great parental emotional distress. Outcomes vary according to the gestation at delivery – the content of a conversation with a woman expected to deliver at 33, 27 and 22 weeks gestation differs dramatically.	Evidence exists that professional perspectives on the delivery of preterm infants varies considerably. It is very likely indeed that key informants for women, particularly those at risk of delivery at the lowest gestations, receive information which varies greatly in factual content and therapeutic approach. If information is given by a trained member of staff in association with an approved patient information leaflet, unwarranted variation between and within cases will be minimised. Parental distress will be minimised, and appropriate therapeutic expectations on part of professionals and parents will result.	A large literature exists on variation in initiation of intensive care at borderline gestations between countries within Europe. Available UK data suggests that variation in survival is in part explained by variation in rates of admission for intensive care of babies at lowest gestations.
Prophylactic vaginal progesterone and prophylactic cervical cerclage					
005	King's College London (Division of Women's Health)	Provision of antenatal preterm surveillance for all high risk women.	Evidence suggests that interventions, such as progesterone and cervical cerclage can reduce preterm birth in women who are at high risk e.g.	These recommended interventions can only be offered to women who have been identified as being at risk, and monitored using transvaginal ultrasound cervical length measurement. This is not currently routine	Please see NICE PTB guideline http://www.nice.org.uk/guidance/ng25

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			<p>previous preterm birth or late miscarriage, short cervical length or a history of cervical trauma (see NICE guideline “Preterm Labour and Birth 2015”). For example, the new NICE guideline recommends that high risk women who are found to have a short cervix (i.e. <25mm) between 16 and 24 weeks’ gestation should be offer a choice of either progesterone or prophylactic cervical cerclage to women.</p>	<p>practice in UK antenatal care. Specialist preterm clinics exist, but provision varies widely around the UK (Sharp & Alfirevic, 2014).</p>	<p>Please see: Sharp, A. & Alfirevic, Z. 2014, "Provision and practice of specialist preterm labour clinics: a UK survey of practice", BJOG: An International Journal of Obstetrics & Gynaecology, vol. 121, no. 4, pp. 417-421. DOI: 10.1111/1471-0528.12512</p> <p>Please see presentation film outlining the work of St Thomas’ Hospital Preterm Surveillance Clinic, NHS Innovations Challenge Prize Winner 2013 and the Alasdair Liddell Memorial Award for Outstanding Contribution to Healthcare Innovation 2013. https://youtu.be/yASYom2m3Mo</p>
006	Royal College of Paediatrics and Child Health	Use of Prophylactic vaginal progesterone and cervical cerclage	Relatively new interventions	Relatively new interventions	NICE NG25
007	SCM 3	Prevention of Pre term Birth	Preterm birth is the single biggest cause of neonatal mortality and	Evidence of benefit is not high enough to recommend that all women at risk of preterm	http://www.nice.org.uk/guidance/ng25/evidence/full-

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			<p>morbidity in the UK. NICE Guideline recommends offering a choice of either prophylactic vaginal progesterone or prophylactic cervical cerclage</p>	<p>birth due to a previous history and/or a short cervix should have prophylactic cerclage, but neither is there evidence of great enough harm that would justify recommending against its use.</p>	<p>guideline-2176838029 NICE Preterm Labour and Birth Guideline</p>
008	SCM1	<p>Standardisation of technique and indications for sonographic measurement of cervical length</p>	<p>NICE Preterm Labour guideline recommends that cervical length is used as the preferred first line diagnostic test for women in threatened preterm labour over 30 weeks gestation.</p> <p>NICE Preterm Labour guideline recommends intervention for specific subgroups of women at increased risk of preterm birth based on measurement of cervical length of less than 25mm.</p>	<p>There are no nationally recognised guidelines for this technique and it is not currently part of the RCOG basic ultrasound training module for obstetrics and gynaecology trainees. NSC has not recommended routine cervical length screening in otherwise low risk women and therefore has not published any guidelines on the technique Incorrect measurement may lead to false positives and unnecessary intervention or false negatives and risk of poor outcome associated with preterm birth</p>	<p>https://www.rcog.org.uk/en/careers-training/specialty-training-curriculum/ultrasound-training/</p> <p>legacy.screening.nhs.uk/policydb_download.php?doc=491</p>
009	SCM2	<p>Use of antenatal progesterone to prevent preterm labour</p>	<p>Progesterone prophylaxis is recommended for women at risk of preterm labour, but is far from routinely available or practised in the UK</p>	<p>Data suggest that women who are appropriately risk stratified may gain significant benefits to their baby by prolonging pregnancy. When delivered, on account of lesser degrees of prematurity, significant benefits may be accrued by the babies</p>	<p>See for eg Dodd JM, Jones L, Flenady V, Cincotta R, Crowther CA. Prenatal administration of progesterone for preventing preterm birth in women considered to be at risk of preterm birth. Cochrane Database of Systematic Reviews 2013, Issue 7. Art. No.: CD004947. DOI:</p>

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					10.1002/14651858.CD004947.pub3.
Identifying infection in women with P-PROM					
010	Royal College of Paediatrics and Child Health	Identifying infection in women with P-PROM	Important factor for Neonatal outcome	Important factor for Neonatal outcome	NICE NG25
Diagnosing preterm labour for women with intact membranes					
011	Hull & East Yorkshire Hospitals NHS Trust	Point of care diagnostic tests to diagnose : 1. Likelihood of premature delivery 2. Likelihood of pre-eclampsia	There is widespread evidence that there should be greater use across UK maternity services of simple to use point of care diagnostic tests to diagnose : 1. Likelihood of premature delivery 2. Likelihood of pre-eclampsia	Two reasons – the wider use of the two tests signposted under the ‘Supporting Information’ column will give a much better indication of the risks an individual woman faces thus giving improved clinical management. Secondly – the default position with potential at risk women is often to deliver a range of ‘just-in-case’ treatment and hospitalisation. Use of definitive point of care diagnostics will allow treatment to be targeted only at ‘at risk’ women thus saving large amounts of money as well as improving care.	http://www.evidence.nhs.uk/Search?q=fetal+fibronectin 1.An example of the foetal fibronectin test for diagnosing those at risk of pre-term delivery is : http://www.hologic.com/products/clinician-diagnostic-solutions/perinatal/ffn-test ***** ***** http://www.pregnancyhypertension.org/article/S2210-7789(11)00158-9/abstract 2.An example of a test for diagnosing those at risk of pre-eclampsia is : http://www.alere.com/en/home/product-

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					details/triage-plgf-test.html?c=AU
012	King's College London (Division of Women's Health)	Fetal fibronectin testing and transvaginal cervical length measurement in the assessment of pregnant women with symptoms of threatened preterm labour (TPTL).	Interventions, such as hospital admission, in utero transfer and antenatal corticosteroids can reduce the risks associated with preterm birth. Evidence shows that fetal fibronectin and transvaginal ultrasound measurement of cervical length are useful in the assessment with women with symptoms where the diagnosis of labour is uncertain.	The interventions offered to women at risk of preterm birth are relatively safe, but are not without risk of adverse effects and costs. Preterm labour is difficult to diagnose and many women with symptoms do not deliver early. Including fetal fibronectin testing and transvaginal cervical length measurements in the assessment of women with symptoms provides clinicians with additional information on risk of delivery that should lead to interventions being offered appropriately to those that need them, and reduce the number given unnecessarily. A recent survey of UK maternity units showed that the tests used in TPTL assessment varies around the UK (Stock et al., 2015).	Please see NICE PTB guideline http://www.nice.org.uk/guidance/ng25 Stock, S.J., Morris, R.K., Chandiramani, M., Shennan, A.H. & Norman, J.E. 2014, "Variation in management of women with threatened preterm labour", Archives of Disease in Childhood - Fetal and Neonatal Edition, 2015;100:F276 DOI: 10.1136/archdischild-2014-307806
013	Royal College of Paediatrics and Child Health	Use of fetal Fibronectin or other tests in diagnosing preterm labour	The role of maternal fibronectin/other markers in determining the need of imminent preterm delivery. How this can be utilised to support in-utero transfer of preterm delivery to a level 3 neonatal facility for the delivery to occur there.	Will help in deciding in-utero transfers	NICE NG25
014	SCM2	Delivery of cervical cerclage service for relevant women booked to service when	NICE guidance recommends use of cerclage for women who may book in any hospital, but services to risk stratify (transvaginal ultrasound)	Not all services have access to cervical cerclage, fetal fibronectin or transvaginal ultrasound services in a timely fashion, making it impossible for them to deliver services	

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		indicated.	and treat women at risk are not available in all hospitals, and not out of hours.	<p>according to NICE guidance.</p> <p>Any lack of these risk stratification, risk modification and rescue techniques will limit the abilities of services to prolong pregnancies appropriately, and therefore to minimise harms associated with prematurity.</p> <p>Additionally, availability and use of techniques such as fibronectin testing and cervical length measurement will inform appropriate decisions as to whether antenatal maternal transfer should occur to hospitals where intensive care can be delivered for the baby.</p>	
015	SCM2	Availability of transvaginal ultrasound assessments of women either at risk or, or potentially in preterm labour	NICE guidance recommends use of TV ultrasound for risk stratification of women, suggesting a need for daylight hours service.	<p>Any lack of these risk stratification, risk modification and rescue techniques will limit the abilities of services to prolong pregnancies appropriately, and therefore to minimise harms associated with prematurity.</p> <p>Additionally, availability and use of techniques such as fibronectin testing and cervical length measurement will inform appropriate decisions as to whether antenatal maternal transfer should occur to hospitals where intensive care can be delivered for the baby.</p>	
Tocolysis					
016	Royal College	Use of Tocolysis	Will help in deciding in-utero	Will help in deciding in-utero transfers	NICE NG25

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	of Paediatrics and Child Health		transfers		
Maternal corticosteroids					
017	King's College London (Division of Women's Health)	For women at imminent risk of preterm birth between 24 and 34 weeks' gestation, antenatal corticosteroids should be administered within 7 days of delivery.	Evidence suggests that the administration of this intervention results in significant reduction in death and serious morbidities in preterm babies. However, repeated doses may adversely affect fetal growth.	The timing of administration of this intervention is critical for maximising the benefit and minimizing potential harms and yet evidence suggests that practice is not consistent.	<p>Please see NICE PTB guideline http://www.nice.org.uk/guidance/ng25</p> <p>World Health Organisation recommendations on interventions to improve preterm birth outcomes http://apps.who.int/iris/bitstream/10665/183037/1/9789241508988_eng.pdf?ua=1</p> <p>Sanya, R., Al Naggar, E., Gasim, M. & Ahmed, B.I. 2014, "Use or overuse of antenatal corticosteroids for suspected preterm birth", The Journal of Maternal-Fetal & Neonatal Medicine, vol. 27, no. 14, pp. 1454-1456.</p> <p>Adams, T.M., Kinzler, W.L., Chavez, M.R. & Vintzileos,</p>

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					A.M. 2015, "The timing of administration of antenatal corticosteroids in women with indicated preterm birth", American Journal of Obstetrics and Gynecology, vol. 212, no. 5, pp. 645. e1-645. e4.
018	Royal College of Paediatrics and Child Health	Use of maternal Corticosteroids	Important factor for Neonatal outcome	Important factor for Neonatal outcome	NICE NG25
Magnesium sulfate for neuroprotection					
019	King's College London (Division of Women's Health)	Administration of magnesium sulfate for neuroprotection of the preterm baby.	Evidence suggests that the administration of this intervention results in significant reduction in cerebral palsy.	The new NICE guideline recommends that this intervention should be offered to women between 24+0 and 29+6 weeks of pregnancy who are: in established preterm labour or having a planned preterm birth within 24 hours (1.10.1). Despite good evidence for this intervention for some years, and the familiarity with the drug, it has not become a labour ward norm (Stock et al., 2015). There is a need to evaluate current practice and address obstacles to compliance.	Please see NICE PTB guideline http://www.nice.org.uk/guidance/ng25 Please see: Magnesium sulphate for women at risk of preterm birth for neuroprotection of the fetus, Doyle et al. Cochrane Review 2009. Stock, S.J., Morris, R.K., Chandiramani, M., Shennan, A.H. & Norman, J.E. 2014, "Variation in management of women with threatened preterm labour", Archives of

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					Disease in Childhood - Fetal and Neonatal Edition, 2015;100:F276 DOI: 10.1136/archdischild-2014-307806
020	Royal College of Paediatrics and Child Health	Routine administration of magnesium sulfate to mothers likely to deliver preterm (as defined in the NICE guidance)	There is now very strong evidence of the benefit to the neonate, in terms of improved neurodevelopmental outcome, from giving MgSO4 to the mother some hours ahead of delivery.	Although the use of MgSO4 has become much more widespread, even before the NICE PTLB guideline, its further penetration into routine practice cannot be assumed. Although, as with steroids, some women will deliver very rapidly and thus miss out on the administration of MgSO4, it should be possible to measure the use of MgSO4 against a quality standard to encourage uptake of this practice.	NICE PTLB guidance.
021	SCM 3	Magnesium sulfate for neuroprotection	Neurological effects of preterm birth are common and may cause severe disability. The use of neuroprotective agents may reduce long-term disability and health needs.	Some evidence suggests that those whose mothers were treated with magnesium sulfate during pregnancy were significantly less likely to have infants diagnosed with cerebral palsy (CP) compared with those who were not treated	Evidence reviewed in NICE Preterm Labour and Birth Guideline
022	SCM2	Use of intrapartum magnesium sulphate	This is recommended treatment within NICE guidance (give at less than 30 weeks, "consider" at 30-31 weeks), but is far from routine practice in UK at present.	Evidence suggests that use of intrapartum magnesium reduces the proportion of infants affected by cerebral palsy (RR 0.68) without important disadvantage. Because some level of preterm delivery probably can not be prevented, it is appropriate that women who go on to deliver preterm have optimal treatment to minimise adverse outcomes such as cerebral palsy.	See for eg http://fn.bmj.com/content/100/6/F553.full.pdf+html
023	West of	Intrapartum Magnesium	Cochrane Meta-analysis	The uptake of Magnesium Sulphate given	UK Vermont Oxford

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	England Academic Health Science Network (WEAHSN)	Sulphate for mothers in preterm labour as neuroprotection for the baby	<p>demonstrated a 40% reduction of cerebral palsy in preterm babies with this simple and cost effective intervention.</p> <p>NICE Preterm Labour Guideline (Published November 2015): Maternal Intrapartum Magnesium Sulphate for neuroprotection of the fetus is recommended for preterm labour before 30 weeks' gestation</p>	<p>before preterm delivery for neuroprotection is suboptimal and variable in the UK.</p> <p>UK Vermont-Oxford (VON) data for 2014, which covers a large proportion of the UK, indicates that of babies born before 30 weeks' gestation less than 1:4 delivered in local units (outborns) and less than 1:2 delivered in tertiary level units (inborns) received Magnesium Sulphate for neuroprotection. Despite the advantages of a national health service UK uptake of Magnesium Sulphate for fetal neuroprotection is much lower than leading countries in the field (US and Australasia). For comparison the VON International data is 60% for inborns and 34% for outborns.</p> <p>There is an urgent need for national Quality Improvement programmes to educate and improve care in this area.</p> <p>There is strong evidence that implementation of a purpose designed QIP and educational package can improve uptake rapidly (West of England Academic Health Science Network PreCePT QI package).</p>	<p>Benchmarking data</p> <p>Uptake improved across West of England (5 Trusts) from 26% to 85% of eligible births within 6 months of implementation of the PreCePT QIP.</p> <p>http://www.weahsn.net/what-we-do/involving-our-patients-and-the-public/case-study-preventing-cerebral-palsy-in-babies/</p>
Timing of cord clamping for preterm babies (born vaginally or by caesarean section)					
024	Bliss	Cord clamping practices	There is good evidence to suggest that delayed cord clamping (DCC) can significantly increase blood volume in infants after birth, which	Newborn babies receive a considerable amount of their blood volume immediately after birth. DCC can increase blood volume up to 50% in babies born preterm. This increased	Burleigh A, 'Cord clamping: the critical first few minutes,' Mum and baby academy (September 2015)

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			<p>has many benefits.</p> <p>The NICE Preterm Labour and Birth guidance says cord clamping should take place no more than three minutes after birth, which would allow for DCC. DCC should be encouraged to take place after all births, where it is safe. Bliss believes the scope of 1.1.3 of the NICE guideline can be extended to encourage DCC even when the child needs to be resuscitated.</p>	<p>blood volume has a range of benefits including:</p> <ul style="list-style-type: none"> · Improving systemic blood pressure and increases cerebral oxygen perfusion. · Reduces the need for blood transfusions · Lowers the risk of Necrotising Enterocolitis · Reduces the risk of brain haemorrhage <p>There is also emerging evidence that DCC may improve longer term outcomes for children. For example, children whose cord was cut early were twice as likely to be iron deficient at 3 to 6 months compared with DCC. The need for the baby to be resuscitated does not necessarily influence the time of cord clamping. A mobile neonatal resuscitation unit trolley can be used, which allows newborn babies to be treated alongside their mother with, or without, an intact cord. This allows the mother to touch and speak to her newborn baby while they are undergoing assessment or resuscitation, and the baby can simultaneously be benefiting from DCC.</p>	<p>Weeks AD, Watt P, Yoxall CW, et al 'Innovation in immediate neonatal care: development of the Bedside Assessment, Stabilisation and Initial Cardiorespiratory Support (BASICS) trolley,' BMJ Innovations (2015) Thomas M, Yoxal C, Weeks A, Duley L, 'Providing newborn resuscitation at the mother's bedside: assessing the safety, usability and acceptability of a mobile trolley' BMC Paediatrics (2014)</p>
025	Royal College of Paediatrics and Child Health	Delayed cord clamping/cord milking	The evidence of benefit for preterm babies has continued to grow since the NICE GDG considered the efficacy of delayed cord clamping or cord milking to enhance the amount of placental transfusion. There is now evidence	At the time of delivery, whether by caesarean section or vaginally, the operator does not always remember to ensure that the cord is milked or that clamping is delayed. Given the benefit of this simple procedure, there needs to be an incentive for record, and thus to audit, its use in preterm deliveries.	NICE PTLB guidance.

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			that cord milking is superior to delayed clamping in terms of neonatal cardiovascular status.		
Additional areas					
026	Advanced Global Health Ltd – UK Distributors of AmniSure (PAMG-1) & PartoSure (PAMG-1)	Improve diagnosis of Rupture Of Membrane (ROM) using PAMG-1 protein test.	There is very good evidence that the PAMG-1 protein is the most reliable protein to aid in the diagnosis of rupture of membranes. As the PAMG-1 protein is exclusively found in amniotic fluids (unlike IGFBP1), it is logical that it should be considered as single choice of protein to diagnose PROM.	It has been clearly documented in peer-reviewed literature that the PAMG-1 test is the only test to maintain a very high sensitivity and specificity in both ‘known’ and ‘unknown’ cases. An ‘unknown’ case is identified as non-obvious pooling following a speculum examination i.e. when NHS clinicians are advised to use the test. The IGFBP-1 test has been found to be accurate in ‘known’ cases i.e. obvious pooling, which is identifiable via speculum, but to have a significantly lower sensitivity and specificity in ‘unknown’ cases. The literature used to evaluate the tests has not focussed on ‘unknown’ cases and so is not reflective or the clinical procedures completed within the NHS.	The aforementioned points are highlighted in a well-cited meta-analysis by Ramsauer et al. (2013) - http://www.ncbi.nlm.nih.gov/pubmed/23314505 . The accuracy of the PAMG-1 is further outlined when is completed in a head to head study with Indigo Carmine (the 100% accurate Gold Standard). The PAMG-1 test correlated with Indigo Carmine in 126 out of 127 cases - Silva E, Martinez JC. Diagnosing ROM: a comparison of the gold standard, indigo carmine amnio-infusion, to the rapid immunoassay, the Aminsure ROM test. J Perinat Med. 2009;37:956. Furthermore in the European Guidelines PAMG-1 has been

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					identified as the most accurate test and thus most advisable to use - http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3267524/
027	Bliss	Psychological support for parents	Further recent Bliss research, which looked at how well neonatal services are operating in England against core national standards of safety and quality, has revealed a lack of access to psychological support for parents. 41% of units reported being unable provide parents access to a trained mental health worker and at 30% of units there was no access to any psychological support at all. Mothers whose babies spend time in a neonatal unit are far more likely to suffer from post-natal depression. Parents are also more likely to suffer from longer term mental health conditions such as Post-traumatic stress disorder as a result of their experiences too.	It is therefore vital that parents are informed about what psychological support is available to them. Where specific psychological services for parents of babies on the neonatal unit are not in place, information and signposting must be provided to parents about how they can access psychological support, as well as support organisations, such as Bliss.	O'Brien K, Bracht M, Macdonell K, McBride T, Robson K, O'Leary L, Christie K, Galarza M, Dicky T, Levin A, Lee S. 'A pilot cohort analytic study of Family Integrated Care in a Canadian neonatal intensive care unit,' BMC Pregnancy and Childbirth. 13(Suppl 1):S12, (2013) Kaffashi F, Scher M, Ludington-Hoe S, Loparo K 'An analysis of the kangaroo care intervention using neonatal EEG complexity: a preliminary study,' Clinical Neurophysiology. 124(2):238-46 (2013)
028	Bliss	Post-natal ward layout	If the mother requires in-patient care while her child is being treated in the neonatal unit, being separated from them in the	Bliss has heard from many parents through our support services and recent focus groups, that poor post-natal ward layout and communication can negatively affect their	

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			<p>postnatal ward can cause anxiety and frustration.</p> <p>Having clear communication between post-natal and neonatal wards and caring for the woman in the most suitable environment can help mitigate some of this anxiety.</p>	<p>mental health and wellbeing.</p> <p>Women have reported to us that, often due to space constraints or staffing issues, they were cared for on post-natal wards with other women who had their healthy babies with them. They reported that this had a significant detrimental impact on their mental health and intensified their feelings of separation anxiety and distress.</p> <p>Effective use of single occupancy rooms, or dividing wards up so mothers with a baby being cared for in neonatal care are located away from other mothers can help alleviate this source of unnecessary distress.</p> <p>Feedback from parents also highlights that many feel that staff on the post-natal ward are not adequately aware of how they may be feeling or what their emotional needs are. This means mothers can be left alone for long periods of time, without enough information and updates about their baby's condition and when they can go to see their baby.</p>	
029	Health Ltd – UK Distributors of AmniSure (PAMG-1) & PartoSure	The use of the new PAMG-1 test (PartoSure) to aid in the likely delivery of preterm birth, or Time To Delivery (TTD).	Currently up to 85% of mother's who have symptoms of preterm birth are unnecessarily admitted and/or transferred. This is a significant financial burden for NHS	A more accurate method of identifying whether a mother is likely to deliver preterm in 7 days is required. The PAMG-1 (PartoSure) test is becoming proven as an affordable and reliable test with a high positive predictive	The following 2 studies outline the high positive predictive value of the PAMG-1 (PartoSure) test: http://www.ncbi.nlm.nih.g

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	(PAMG-1)		maternity units. The current proposed methods of deciding whether to admit and/or transfer a mother have very low specificities and thus lead to high rates of unnecessary admissions and/or transfers.	value. Emphasis should be placed on considering the PAMG-1 (PartoSure) test to help reduce unnecessary admissions and/or transfers.	ov/pubmed/25562603 and http://www.ncbi.nlm.nih.gov/pubmed/24334429 .
030	Health Ltd – UK Distributors of AmniSure (PAMG-1) & PartoSure (PAMG-1)	Use of PartoSure (PAMG-1) to identify preterm birth delivery.	There is very good evidence that the PartoSure test (PAMG-1 protein) has a greatly improved positive predictive value versus the Fetal Fibronectin test and Cervical Length.	Currently there are high rates of unnecessary admissions and treatments in relation to preterm birth. It is well documented that Fetal Fibronectin and/or Cervical length measurements are poor predictors of spontaneous delivery. Subsequently up to 85% of women are unnecessarily admitted and treated in relation to preterm birth. The administration of steroids based on a positive Fetal Fibronectin2 result and/or a cervical length <25mm3. Clinical research to date highlights the superior positive and negative predictive value of the PAMG-1 (PartoSure test)4 versus the proposed methods of diagnosing preterm birth in the recent NICE guidelines3. Understandably further research is required but NHS Trusts that use the test have found fantastic benefits including a reduction in unnecessary admissions/treatments and transfers. All of which have produced improved clinical care and importantly significant financial savings. The PAMG-1 (PartoSure) test should be	<ol style="list-style-type: none"> 1. Evidence of high rates of unnecessary admissions and treatment - http://fetalmedicine.com/synced/fmf/2007_2.pdf. 2. Quantitative Fetal Fibronectin, low PPV - http://www.ajog.org/article/S0002-9378(12)02037-6/abstract. 3. Low PPV for CL measurements as an indicator or preterm birth - http://www.ncbi.nlm.nih.gov/pubmed/25562603 High positive and negative predictive value of PAMG-1 test (PartoSure) - http://www.ncbi.nlm.nih.gov/pubmed/24334429 .

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				considered in detail as an option to reduce unnecessary admissions/treatment and transfers.	
031	King's College London (Division of Women's Health)	Multidisciplinary team care/management of women with medical complexities in pregnancy – in particular those with pre-existing medical conditions.	Increasing numbers of women with pre-existing medical conditions (e.g. T1/T2 DM, Heart disease) are becoming pregnant. These pregnancies are associated with an increased risk of adverse outcomes for both mother and baby, including preterm birth (RCOG, 2011; McElduff et al, 2012; Thorne et al, 2006; ESC, 2011).	The most recent confidential enquiry into maternal deaths in the UK and Ireland during the period 2009-2012 found that indirect causes (exacerbation or new onset of medical or psychiatric disease) accounted for two thirds of maternal deaths during or within the first 42 days after pregnancy (Knight et al, 2014). A key recommendation was to ensure that women who had medical disorders in pregnancy should have access to a co-ordinated multi-disciplinary team (MDT) obstetric and medical clinic, to avoid need for multiple appointments and poor communication between senior specialists responsible for women's care (Nelson-Piercy et al 2014).	Despite numerous reports (CMACE, 2011; King's Fund, 2008; WHO, 2012; Healthcare Commission, 2008) citing the need for improved MDT to reduce morbidity and mortality for these women and for their infants there is a lack of evidence to inform the structure or working practices of such teams, or of their beneficial impact on maternal and infant outcomes or healthcare resources (Bick et al, 2014). We also have survey data (submitted but not published yet) showing the variability in models of MDT care for women who have cardiac conditions or diabetes in pregnancy.
032	NHS ENGLAND	Experiences of neonatal care	Addressing the experience of care is a key requirement of the outcomes framework and evidence confirms that creating a positive	There is no nationally mandated survey to capture experiences of neonatal care. BLISS have advocated for a national survey and some Trusts have participated in a voluntary	BLISS, SANDS, Picker Institute

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			experience of care improves outcomes	survey supported by Picker, so a suite of questions that have been cognitively tested are available. The Care Quality Commission should consider making neonatal experiences part of their national surveys programme to support achievement of NICE QS15 in neonatal care. There is currently no nationally agreed mechanism for experiences of parents who experience bereavement and for these experiences to be addressed and fed into the organisational learning of the Trust, this requires further focus.	
033	Royal College of Paediatrics and Child Health	the delivery of an extremely preterm neonates in a maternity unit affiliated to NICU level 3 facilities	There is good evidence to support the delivery of an extremely preterm neonates in a maternity unit affiliated to NICU level 3 facilities	The results of Epicure 1 and 2 studies suggest that the delivery of preterm neonate (22-26) in a level 3 neonatal facility is associated with better outcomes.	Epicure 1 and 2 studies.
034	SCM1	Establishment of specialist Preterm Birth Clinics with guidelines on indications for referral, protocols for management and audit	NICE Preterm Labour guideline recommends cervical cerclage and progesterone for women with history-based factors which put them at increased risk of preterm birth with a cervical length of less than 25mm identified at 16-24 weeks from a single or serial ultrasound measurement	Identification of high risk women and appropriate intervention has the potential to reduce preterm birth The provision of such a service in UK is inconsistent and within those specialist clinics which do exist, there is heterogeneity in management.	Provision and practice of specialist preterm labour clinics: a UK survey of practice. BJOG. 2014 Mar;121(4):417-21. doi: 10.1111/1471-0528.12512. Epub 2013 Dec 3
035	SCM2	Delivery of babies predictably requiring intensive care in centres	NICE guidance recommends facilitating delivery in centres equipped to provide full neonatal	Evidence exists that mortality is lower in units with higher throughput – this underpins national guidance (eg E-08 neonatal intensive	https://www.england.nhs.uk/commissioning/spec-services/npc-crg/group-

ID	Stakeholder	Suggested key area for quality improvement	Why is this important?	Why is this a key area for quality improvement?	Supporting information
		with on site NICU facilities.	intensive care	care service specification) that mandates patterns of neonatal service delivery, in line with professional recommendations – by gestational thresholds. Postnatal transfer of babies needing intensive care is higher risk for babies, and more disruptive for babies, families, transport services and units alike.	e/e08/ N Marlow, C Bennett, E S Draper, E M Hennessy, A S Morgan, K L Costeloe Perinatal outcomes for extremely preterm babies in relation to place of birth in England: the EPICure 2 study Arch Dis Child Fetal Neonatal Ed 2014;99:3 F181-F188 Published Online First: 6 March 2014 doi:10.1136/archdischild-2013-305555
036	Bliss	Practical information for parents	<p>Bliss welcomes the clinical guidelines focusing on providing sufficient information and support to the mother when having a planned or unexpected preterm labour.</p> <p>However, the quality of this information and support could be improved through a quality standard, by also signposting to sources of practical and emotional support to mothers and their partners.</p>	The financial burden on parents of having a baby born needing neonatal care is significant, and for many presents a serious barrier for them being as actively involved in their baby's care as they would like. The 'enforced' separation of parents from their babies due to financial and practical reason not only adds to the trauma for the parents but also impedes the baby's recovery through, for example skin to skin care and breastfeeding. Bliss research has shown that on average families spend and additional £2,200 on top of the normal costs associated with having a new baby over the course of their baby's stay in hospital – this	Bliss, 'It's not a game: the very real costs of having a premature or sick baby,' (2014) Bliss, 'Bliss baby report: hanging in the balance,' (2015) Bliss, 'Bliss family friendly accreditation scheme: helping to make family-centred care a reality on your neonatal unit,' (2015) Flacking R, Lehtonen L, Thomson G, Axelin A,

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				<p>amounts to £282 of additional spending every week. The extra costs come from a variety of different areas including:</p> <ul style="list-style-type: none"> · Paying for often extensive travel between home and the neonatal unit. · Paying for car parking at the hospital where their baby is receiving care. · Buying food and drink from the hospital. · Paying for accommodation close to the hospital, if the hospital is far from home. <p>Each hospital has a different package of support for families to help with these everyday costs and practicalities. It is vital that information about practical issues such as parking permits, food discounts, onsite accommodation or anything else the unit can offer to families to help alleviate some of this burden is available to parents alongside information about their baby’s condition and treatment.</p>	<p>Ahlqvist S, Hall Moran V, Ewald U, Dykes F. (2012) ‘Closeness and separation in neonatal intensive care,’ Acta Pædiatrica 101:1032–1037, (2013)</p>
037	Royal College of Nursing	This is to inform you that the RCN has no comments to submit to inform on the above topic engagement at this time.			