NHS England

Saving Babies' Lives Version Two

A care bundle for reducing perinatal mortality

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Executive summary

Version two of the Saving Babies' Lives Care Bundle (SBLCBv2), has been produced to build on the achievements of version one and address the issues identified in the SPiRE evaluation[1]. It aims to provide detailed information for providers and commissioners of maternity care on how to reduce perinatal mortality across England. The second version of the care bundle brings together five elements of care that are widely recognised as evidence-based and/or best practice:

1. **Reducing smoking in pregnancy**
   This element provides a practical approach to reducing smoking in pregnancy by following NICE guidance. Reducing smoking in pregnancy will be achieved by offering carbon monoxide (CO) testing for all women at the antenatal booking appointment, and as appropriate throughout pregnancy, to identify smokers (or those exposed to tobacco smoke) and offer them a referral for support from a trained stop smoking advisor.

2. **Risk assessment, prevention and surveillance of pregnancies at risk of fetal growth restriction (FGR)**
   The previous version of this element has made a measurable difference to antenatal detection of small for gestational age (SGA) babies across England[2]. It is however possible that by seeking to capture all babies at risk, interventions may have increased in women who are only marginally at increased risk of FGR related stillbirth. This updated element seeks to address this possible increase by focussing more attention on pregnancies at highest risk of FGR, including assessing women at booking to determine if a prescription of aspirin is appropriate. The importance of proper training of staff who carry out symphysis fundal height (SFH) measurements, publication of detection rates and review of missed cases remain significant features of this element.

3. **Raising awareness of reduced fetal movement (RFM)**
   This updated element encourages awareness amongst pregnant women of the importance of detecting and reporting RFM, and ensuring providers have protocols in place, based on best available evidence, to manage care for women who report RFM. Induction of labour prior to 39 weeks gestation is only recommended where there is evidence of fetal compromise or other concerns in addition to the history of RFM.

4. **Effective fetal monitoring during labour**
   Trusts must be able to demonstrate that all qualified staff who care for women in labour are competent to interpret cardiotocographs (CTGs), always use the buddy system and escalate accordingly when concerns arise or risks develop. This element now includes use of a standardised risk assessment tool at the onset of labour and the appointment of a Fetal Monitoring Lead with the responsibility of improving the standard of fetal monitoring.

5. **Reducing preterm birth**
   This is an additional element to the care bundle developed in response to The Department of Health's 'Safer Maternity Care' report which extended the 'Maternity

Safety Ambition' to include reducing preterm births from 8% to 6%. This new element focuses on three intervention areas to improve outcomes which are prediction and prevention of preterm birth and better preparation when preterm birth is unavoidable.

These five elements of the SBLCBv2 were co-developed with clinical experts and representatives from the Royal College of Obstetricians and Gynaecologists (RCOG), British Maternal and Fetal Medicine Society (BMFMS) and NHS Improvement. NHS England has engaged extensively with stakeholders including the Royal College of Midwives (RCM) and the Maternity Transformation Programme Stakeholder Council, which includes representation from professional societies, charities, the Department of Health and Social Care and health arms-length bodies including NHS Improvement, NHS Digital, Public Health England (PHE), Health Education England (HEE) and Maternity Voice Partnerships (MVPs).

The second version of the care bundle includes a greater emphasis on continuous improvement with a reduced number of process and outcome measures. The implementation of each element will require a commitment to quality improvement with a focus on how processes and pathways can be developed and where improvements can be made.

SBLCBv2 includes sections which reference the importance of other interventions outside of the remit of the care bundle, such as continuity of carer models, following NICE guidance, delivering 'healthy pregnancy messages' before and during pregnancy and offering choice and personalised care to all women. These are not mandated by the care bundle but reflect best practice care and are recommended to be followed in conjunction with the care bundle.

Contents

Forewords

The first version of the Saving Babies' Lives Care Bundle appears to have contributed to the stillbirth rate in England falling to a historical low. The independent evaluation of the care bundle by Tommy's Stillbirth Research Centre at the University of Manchester demonstrated that there is however room for further improvement. This latest version of the care bundle once again bridges the gap between evidence based medicine and best practice care to promote pragmatic pathways designed to improve outcomes for women and babies. Its scope now extends to reducing preterm birth and improving care when preterm birth cannot be avoided. I am immensely grateful to all who have contributed their time, knowledge and expertise to develop version two of the Saving Babies' Lives Care Bundle which is designed to be even more effective and minimise unwarranted intervention.

In addition to the five elements this document recommends adopting other examples of best practice care. It highlights the important principles of good communication, choice and personalisation which help empower women to be involved in decision making about their care. A good way to apply these principles is through the implementation of continuity of carer which is particularly important in improving outcomes for women and babies from BAME backgrounds and economically disadvantaged groups.

While developing this document, the team have intentionally kept outcome measures to a minimum preferring to promote quality improvement through a process of continuous learning. Within the next year most of the required data collection will be achievable through monthly submissions to the Maternity Services Data Set or use of the Perinatal Mortality Review Tool.

The success of the Saving Babies' Lives Care Bundle version 2 ultimately rests on its implementation. It was heartening to see so many maternity services enthusiastically implement version one with some achieving dramatic reductions in mortality. The NHS Long Term Plan reiterates the NHS's commitment to a 50% reduction in stillbirth, maternal mortality, neonatal mortality and serious brain injury and a reduction in preterm birth rate, from 8% to 6%, by 2025. To this end, implementation of the care bundle has been included in the planning guidance and incorporated into the standard contract for 2019/20.

NHS England

Matthew Jolly
National Clinical Director for Maternity and Women's Health, NHS England

On behalf of the Royal College of Midwives, I welcome the publication of this second version of the Saving Babies' Lives Care Bundle. The RCM fully supports the ambition to achieve a 50% reduction in stillbirths and maternal and neonatal deaths by 2025 and believes that implementation of the care bundle will make a vital contribution to achieving this. There is already emerging evidence of significant reductions in stillbirth rates at maternity units that are implementing the care bundle.

The relationships that professionals form in the workplace, in their teams and with women, are key to safety and preventing the avoidable tragedies of stillbirth and the death of babies. We are therefore pleased to see the emphasis in this version of the care bundle on professionals working with women to help them to make choices about their care and reduce the risks to their baby. We also welcome the emphasis on the contribution that continuity of carer and midwife-led care can make to improving outcomes for babies.

I am delighted that the RCM was able to contribute to the development of this version of the care bundle and we look forward to working in partnership with our colleagues in the other Royal Colleges and NHS organisations to achieve continued improvements in maternity safety.

Gill Walton
Chief Executive, Royal College of Midwives

This second version of the Saving Babies' Lives Care Bundle (SBLCBv2) builds on the elements of care of its predecessor and adds a new element with the aim of reducing preterm birth and maximising the care of women delivering preterm. Whilst accepting its limitations – particularly where the evidence-base is limited - the BMFMS welcomes and fully supports the pragmatic initiatives included in the bundle and the opportunity to stimulate further improvements in maternity care.

It is recognised that the previous bundle imposed significant burdens on service providers. In particular, increased numbers of ultrasound scans and increased rates of induction of labour and emergency caesarean sections were observed. By being more specific this bundle will help focus intervention more in pregnancies genuinely at risk of complication. An important aspect of each element is the focus on continuous improvement ensuring that data is used to highlight where improvements can be made and learning from both incidents and excellence is utilised.

Similarly, the second version has a greater emphasis on involving women in their care and a need to reduce unnecessary interventions, including, for example, early term induction of labour. The inclusion of healthy pregnancy messages and attention to the need to involve women in decisions regarding interventions places women at the centre of care.

Proving that that the first care bundle was responsible for the observed significant reduction in stillbirth was never going to be possible. At the very least, however, evaluation has provided encouraging evidence of the value of a care bundle in maternity care. This second bundle strives to stimulate better care and help reduce further the number of stillbirths.

British Maternal & Fetal Medicine Society

Myles Taylor
President, British Maternal and Fetal Medicine Society

This second version of the Saving Babies' Lives Care Bundle heralds a significant commitment to meet the national ambition set by the Secretary of State, recently reiterated in the NHS long-term plan, to achieve a 50% reduction in the rate of pre-term and stillbirths in the UK by 2025.

The RCOG welcomes the clear focus on the five key aspects of the care bundle and will continue to work collaboratively with other Royal Colleges, national policymakers and frontline safety leaders to support its implementation across the country.

Each Baby Counts (EBC) is the RCOG's national quality improvement programme to reduce the number of babies who die or are left severely disabled as a result of incidents occurring during term labour. The EBC progress report, published in November 2018, identified a number of issues in the care of women and babies that might have led to a different outcome. These findings included not following guidelines, communication issues and concerns relating to anaesthetic care. The five key priorities of this care bundle align with and complement our findings from the EBC programme, as well as other work such as the Perinatal Mortality Review Tool.

The RCOG will continue to work with partners to ensure that frontline maternity teams are supported to continuously improve the quality and safety of care that women and babies receive in the UK. This includes the development of a new service improvement programme, Each Baby Counts Learn and Support, announced as part of the maternity safety strategy. The service aims to empower healthcare staff on the frontline to learn locally, and place women, their babies and families at the heart of improvements.

The Saving Babies' Lives Care Bundle is one amongst a number of initiatives to improve maternity safety and it is critical that we continue to work collaboratively to ensure that efforts are aligned to ensure that we achieve the national ambition. With this in mind the RCOG is calling for a national centre of excellence for maternity care in the UK, to bring together the shared expertise and experience of women and families, frontline maternity teams, academics and policymakers.

Royal College of Obstetricians & Gynaecologists

Professor Lesley Regan
President, Royal College of Obstetricians and Gynaecologists

The evaluation of version one of the Saving Babies' Lives Care Bundle was carried out by the SPiRE research team in the early stages of implementation; it involved early adopter sites and for these units there was no demonstrable relationship between the stillbirth rate and the overall implementation score of the care bundle. The evaluation team were suitably cautious in their interpretation of the findings, nevertheless, the fact that there was a reduction in the stillbirth rate across the adopter sites was encouraging. The wider impact of the care bundle across England is similarly difficult to discern at this stage with only 2017 national stillbirth rates available since the care bundle was launched in March 2016.

This, the second iteration of the bundle, includes a series of important developments. The focus of the bundle has been widened to encompass neonatal deaths in addition to stillbirths; the details of the original four elements, particularly for risk assessment and surveillance of fetal growth restriction, have been tightened with the intention of avoiding inadvertent effects on other aspects of service delivery, for example, scanning and inductions; and a fifth element addressing preterm birth has been introduced.

We know from MBRRACE-UK surveillance data that 70% of all stillbirths and neonatal deaths occur in babies born before term and nearly 40% are extremely preterm, being born before 28 weeks' gestation. From this it is clear that achieving the national ambition to halve perinatal deaths will not be met until we focus efforts on preventing preterm birth and optimising the management for those babies who are nevertheless born preterm. The extension of the national ambition to include a preterm birth reduction ambition, with the commensurate inclusion of preterm births as a fifth element in the care bundle, are therefore essential and welcome developments. The inclusion of the algorithm for risk assessment, the surveillance pathway and management of women at risk of preterm birth provides a helpful practical addition.

Less practical help is provided to ensure that when preterm birth is unavoidable or clinical indicated that women in units without the appropriate neonatal services are transferred prior to birth to a unit with the necessary level of neonatal care based on gestational age and other anticipated complications. Analysis of data from the National Neonatal Research Database has shown that extremely preterm birth outside an obstetric unit co-located with a tertiary neonatal intensive care unit (NICU) is associated with a 50% increase in neonatal death or severe brain injury, yet in 2016 approximately 1 in 3 extremely preterm births were in a hospital without a NICU. The organisational complexities of ensuring in utero transfer of women at risk of preterm birth should not be under-estimated, yet will be vital if we are to achieve the national ambition of halving perinatal deaths and neonatal brain injury. Lines of accountability to ensure that referral arrangements are in place will be essential and will require planning between local maternity systems, neonatal operational delivery networks and local Trusts, and will need to take account of the recommendations from the ongoing Neonatal Critical Care Review when these are published.

MBRRACE-UK
Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK

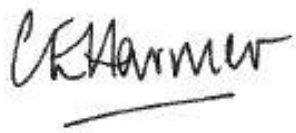
Professor Jenny Kurinczuk
Professor of Perinatal Epidemiology, Director, National Perinatal Epidemiology Unit, National Programme Lead MBRRACE-UK/PMRT, University of Oxford

Too many parents and families are devastated by the death of their baby. This second version of the Saving Babies' Lives Care Bundle is the next step on the journey towards ensuring that fewer families have to suffer that grief and loss, and to meeting the National Ambition to halve stillbirths and neonatal baby deaths by 2025.

This new version provides not only an important focus on preterm birth, but also encourages women to ensure that they keep themselves and their baby/babies as safe as possible during pregnancy. Helping parents to understand the risks associated with baby loss and to recognise warning signs is key in preventing baby deaths.

Listening to bereaved parents' experiences is vital in understanding why babies die, and learning from every baby's death is an integral part of the continual improvement that underpins this Care Bundle. Parents tell us that if lessons can be learned from the death of their baby it can help them live with their grief, providing an important and lasting legacy.

This second version of the Saving Babies' Lives Care Bundle carries essential knowledge for every healthcare professional who supports and works with pregnant women. We welcome its implementation and believe that it provides an opportunity for safer care to protect babies' lives in the future.



Sands
Stillbirth & neonatal death charity

Clea Harmer
Chief Executive, Sands

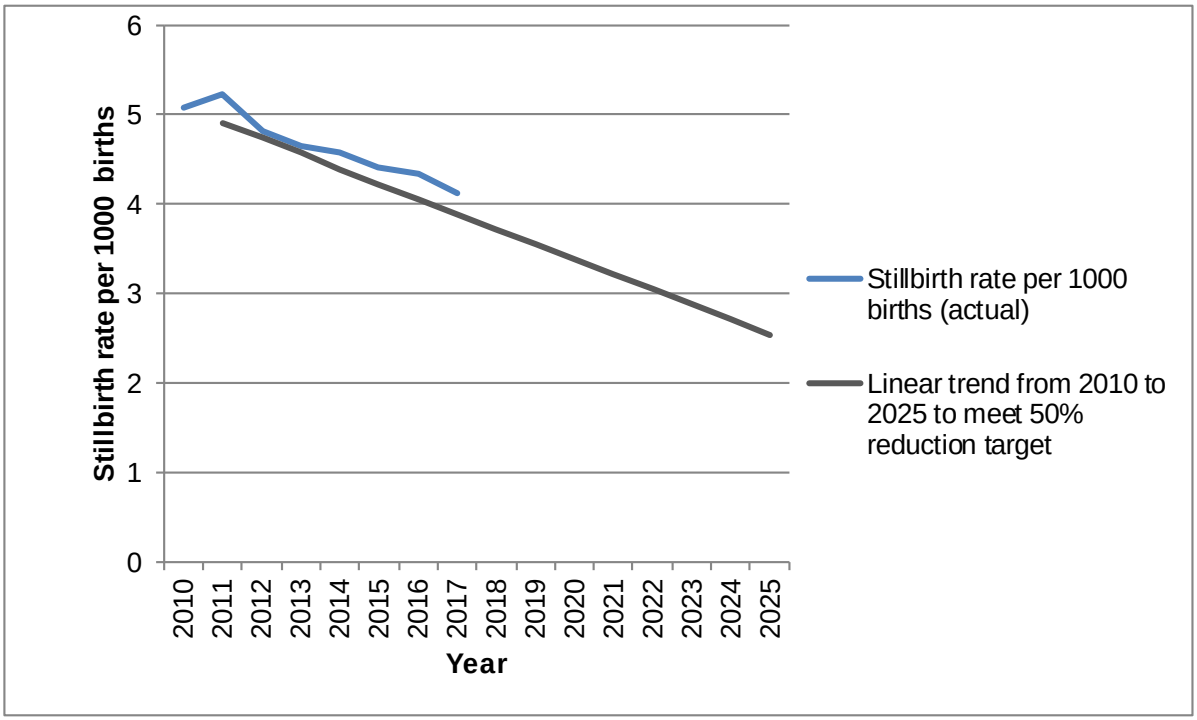
Introduction

In November 2015, the Secretary of State for Health announced a national ambition to halve the rates of stillbirths, neonatal and maternal deaths and intrapartum brain injuries by 2030, with a 20% reduction by 2020[3]. The first version of the Saving Babies' Lives Care Bundle (SBLCB) was published in March 2016[4] and focussed predominantly on reducing the stillbirth rate. In November 2017, the ambition was extended to include reducing the rate of preterm births from 8% to 6% and the date to achieve the ambition was brought forward to 2025[5]. In response to the extended ambition, SBLCB version two (SBLCBv2) additionally includes the aim to reduce preterm birth and improve outcomes when preterm birth is unavoidable to further decrease perinatal mortality.

The 2017 Office for National Statistics (ONS) report[6] shows a fall in stillbirth rates in England to 4.1 per thousand. This is testament to the continued efforts of maternity services across England to deliver system-wide improvements in maternity care. The fall should be seen within the context of the Maternity Transformation Programme which is implementing the recommendations from the 'National Maternity Review Better Births' report. It would however be wrong to solely attribute the fall in stillbirth rates entirely to implementation of the SBLCB, but it is reasonable to assume that the first version of the SBLCB has made a valuable contribution.

The fall in the stillbirth rate represents an 18% reduction in the stillbirth rate since 2010, resulting in 827 fewer stillbirths in 2017 compared to 2010. While this reduction shows that the NHS is on target to meet the interim ambition of a 20% reduction in stillbirths by 2020 there are still too many avoidable deaths and further changes are required to achieve a 50% to reduction by 2025 (figure 1).

Figure 1: Stillbirth rate against linear trend required to meet a 50% reduction by 2025



The MBRRACE-UK Perinatal Mortality Surveillance report for births in 2016[7] showed that overall the national extended perinatal mortality rate in 2016 had not changed from 2015. Earlier enquiries have shown that a significant proportion of these deaths are preventable[8] and that improvements in care have the potential to reduce deaths.

SBLCBv2 incorporates learning from the SPiRE evaluation[9] and the elements have been refined in response to analysis and evaluation. The changes are designed to make it more effective and reduce unnecessary interventions whilst avoiding any unnecessary burden on Trusts. It has been developed through a collaboration of clinical experts and key organisations. The purpose remains to support providers, commissioners and healthcare professionals to reduce perinatal mortality.

SBLCBv2 should not be implemented in isolation but as one of a series of important interventions to help reduce perinatal mortality and preterm birth. It is important that providers implement best practice care whenever possible, including by following NICE guidance and continuity of carer models which the Maternity Transformation Programme supports. Continuity of carer models are particularly important in improving outcomes for women and babies from black, Asian and minority ethnic (BAME) backgrounds and economically disadvantaged groups.

The NHS Long Term Plan (LTP) reiterates the NHS's commitment to a 50% reduction in stillbirth, maternal mortality, neonatal mortality and serious brain injury and a reduction in preterm birth rate, from 8% to 6%, by 2025. An additional element has been included in the SBLCBv2 to address the increasing prevalence of preterm birth. This element focuses on predicting and preventing preterm birth and, when preterm birth cannot be avoided, preparing the mother and baby appropriately. Clinically appropriate use of magnesium sulphate is also encouraged in the SBLCBv2 and included in the LTP, which is estimated to help reduce the number of babies born preterm with cerebral palsy. Reducing preterm birth rates is linked with reducing smoking in pregnancy, another element of the care bundle; the LTP includes funding for all Trusts to provide smoking cessation advice and support for all patients who agree to quit. There is a commitment to fully implement this second version of the care bundle by 30th March 2020.

The SBLCBv2 will be included in the planning guidance and incorporated into the standard contract for 2019/20. Providers and commissioners should implement this version of the care bundle, and are encouraged to continue to be involved in the analysis and evaluation of its impact.

Summary of the Saving Babies' Lives Care Bundle Evaluation Report

In May 2016 NHS England commissioned the Tommy's Stillbirth Research Centre at the University of Manchester to evaluate the SBLCB. The report, 'Evaluating the implementation of the Saving Babies' Lives Care Bundle in NHS Trusts in England: stillbirth rates, service outcomes and costs' was published in July 2018. The report shows the findings of the evaluation which involved nineteen NHS Trusts in England implementing the care bundle from April 2015. The purpose of the evaluation was to "assess the effectiveness of the care bundle at reducing stillbirth rates and the associated costs". It also assessed to what extent the care bundle had been implemented across the Trusts.

The evaluation found that all Trusts involved were implementing all elements of the care bundle to some degree and some of the key findings of the report were as follows:

- Stillbirth rates declined by 20% in the participating Trusts during the period in which the care bundle was implemented. This fall cannot be explicitly attributed to implementation of the care bundle due to other improvement activities happening across England during this period, however it is highly plausible they are linked.
- Carbon monoxide (CO) testing of pregnant women was implemented in almost all Trusts in the study, however referral to and uptake of smoking cessation services was poor.
- Detection of small for gestational age (SGA) babies during the antenatal period increased by 59% in participating Trusts during the implementation period.
- Most of the participating Trusts were giving women the recommended reduced fetal movement (RFM) leaflet[10] which women were reading and taking the information into consideration.
- Most of the participating Trusts have a buddy system in place for cardiotocograph (CTG) monitoring, however there were very few Trusts able to provide up-to-date staff training records in CTG interpretation and intermittent auscultation (IA) and competency assessments.
- There were a number of impacts on the services provided by Trusts, including an increase in the number of ultrasound scans and interventions at or around the time of birth (including inductions and caesarean sections).

The SBLCBv2 has been developed taking into consideration the specific recommendations published in the evaluation report, building upon the successful aspects identified and specifically addressing increased interventions.

Rationale for changes in version two of the Saving Babies' Lives Care Bundle

The independent evaluation of SBLCB[11] shows that it appears to help reduce stillbirth rates but the evaluation suggests there is room for improvement. The introduction of any new pathway carries a risk of 'intervention creep' and the increases in induction of labour, preterm birth and caesarean section suggest that there are opportunities to reduce obstetric intervention. The development teams for each element have made changes to improve the effectiveness of their elements and minimise unwarranted intervention.

Prior to 39 weeks gestation, induction of labour or operative delivery is associated with small increases in perinatal morbidity. However, at 39 weeks gestation and beyond, induction of labour is not associated with an increase in caesarean section, instrumental vaginal delivery, fetal morbidity or admission to the neonatal intensive care unit. Thus, a recommendation for delivery before 39 weeks should be based upon objective concerns.

The reporting burden on trusts has been kept to a minimum. NHS England are working with NHS Digital to make many of the SBLCBv2 metrics available through NHS Digital's new data access environment during 2019. A supplementary appendix to SBLCBv2 specifying the numerators and denominators of the metrics available on the data access environment will be published in 2019 once the primary data standards and appropriate SNOMED CT codes have been finalised. This data capability has been developed as part of the Maternity Transformation Programme and the coming together of three separate projects:

1. Development of primary data standards for maternity services
2. Development of the MSDS (Maternity Services Data Set) version two which goes live April 2019
3. Launch of the new NHS Digital's 'data access environment' which will enable Trusts to view pre-configured analyses of national maternity data.

The outcome measures for SBLCBv2 now include outputs from the Perinatal Mortality Review Tool (PMRT) which supports a systematic, multidisciplinary review of the circumstances and care leading up to and surrounding perinatal death, including an assessment of compliance with best practice care. The PMRT will provide invaluable information to commissioners and providers about where change is required and the data will be compiled into national reports.

The aim of these outcome measures is to facilitate a better understanding of maternity services and identify where there are opportunities for quality improvement. To this end each element now contains a continuous learning section which has been developed in conjunction with the Maternal and Neonatal Health Safety Collaborative.

It has been necessary to restrict the scope of the SBLCBv2 to ensure it is deliverable. Consequently, there are important interventions to reduce perinatal mortality which are not covered by the by the SBLCBv2 most of which are covered by NICE guidelines, for example the management of diabetes in pregnancy, hypertension in pregnancy and multiple pregnancy.

Important principles to be applied when implementing version two of the Saving Babies' Lives Care Bundle

The following principles should be considered when implementing the care bundle.

Offer choice and personalised care and respect women's autonomy

Maternity staff know that providing great care is about good communication, choice and personalisation, not simply meeting targets. It was recommended in Better Births[12] that 'women should be able to make decisions about their care during pregnancy, during birth and after their baby's birth, through an ongoing dialogue with professionals that empowers them. They should feel supported to make well informed decisions through a relationship of mutual trust and respect with health professionals, and their choices should be acted upon'.

It is self-evident that a woman's autonomy is paramount and that care should be delivered in a way which informs and empowers. Women should have access to best practice care and their decision to accept or decline an intervention should always be respected.

Promote the availability of continuity of carer to women

The SBLCBv2 should not be implemented in isolation but as one of a series of important interventions to help reduce perinatal mortality and preterm birth. It is acknowledged how important it is for women to know and form a relationship with the professionals caring for them[13]. An inability for some groups in society to access health care is a recurring theme within confidential enquiries. The Maternity Transformation Programme is also supporting the roll out of continuity of carer, so that by 2021 most women will be offered the opportunity to have the same midwife caring for them throughout their pregnancy, birth and postnatally. Evidence shows that continuity models improve safety and outcomes; women who receive continuity of carer are 16% less likely to lose their baby, 19% less likely to lose their baby before 24 weeks and 24% less likely to experience preterm birth[14]. This model of care will also be targeted towards women from BAME groups and those living in deprived areas, for whom midwifery-led continuity of carer is linked to significant improvements in clinical outcomes[15]. The woman's midwife should liaise closely with obstetric, neonatal and other services, ensuring that she gets the care she needs and that it is joined up with the care she is receiving in the community[16].

Provide 'Safe and Healthy Pregnancy Information' to help women reduce the risks to their baby

It is important that women have access to high quality information before and during their pregnancy to enable them to reduce the risk to their baby. Public Health England and Sands have developed some key messages.

Pre-pregnancy:

- Choose when to start or grow your family by using contraception.
- Eat healthily and be physically active to enter pregnancy at a healthy weight.
- Take a daily supplement of folic acid before conception and until 12 weeks of pregnancy.
- Ensure that you are vaccinated against rubella.
- Find out if you think you or your partner could be a carrier for a genetic disorder.
- Stop smoking.

During pregnancy:

- Pregnant women should have 10µg of vitamin D a day.
- Don't drink alcohol.
- Don't smoke and avoid second hand smoke.
- Don't use illegal street drugs or other substances.
- Have the seasonal flu vaccination.
- Have the pertussis (whooping cough) vaccination.
- Avoid contact with people who have infectious illnesses, including diarrhoea, sickness, childhood illnesses or any rash-like illness.
- Remember the importance of handwashing to reduce the risk of CMV (cytomegalovirus) infection.
- Go to all antenatal appointments.
- Contact the maternity service promptly if you are worried. Don't wait!
- In later pregnancy (after 28 weeks), it is safer to go to sleep on your side than on your back.

Appendix B provides more detailed information on how women can plan, prepare and look after themselves before and during pregnancy. This information is also available at NHS.uk and Sands website.

Implement NICE guidance

Providers and commissioners are strongly encouraged to implement NICE guidance relating to antenatal, intrapartum and postnatal care. Implementation of the NICE guidance on the management of diabetes in pregnancy, hypertension in pregnancy and multiple pregnancy are particularly important if the government's ambition to halve stillbirth by 2025 is to be met.

Local Maternity Systems (LMSs) should bear in mind that Clinical Commissioning Groups (CCGs) are under an obligation in public law to have regard for NICE guidance and to provide clear reasons for any general policy that does not follow NICE guidance.

Implement best practice care in the event of a stillbirth

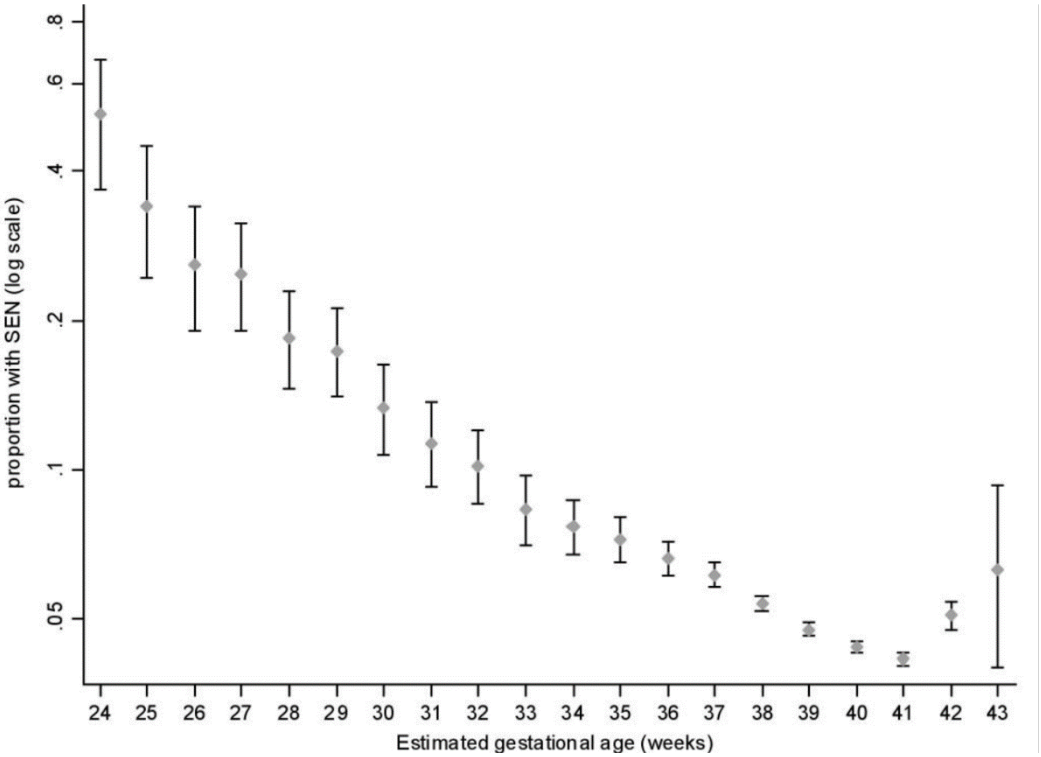
Despite the reduction in stillbirth rates sadly thousands of parents each year will experience the devastation of their baby dying before, during or shortly after birth. The Greater Manchester and Eastern Cheshire Maternity Clinical Network have published a best practice pathway for the clinical management of women experiencing stillbirth. This pathway is available on the Greater Manchester and Eastern Cheshire Clinical Network website.

Sands have developed a National Bereavement Care Pathway to help ensure that all bereaved parents are offered equal, high quality, individualised, safe and sensitive care when they experience pregnancy or baby loss. This pathway is available at www.nbcpathway.org.uk.

Inform women of the long-term outcomes of early term birth

One of the key interventions in elements 2 and 3 of the SBLCBv2 is offering early delivery for women at risk of stillbirth. It is important that this intervention is not extended to pregnancies not at risk. The Avoiding Term Admissions Into Neonatal units (Atain) programme has identified that babies born at 37 – 38 weeks gestation were twice as likely to be admitted to a neonatal unit than babies born at later gestations. There are also concerns about long term outcomes following early term birth (defined as 37 and 38 weeks). These concerns relate to potential long term adverse effects on the baby due to delivery prior to reaching maturity, for example, the baby's brain continues to develop at term. Delivery results in huge changes to the baby's physiology, for example, the arterial partial pressure of oxygen increases by a factor of three to four within minutes following birth and it is plausible that earlier exposure to these changes could alter long term development of the child's brain and data exist to support this possibility[17]. One example is the risk that the child will subsequently have a record of special educational needs (SEN). The risk of this outcome is about 50% among infants born at 24 weeks of gestational age and it progressively falls with increasing gestational age at birth, only to bottom out at around 40 – 41 weeks.

Figure 2: Prevalence of special educational needs by gestation at delivery[18].



After adjusting for maternal and obstetric characteristics and expressed relative to delivery at 40 weeks, the risk of SEN was increased by 36% (95% CI (confidence interval)) 27 – 45) at 37 weeks, by 19% (95% CI 14 – 25) at 38 weeks and by 9% (95% CI 4 – 14) at 39 weeks. The risk of subsequent SEN was 4.4% at 40 weeks. Hence, assuming causality, there would be one additional child with SEN for every 60 inductions at 37 weeks, for every 120 inductions at 38 weeks, and for every 250 inductions at 39 weeks compared with the assumption that they would otherwise have delivered at 40 weeks[19].

Consider how the risks of induction of labour change with gestational age

For uncomplicated pregnancies NICE guidance on induction of labour should be followed[20]. In all cases of induction, it is important women receive a clear explanation about why they are being offered induction and that the risks, benefits and alternatives are discussed.

At 39+0 weeks gestation and beyond, induction of labour is not associated with an increase in caesarean section, instrumental vaginal delivery, fetal morbidity or admission to the neonatal intensive care unit[21]. The NICE guidance[22] and data from the ARRIVE study[23] provide contradictory evidence as to whether induced labours are associated with a longer hospital stay or more painful labours. Induction of labour may also increase the workload of the maternity service which has the potential to impact the care of other women.

Reduce the risks of human error through the use of antepartum computerised CTG

When the available evidence is inconclusive SBLCBv2 aims to implement pragmatic best practice care, based upon clinical experience and a recognition of the important human factors. Human error in antepartum CTG interpretation has been identified as a significant root cause of stillbirth and serious brain injury[24]. A failure to meet the Dawes/Redman criteria usually prompts even the most experienced clinician to re-evaluate their clinical assessment. It provides a second line of defence when a less experienced doctor or midwife interprets a CTG. Therefore, with a recognition that the evidence is inconclusive, SBLCBv2 recommends the antepartum use of computerised CTG over and above visualised CTG due to the potential to reduce the risks of human error.

Organisational responsibilities and agreeing local variation in elements

Successful implementation of SBLCBv2 requires providers, commissioners and networks to collaborate successfully. It is important that organisations are clear about their responsibilities:

- Providers are responsible for implementing SBLCBv2.
- CCGs are responsible for commissioning maternity care which includes SBLCBv2.
- Clinical Networks are responsible for providing advice to commissioners and providers. Where there is unresolved clinical debate about a pathway, providers may wish to agree a variation to an element of the care bundle with their commissioner (CCG). It is important that specific variations from the pathways described within SBLCBv2 are agreed as acceptable clinical practice by their Clinical Network.
- LMSs' responsibilities include ensuring that the learning from the implementation and ongoing provision of SBLCBv2 is shared across the LMS.
- Local Learning Systems (LLS) are 'improvement forums' where individuals come together to share and learn about improvement approaches and outcomes. The LLS will provide a forum for organisations that are part of the NHS Improvement led Maternal and Neonatal Health Safety Collaborative and may choose to support the implementation of SBLCBv2 along with the continuous improvement work associated with the provision of SBLCBv2.

Continuous improvement and the Maternal and Neonatal Health Safety Collaborative

As part of the SBLCBv2, we are including a greater emphasis on continuous improvement. Within each element the focus is on a small number of outcomes with fewer process measures. The implementation of the elements will require a more comprehensive evaluation of each organisation's processes and pathways and as such an understanding of where improvements can be made.

Each organisation will be expected to look at their performance against the outcome measures for any given element in relation to other local providers or comparable peers with a view to understanding where improvement may be required. We have provided suggested areas for improvement within each element, but these lists are not meant to be exhaustive.

There is an expectation that as well as reporting on the organisation's performance within each element, there will be complimentary reporting of ongoing improvement work (with associated detail of interventions, and improvement in process measures and outcomes) within each element. An integral component of this improvement work will be a focus on learning from incidents or enquiry. Harm may have occurred in relation to implementation of or non-compliance with an element described in the care bundle. The use of the Perinatal Mortality Review Tool will complement the investigation and learning in this context.

Both the Maternal and Neonatal Health Safety Collaborative and the SBLCBv2 are key components of the 'Promoting Good Practice Through Safer Care' workstream of the Maternity Transformation Programme. The collaborative has a clear aim to improve outcomes and reduce unwarranted variation by providing a safe, high quality healthcare experience for all women, babies and families across maternity care settings in England. The collaborative is aiming to do this by focusing on five core clinical interventions. To support work in these areas, the collaborative is developing improvement capability in each maternity provider in England and aiming to both examine and improve safety culture in these organisations.

There is a clear overlap with the ambitions of the collaborative and that of the SBLCBv2. Two of the original four elements of the care bundle are reflected within the national driver diagram for the collaborative (improve the proportion of smoke-free pregnancy and improve the early recognition and management of deterioration during labour and early postpartum period). Moving forwards, the ambition to reduce the rate and consequence of preterm delivery is also reflected in the ambitions of the collaborative. Our focus on optimisation of the preterm baby aims to improve care in the antenatal, peripartum and postpartum period. These interventions form part of a wider focus on the consequences of preterm delivery.

Element 1: Reducing smoking in pregnancy

Element description
Reducing smoking in pregnancy by assessing exposure to carbon monoxide (CO) as appropriate to assist in identifying smokers (or those exposed to CO through other sources) and refer them for support from a trained stop smoking advisor.
Interventions
1.1 CO testing should be offered to all pregnant women at the antenatal booking appointment, with the outcome recorded. 1.2 Additional CO testing should be offered to pregnant women as appropriate throughout pregnancy, with the outcome recorded. 1.3 CO testing should be offered to all pregnant women at the 36 week antenatal appointment, with the outcome recorded. 1.4 Referral for those with elevated levels (4ppm or above) for support from a trained stop smoking specialist, based on an opt-out system. Referral pathway must include feedback and follow up processes. 1.5 All relevant maternity staff should receive training on the use of the CO monitor and having a brief and meaningful conversation with women about smoking (Very Brief Advice - VBA).
Continuous learning
1.6 Maternity care providers must examine their outcomes in relation to the interventions and trends and themes within their own incidents where smoking in pregnancy is felt to have been a contributory factor. 1.7 Individual Trusts must examine their outcomes in relation to similar Trusts to understand variation and inform potential improvements. 1.8 Maternity providers are encouraged to focus improvement in the following areas: a. Effective identification of women who smoke during their pregnancies. b. Increase the provision of effective training of staff in relation to smoking during pregnancy. c. Working with local partners to develop effective pathways of care for referral for specialist stop smoking advice.

Process indicators	Outcome indicators
i. Recording of CO reading for each pregnant woman on Maternity Information System (MIS) and inclusion of these data in the providers' Maternity Services Data Set (MSDS) submission to NHS Digital. ii. Percentage of women where CO measurement at booking is recorded. iii. Percentage of women where CO measurement at 36 weeks is recorded.	i. Percentage of women with a CO measurement ≥4ppm at booking. ii. Percentage of women with a CO measurement ≥4ppm at 36 weeks. iii. Percentage of women who have a CO level ≥4ppm at booking and <4ppm at the 36 week appointment.

Rationale

There is strong evidence that reducing smoking in pregnancy reduces the likelihood of stillbirth[25]. It also impacts positively on many other smoking-related pregnancy complications, such as preterm birth, miscarriage, low birthweight and Sudden Infant Death Syndrome (SIDS)[26]. Whether or not a woman smokes during her pregnancy has a far-reaching impact on the health of the child throughout his or her life[27].

This element is strongly evidence based and provides a practical approach to reducing smoking in pregnancy by following NICE guidance[28]. It requires electronic testing of all pregnant women for CO exposure and referring those with a positive reading to a trained stop smoking advisor. We know adherence to the NICE guidance and access to smoking cessation services is variable and this is an issue LMSs need to address. The NHS Long Term Plan includes funding for all Trusts to provide smoking cessation advice and support for all patients who agree to quit.

This element impacts positively on the other care bundle elements. Reducing smoking in pregnancy will reduce instances of fetal growth restriction, intrapartum complications and preterm birth. This demonstrates the complementary and cumulative nature of the care bundle approach.

This element also reflects the wider prevention agenda, impacting positively on long term outcomes for families and society. It will enhance the midwives role in promoting public health messages and interventions.

Implementation

Healthcare professionals must have the time and the tools to carry out the activities required by this element. Midwives need adequate time at the first booking appointment to carry out the CO test and deliver key messages.

Key factors for effective implementation include:

CO testing: All staff providing antenatal care should have access to a CO monitor (and training in how to use it), with appropriate procurement processes in place for obtaining CO monitors and associated consumables (for example, tubes and batteries).

Pathways: Effective pathways are in place from maternity services into specialist stop smoking support with access to nicotine replacement (for example, immediate referral for specialist support, specialist appointments within 24 hours, co-location of antenatal and stop smoking clinics and in house stop smoking specialist).

CO testing at the 36 week appointment: CO testing should be offered, and the result recorded, if the woman attends this appointment in her 35th or 36th week of pregnancy. If at any subsequent appointment it is apparent that CO testing at the 36 week appointment has been missed the practitioner should offer CO testing then. Testing of all women at the 36 week appointment can be used to reassure women with a low CO level regarding their exposure, to congratulate and encourage those who have stopped smoking, and to refer women with a CO measurement of 4ppm or above for specialist support, highlighting the

importance of a smoke-free home for their baby.

Considerations for frequency of additional testing: Additional testing of all women at the 16 or 25 week appointment to identify smokers who have not engaged with specialist support or those who may have relapsed. Additional monitoring should also be considered at each antenatal appointment for women who smoke or were recorded as recent/ex-smoker at booking.

Training: All relevant maternity staff should be trained to appropriately and effectively introduce the issue of CO testing, delivering VBA and having a brief and meaningful conversation on smoking with women, including the use of a CO monitor. Additional training should be in place for designated specialists who will deliver stop smoking interventions.

Increasing reach: A multidisciplinary approach should be utilised to share the workload (for example, conducting CO monitoring and the provision of VBA by Maternity Support Worker (MSW) or other healthcare professionals (HCPs)), and engage and support partners and/or other family members to achieve a smoke-free pregnancy.

Recording data: There should be routine recording of the CO reading for each pregnant woman on maternity information systems (MIS) and inclusion in the MSDS submission to NHS Digital will enable calculation of the required outcome measures for the element.

Review and act upon local data: Use tools available (for example, the Clinical Quality Improvement Metrics[29]) to review the current situation with smoking and data quality, compare with other nearby or demographically similar Trusts and identify if your Trust is an outlier and/or where improvements can be made.

Resources: Information and links to further resources are available from the Maternal and Neonatal Health Safety Collaborative. The Smoking in Pregnancy Challenge Group will be producing annual briefings for LMSs that will include national data broken down to LMS level, information about local authority stop smoking provision and signpost to current resources and information. Those with an interest can also join the Smokefree Pregnancy Information Network administered by Action on Smoking and Health, which will provide up to date information throughout the year. For more information contact admin@smokefreeaction.org.uk.

Element 2: Risk assessment, prevention and surveillance of pregnancies at risk of fetal growth restriction

Element description
Risk assessment and management of babies at risk of fetal growth restriction (FGR).
Interventions
Prevention 2.1 Assessing women at booking to determine if a prescription of aspirin is appropriate using the algorithm given in Appendix C or an alternative which has been agreed with local commissioners (CCGs) following advice from the provider's Clinical Network. 2.2 Assessment of smoking status (see Element 1) and efforts for the pregnancy to be smoke free before 16 weeks will also reduce FGR rates. **Risk assessment and surveillance of women at increased risk of FGR** 2.3 Use a risk assessment pathway (for example, Appendix D) which triages women at increased risk of FGR into an appropriate clinical pathway to provide surveillance for FGR. The pathway must be agreed with local commissioners (CCGs) following advice from the provider's Clinical Network. **Risk assessment and management of growth disorders in multiple pregnancy** 2.4 Risk assessment and management of growth disorders in multiple pregnancy should comply with NICE guidance or a variant that has been agreed with local commissioners (CCGs) following advice from the provider's Clinical Network. **Surveillance of low risk population** 2.5 In women not undergoing serial ultrasound scan surveillance of fetal growth, assessment is performed using antenatal symphysis fundal height (SFH) charts by clinicians trained in their use. All staff performing these measurements are to be competent in measuring, plotting, interpreting appropriately and referring when indicated. **Management of the SGA and growth restricted fetus** 2.6 Staff managing fetal growth problems should appreciate that small for gestational age (SGA) (estimated fetal weight (EFW) <10th centile) and FGR (where a fetus fails to reach its growth potential) are distinct entities. Although SGA babies are at increased risk of FGR compared to appropriately grown fetuses, fetuses <3rd centile are far more likely to be FGR than fetuses between 3rd – 10th centile. 2.7 When SGA is detected, the frequency of ultrasound review of estimated fetal weight (EFW) should follow the guidance in Appendix D or an alternative which has been agreed with local commissioners (CCGs) following advice from the provider's Clinical Network.

2.8 Maternity care providers caring for women with FGR identified prior to 34+0 weeks must have an agreed pathway for management which includes network fetal medicine input (for example, through referral or case discussion by phone).

2.9 Accepting the proviso that all management decisions should be agreed with the mother in the cases of fetuses <3rd centile and with no other concerning features, initiation of labour and/or delivery should occur at 37+0 weeks and no later than 37+6 weeks gestation. Delivery <37+0 weeks can be considered if there are additional concerning features, but these risks must be balanced against the increased risks to the infant of delivery at earlier gestations[30].

2.10 Fetuses between 3rd – 10th centile will often be constitutionally small and therefore not at increased risk of stillbirth. Care of such fetuses should be individualised and the risk assessment should include Doppler investigations, the presence of any other high risk features for example, recurrent reduced fetal movements, and the mother's wishes. In the absence of any high risk features, delivery or the initiation of induction of labour should be offered at 39+0 weeks.

Continuous learning

Learning from excellence and error, or incidents

2.11 Maternity care providers must determine and act upon all themes related to FGR (risk assessment, detection or management) that are identified from investigation of incidents, perinatal reviews and examples of excellence. This should include demonstration of improvement by reassessment of the elements of the care pathway involved.

2.12 Maternity care providers will provide data to the Trust Board and share this with the LMS in relation to the following:

a. Publication of SGA/FGR detection rates and percentage of babies born <3rd centile >37+6 weeks' gestation.
b. Ongoing case-note audit of <3rd centile babies not detected antenatally, to identify areas for future improvement (at least 20 cases per year, or all cases if less than 20 occur).
c. Monitoring of babies born >39+6 and <10th centile to provide an indication of detection rates and management of SGA babies.

2.13 Use the PMRT to calculate the percentage of perinatal mortality cases annually where the screening and management of FGR was a relevant issue.

2.14 Individual Trusts must examine their outcomes in relation to similar Trusts to understand variation and inform potential improvements.

2.15 Maternity providers are encouraged to focus improvement in the following areas:

a. Appropriate risk assessment at the beginning of pregnancy for placental dysfunction and the associated potential for growth restriction and robust referral processes to appropriate care pathways following this.
b. Appropriate prescribing of aspirin in line with this risk assessment in women at risk of placental dysfunction.
c. Effective measurement and recording of SFH.

2.16 Maternity providers will share evidence of these improvements with their Trust Board and the LMS and demonstrate continuous improvement in relation to process and outcome measures.

Process indicators	Outcome indicators
i. Percentage of pregnancies where a risk status for FGR is identified and recorded at booking. (This should be recorded on the provider's MIS and included in the MSDS submission to NHS Digital once the primary data standard is in place.) ii. Percentage of pregnancies where an SGA fetus is antenatally detected and this is recorded on the provider's MIS and included in their MSDS submission to NHS Digital. iii. Percentage of perinatal mortality cases annually where the screening and management of FGR was a relevant issue (using the PMRT).	i. Percentage of babies <3rd centile born >37+6 weeks (this is a measure of the effective detection and management of FGR).

Rationale

There is strong evidence to suggest that FGR is the biggest risk factor for stillbirth[31 32]. Therefore, antenatal detection of growth restricted babies is vital and has been shown to reduce stillbirth risk significantly because it gives the option to consider timely delivery of the baby at risk.

The previous version of this element has made a measurable difference to antenatal detection of SGA across England. However, by seeking to capture all babies at risk, it has potentially also increased interventions in women who are only marginally at increased risk of FGR related stillbirth. This updated element seeks to address this increase by focussing more attention on those at highest risk. It retains the strong commitment of the first version of the care bundle to appropriate training of staff who carry out SFH measurement, publication of detection rates and review of missed cases.

The risks and benefits of early term delivery

It is well recognised that preterm birth is associated with both short and long-term sequelae for the infant. The distinction between preterm and term birth is based on the 37+0 week threshold. However, like any threshold on a continuous scale, the separation into two groups is arbitrary. It is increasingly recognised that some of the risks associated with preterm birth are still apparent at 'early term' gestation, defined as 37 and 38 weeks. The association with short term morbidity can be captured by analysing the risk of admission of the infant to the neonatal unit. One of the best UK analyses was published by Stock et al[33] where they compared the risk of neonatal unit admission associated with induction of labour at the given week with the comparison group of all women delivered at a later week of gestation.

Figure 3: Neonatal unit admission according to week of gestational age, comparing induction of labour versus expectant management[34].

Week of gestational age	Neonatal admission per 1,000		Adjusted odds ratio (95% CI)
	Induction of labour	Delivered later	
37	176	78	2.01 (1.80-2.25)
38	113	74	1.53 (1.41-1.67)
39	93	73	1.17 (1.07-1.20)
40	80	73	1.14 (1.09-1.20)
41	66	84	0.99 (0.93-1.05)

However, delivery of the baby early prevents the subsequent risk of antepartum stillbirth. As antepartum stillbirth is the major single cause of perinatal death at term, earlier delivery will prevent perinatal death. The same paper also reported data on the risk of extended perinatal mortality associated with earlier induction.

Figure 4: Extended perinatal mortality according to week of gestational age, comparing induction of labour versus expectant management[35].

Week of gestational age	Extended perinatal mortality per 1,000		Adjusted odds ratio (95% CI)
	Induction of labour	Delivered later	
37	0.9	2.3	0.15 (0.03-0.68)
38	0.8	2.0	0.23 (0.09-0.58)
39	0.6	1.9	0.26 (0.11-0.62)
40	0.8	1.8	0.39 (0.24-0.63)
41	0.7	2.2	0.31 (0.19-0.49)

The dilemma is that early term delivery reduces the risk of a very rare but serious adverse event (stillbirth or neonatal death) while increasing the risk of much more common but less severe adverse events. Decision-making balances the risks of causing mild harm to relatively large numbers of infants in order to prevent serious harm to a relatively small number. For example, using the data above, at 37 weeks, 10 inductions will lead to one additional baby being admitted for neonatal care but it will require more than 700 inductions to prevent each perinatal death. Hence, current care is aimed at targeting early term induction to those who are at increased risk of perinatal death.

Implementation

This element recognises that there is a range of expert opinions on some interventions and allows some flexibility in the choice of pathways. The pathway in Appendix D is a suggestion but not mandated. A pathway should, however, be agreed with local

commissioners (CCGs) following advice from the provider's Clinical Network as to whether the pathway is acceptable to prevent idiosyncratic care.

In order to implement this element effectively Trusts must:

- ensure that all pregnant women are assessed for their risk of placental dysfunction with the associated potential for FGR in early pregnancy.
- ensure that a robust training programme and competency assessment is included in any screening for SGA, for example measurement of SFH, use and interpretation of charts, ultrasound scanning for growth and uterine artery Doppler measurement to screen for early onset FGR.
- identify which charts will be used antenatally to screen for SGA/FGR for both recording of SGA and EFW (for example, population or customised). All staff must be trained in the use of these charts, and referral pathways when there are concerns regarding fetal growth. Electronic ultrasound database and MIS suppliers should provide EFW centile charts and birthweight centile charts with reference curves for the 3rd and 10th centiles. Providers using paper EFW centile charts and birthweight centile charts should ensure that the charts have reference curves for the 3rd and 10th centiles. Actual birthweight of the baby must be assessed using the same methodology used antenatally (for example, population or customised) to determine antenatal detection rates of SGA/FGR to ensure consistency.

This updated element recognises that uterine artery Doppler screening of high risk pregnancies can improve efficiency by targeting scan resources (Appendix D). The use of uterine artery Doppler screening for women whose pregnancies are at high risk for placental dysfunction will require training of the ultrasonography workforce but allows triage to pathways which require fewer third trimester scans.

The RCOG SGA guideline[36] advises that fetal biometry surveillance scans need not be performed more frequently than every three weeks unless potential abnormalities in fetal growth are identified, in which case scans may need to be performed more frequently (see intervention 2.7). Ultrasound surveillance of biometry in at risk fetuses should continue until delivery. Providers with capacity may wish to use assessment of Middle Cerebral Artery (MCA) Doppler pulsatility indices (PI) in addition to umbilical artery Doppler to help identify and act upon potential fetal compromise in later pregnancy (after 34+0 weeks).

Version two of the MSDS will be in use from April 2019 and enables the recording of antenatally detected SGA using local criteria and the recording of fetal biometry, EFW and birthweight. Providers who submit these data via MSDS will be able to compare their performance with peer organisations using metrics developed by NHS Digital and available as part of the Maternity Data Viewer's Data Access Environment, which is being developed during 2019.

Trusts submitting data to the MSDS will be able to view the percentage of <10th centile and <3rd centile births in each gestational week of the third trimester in their unit annually. These data will allow Trusts to compare outcomes with similar units and to monitor the performance of their SGA and FGR detection programmes over time.

Element 3: Raising awareness of reduced fetal movement

Element description
Raising awareness amongst pregnant women of the importance of reporting reduced fetal movements (RFM), and ensuring providers have protocols in place, based on best available evidence, to manage care for women who report RFM.
Interventions
3.1 Information from practitioners, accompanied by an advice leaflet (for example, RCOG or Tommy's leaflet) on RFM, based on current evidence, best practice and clinical guidelines, to be provided to all pregnant women by 28+0 weeks of pregnancy and RFM discussed at every subsequent contact. 3.2 Use provided checklist (on page 33) to manage care of pregnant women who report RFM, in line with national evidence-based guidance (for example, RCOG Green-Top Guideline 57[37]).
Continuous learning
3.3 Maternity care providers must examine their outcomes in relation to the interventions and trends and themes within their own incidents where the presentation and/or management of RFM is felt to have been a contributory factor. 3.4 Individual Trusts must examine their outcomes in relation to similar Trusts to understand variation and inform potential improvements. 3.5 Maternity providers are encouraged to focus improvement in the following areas: a. Appropriate distribution of leaflets regarding RFM to pregnant women by 28+0 weeks of pregnancy. b. Appropriate care according to local guidance in relation to risk stratification and ongoing care for women presenting with RFM. c. Ensuring appropriate use of induction of labour when RFM is the only indication (for example, induction of labour for RFM alone is not recommended prior to 39+0 weeks).

Process indicators	Outcome indicators
i. Percentage of women booked for antenatal care who had received leaflet/information by 28+0 weeks of pregnancy.	i. Percentage of stillbirths which had issues associated with RFM management identified using PMRT.
ii. Percentage of women who attend with RFM who have a computerised CTG.	ii. Rate of induction of labour when RFM is the only indication before 39+0 weeks' gestation.

Rationale

Enquiries into stillbirth have consistently described a relationship between episodes of RFM and stillbirth, ranging from the 8th CESDI report published in 2001[38] to the MBRRACE-UK reports into antepartum and intrapartum stillbirths respectively[39] [40]. In all of these case reviews unrecognised or poorly managed episodes of RFM have been highlighted as contributory factors to avoidable stillbirths. In addition, a growing number of studies have confirmed a correlation between episodes of RFM and stillbirth[41] [42]. This relationship increases in strength when women have multiple episodes of RFM in late pregnancy (after 28 weeks' gestation)[43] [44].

This element and its interventions are aligned with the RCOG Green-Top Guideline 57 which is the best evidence summary and set of recommendations to date. A revision of the Green-Top Guideline will be completed in summer 2019.

Implementation

It is possible that this element will cause an increase in ultrasound scans and obstetric interventions, such as induction of labour and caesarean section[45]. The AFFIRM study found that a care package which recommended all women have an ultrasound assessment of fetal biometry, liquor volume and umbilical artery Doppler following presentation with RFM after 26 weeks' gestation, and offered induction of labour for recurrent episodes of RFM after 37 weeks' gestation did not significantly reduce stillbirths, but was associated with an increase in induction of labour and caesarean section. However, this care pathway reduced the number of SGA fetuses born at or after 40 weeks' gestation[46].

In order to reduce the number of scans required to implement this element providers are encouraged to offer computerised CTGs. If a computerised CTG has been performed and is normal and there are no other indications for an ultrasound scan then a scan is not required for a first presentation of RFM but should be offered for women reporting recurrent RFM. As stated on page 21 of this document, computerised CTGs are recommended over and above visualised CTG due to the potential to reduce the risks of human error. If an appropriate scan has been performed within the previous two weeks and was normal a repeat scan is not required.

Prior to 39 weeks gestation, induction of labour or operative delivery is associated with small increases in perinatal morbidity and neurodevelopmental delay. Thus, a recommendation for delivery needs to be individualised and based upon evidence of fetal compromise (for example, abnormal CTG, EFW <10th centile or oligohydramnios) or other concerns (for example, concomitant maternal medical disease, such as hypertension or diabetes, or associated symptoms such as antepartum haemorrhage).

At 39 weeks gestation and beyond, induction of labour is not associated with an increase in caesarean section, instrumental vaginal delivery, fetal morbidity or admission to the neonatal intensive care unit. Induction of labour therefore, could be discussed (risks, benefits and mother's wishes) with women presenting with a single episode of RFM after 38+6 weeks gestation. It is important that women presenting with recurrent RFM are additionally informed of the association with an increased risk of stillbirth and given the option of delivery for RFM alone after 38+6 weeks.

Suggested Checklist for the Management of Reduced Fetal Movements (RFM)

1. Ask	
Confirm there is maternal perception of RFM? How long has there been RFM? Is this the first episode? When were movements last felt?	
2. Act	
Auscultate fetal heart (hand-held Doppler/Pinnard) to confirm fetal viability.	
Assess fetal growth by reviewing growth chart, perform SFH if not performed within last 2 weeks.	
Perform CTG to assess fetal heart rate in accordance with national guidelines (ideally computerised CTG should be used).	
Ultrasound scan for fetal growth, liquor volume and umbilical artery Doppler needs only to be offered on first presentation of RFM if there is no computerised CTG or if there is another indication for scan (e.g. the baby is SGA on clinical assessment). Ultrasound scan for fetal growth, liquor volume and umbilical artery Doppler should be offered to women presenting with recurrent RFM after 28+0 weeks' gestation. Scans are not required if there has been a scan in the previous two weeks.	
In cases of RFM after 38+6 weeks discuss induction of labour with all women and offer delivery to women with recurrent RFM after 38+6 weeks.	
3. Advise	
Convey results of investigations to the mother. Mother should be encouraged to re-attend if she has further concerns about RFM.	

IN THE EVENT OF BEING UNABLE TO AUSCULTATE THE FETAL HEART, ARRANGE IMMEDIATE ULTRASOUND ASSESSMENT

Element 4: Effective fetal monitoring during labour

Element description
Effective fetal monitoring during labour.
Interventions
4.1 All staff who care for women in labour are required to undertake annual training and competency assessment on cardiotocograph (CTG) interpretation and use of auscultation. Training should be multidisciplinary and include training in situational awareness and human factors. The training and competency assessment should be agreed with local commissioners (CCG) based on the advice of the Clinical Network. No member of staff should care for women in a birth setting without evidence of training and competence within the last year. 4.2 There is a system agreed with local commissioners (CCG) based on the advice of the Clinical Network to assess risk at the onset of labour which complies with NICE guidance[47], irrespective of place of birth. The assessment should be used to determine the most appropriate fetal monitoring method. 4.3 Regular (at least hourly) review of fetal wellbeing to include: CTG (or intermittent auscultation (IA)), reassessment of fetal risk factors, use of a Buddy system to provide 'Fresh Eyes (or Ears)', a clear guideline for escalation if concerns are raised through the use of a structured process. All staff to be trained in the review system and escalation protocol. 4.4 Identify a Fetal Monitoring Lead for a minimum of 0.4 WTE per consultant led unit during which time their responsibility is to improve the standard of intrapartum risk assessment and fetal monitoring.
Continuous learning
4.5 Maternity care providers must examine their outcomes in relation to the interventions, trends and themes within their own incidents where fetal monitoring was likely to have been a contributory factor. 4.6 Individual Trusts must examine their outcomes in relation to similar Trusts to understand variation and inform potential improvements. 4.7 Maternity providers are encouraged to focus improvement in the following areas: a. Risk assessment of the mother/fetus at the beginning and during labour. b. Interpretation and escalation of concerns over fetal wellbeing in labour.

Process indicators	Outcome indicators
i. Percentage of staff who have received training on CTG interpretation and auscultation, human factors and situational awareness ii. Percentage of staff who have successfully completed mandatory annual competency assessment	i. The percentage of intrapartum stillbirths, early neonatal deaths and cases of severe brain injury* where failures of intrapartum monitoring are identified as a contributory factor.

*Using the severe brain injury definition as used in Gale et al. 2018[48].

Rationale

CTG monitoring is a well-established method of confirming fetal wellbeing and screening for fetal hypoxia. In the case of a high risk labour where continuous monitoring is needed, CTG is the best clinical tool available to carry this out.

However, CTG interpretation is a high-level skill and is susceptible to variation in judgement between clinicians and by the same clinician over time[49]. These variations can lead to inappropriate care planning and subsequently impact on perinatal outcomes[50].

As well as reducing stillbirth rates, there is a need to reduce avoidable fetal morbidity related to brain injury causing conditions such as hypoxic-ischemic encephalopathy (HIE) and cerebral palsy. These conditions have a huge emotional and financial impact upon families. They also have significant economic consequences for the health and social care system through the costs of care needed to support those with an avoidable brain injury throughout their lives and litigation understandably brought by families when something goes wrong during labour.

The importance of good fetal monitoring during labour, in achieving delivery of a healthy baby, is underlined by data from the RCOG's Each Baby Counts report[51], showing that fetal monitoring was identified in 74% of babies as a critical contributory factor where improvement in care may have prevented the outcome. The report highlighted failure to initiate CTG when indicated, failure to record a good-quality CTG, inadequate CTG interpretation and failure to communicate the findings to senior staff in a timely manner. The conclusions resulting from these findings included recommendations for:

- a regular/rolling programme of training in the use of electronic fetal monitoring
- simple guidelines on the interpretation of electronic fetal monitoring
- clear lines of communication when an abnormal CTG is suspected
- guidelines on appropriate management in situations where the CTG is abnormal

Importantly, the report also identified problems with fetal monitoring using IA, including inappropriate assignment of women to 'low risk', delays in responding to abnormalities and switching to CTG monitoring when appropriate. There was also a failure to follow national guidelines about technique and frequency of AI and a failure to recognise transition between the stages of labour.

Many of the findings and recommendations from the Each Baby Counts report are echoed in the 2017 MBRRACE-UK Perinatal Confidential Enquiry[52] that focussed on term, singleton, intrapartum stillbirth and intrapartum-related neonatal death. Recommendations that have now been incorporated into this element of the care bundle include the use of a risk assessment tool on admission and then throughout labour to guide the nature, frequency and interpretation of fetal monitoring, as well as determining the optimal form of

training and competency assessment. In addition, both reports identify the fact that CTG or IA monitoring cannot be used in isolation and are only part of a complex assessment of fetal wellbeing – "Failure to recognise an evolving problem, or the transition from normal to abnormal, was a common theme. It was rarely due to a single issue, more commonly appearing to arise from a more complex failure of situational awareness and ability to maintain an objective overview of a changing situation" (MBRRACE-UK Perinatal Confidential Enquiry). There is, therefore, a real need for all staff to undertake multidisciplinary training that includes situational awareness, human factors and communication. The importance of ensuring situational awareness is present in teams performing complex tasks is also highlighted in the Each Baby Counts report from 2015.

Implementation

Trusts must be able to demonstrate that all qualified staff who care for women in labour are competent to interpret CTG, use the Buddy system at all times and escalate accordingly when concerns arise or risks develop. This includes staff that are brought in to support a busy service from other clinical areas such as the postnatal ward and the community, as well as locum, agency or bank staff (medical or midwifery).

Intervention 1: Owing to a lack of formal assessment it is not possible to be prescriptive about the exact nature of either training packages or indeed competency assessment. However, training packages should adhere to the following principles:

- Include multidisciplinary and scenario-based training – this should involve all medical and midwifery staff who care for women in birth settings.
- Teaching about fetal physiological responses to hypoxaemia, the pathophysiology of fetal brain injury, and the physiology underlying changes in fetal heart rate (FHR). In addition, the impact of factors such as fetal growth restriction and maternal pyrexia.
- Effective fetal monitoring in low risk pregnancies, including the role of IA in initial assessment, in established labour and indications for changing from IA to CTG.
- Interpretation of CTG including:
  - normal CTG
  - impact of intrapartum fetal hypoxia on the FHR
  - Significance of abnormal CTG patterns
  - interpretation in specific clinical circumstances (such as previous caesarean sections, breech and multiple pregnancy).
- Interventions that can affect the FHR (such as medication) and those that are intended to improve the FHR (such as oxygen).
- Additional tests of fetal wellbeing that help clarify fetal status and reduce the false positive rate of CTG.
- Channels of communication to follow in response to a suspicious or pathological trace, risk management strategies including governance and audit.
- Application of NICE fetal monitoring recommendations for low risk women.

- Training in situational awareness and human factors to enable staff to respond appropriately to evolving, complex situations.
- Provision of adequate training is a Trust priority – as a minimum all staff should receive a full day of multidisciplinary training (following the principles outlined above) each year with reinforcement from regular attendance at fetal monitoring review events.

Competency assessment: all staff will have to pass a formal annual competency assessment that has been agreed by the local commissioner (CCG) based on the advice of the Clinical Network. The assessment should include demonstrating a clear understanding of the areas covered in training (see principles above), for example, fetal physiology, recognition of abnormal CTGs and use of IA and situational awareness. Trusts should agree a procedure with their CCG for how to manage staff who fail this assessment.

Intervention 2: The MBRRACE-UK Perinatal Confidential Enquiry report recommended the national development of a standardised risk assessment tool. As this has not yet been developed the procedure should comply with NICE guidance[53]. A case example based upon NICE guidance has been provided in Appendix E, however further assessment tools may be developed in the future.

Intervention 3: The principle underlying this intervention is that fetal wellbeing is assessed regularly (at least hourly) during labour through discussion between the midwife caring for the fetus and another midwife or doctor. This discussion should be documented using a structured proforma. This review should be more than a categorisation of the CTG (or IA).

The discussion should include evaluation of the FHR (CTG or IA), review of risk factors such as persistently reduced fetal movements before labour, fetal growth restriction, previous caesarean section, thick meconium, suspected infection, vaginal bleeding or prolonged labour and should lead to escalation if indicated.

Introduce a Buddy system to pair up more and less experienced midwives during shifts to maximise continuity of care and provide accessible senior advice and fresh eyes, with protocol for escalation of any concerns.

Intervention 4: Some Trusts may choose to extend the remit of the Practice Development Midwife to fulfil the role of Fetal Monitoring Lead, whereas others may wish to appoint a separate clinician. The critical principle is that the Fetal Monitoring Lead has dedicated time when their remit is to support staff working on the labour ward to provide high quality intrapartum risk assessments and accurate CTG interpretation. The role should contribute to building and sustaining a safety culture on the labour ward with all staff committed to continuous improvement.

Element 5: Reducing preterm births

Element description
Reducing the number of preterm births and optimising care when preterm delivery cannot be prevented
Interventions
Prediction 5.1 Assess all women at booking for the risk of preterm birth and stratify to low, intermediate and high risk pathways using the criteria in Appendix F or an alternative which has been agreed with local commissioners (CCGs) following advice from the provider's Clinical Network. **Prevention** 5.2 Assess all women at booking to determine if a prescription of aspirin is appropriate using the algorithm given in Appendix C or an alternative which has been agreed with local commissioners (CCGs) following advice from the provider's Clinical Network. 5.3 Assessment of smoking status (see Element 1) and efforts for the pregnancy to be smoke free before 16 weeks will also reduce preterm birth rates. 5.4 Risk assessment and management in multiple pregnancy should comply with NICE guidance or a variant that has been agreed with local commissioners (CCGs) following advice from the provider's clinical network. 5.5 Assess women with a history of preterm birth to determine whether this was associated with placental disease and discuss prescribing aspirin with the woman based upon her personalised risk assessment. 5.6 All women to be offered screening for asymptomatic bacteriuria by sending off a midstream urine (MSU) for culture and sensitivity at booking. Following any positive culture and treatment, a repeat MSU to confirm clearance is recommended[54]. 5.7 Every provider should have access to transvaginal cervix scanning (TVCS) and a clinician with an interest in preterm birth prevention with a clinical pathway for women at risk of preterm birth that is agreed with local commissioners (CCGs) following advice from the provider's clinical network (for example, UK Preterm Clinical Network guidance or NICE guidance[55]). 5.8 Every provider should have referral pathways to tertiary prevention clinics for the management of women with complex obstetric and medical histories. This should include access to clinicians who have the expertise to provide high vaginal (Shirodkar) and transabdominal cerclage. These procedures are performed relatively infrequently and therefore would be best provided on a supra-regional basis in order to maintain expertise. **Preparation**: optimising care of women and babies at high risk of imminent preterm birth. 5.9 Optimise place of birth – women at imminent risk of preterm birth should be offered transfer to a unit with appropriate and available neonatal cot facilities when safe to do so and as agreed by the relevant neonatal Operational Delivery Network (ODN). 5.10 Antenatal corticosteroids to be offered to women between 24+0 and 33+6 weeks, optimally at 48 hours before a planned birth. A steroid-to-birth interval of greater than seven days should be avoided if possible.

5.11 Magnesium sulphate to be offered to women between 24+0 and 29+6 weeks of pregnancy, and considered for women between 30+0 and 33+6 weeks of pregnancy, who are in established labour or are having a planned preterm birth within 24 hours.

5.12 Ensure the neonatal team are involved when a preterm birth is anticipated, so that they have time to discuss options with parents prior to birth and to be present at the delivery.

5.13 For women between 23 and 24 weeks of gestation, a multidisciplinary discussion should be held before birth between the neonatologist, obstetrician and the parents about the decision to resuscitate the baby. If resuscitation is agreed to be attempted, women should be offered magnesium sulphate and steroids timed according to the above recommended intervals to birth.

Continuous learning

5.14 Maternity care providers must determine and act upon all themes related to preterm birth (prediction, prevention, preparation) that are identified from investigation of incidents, perinatal reviews and examples of excellence. This should include demonstration of improvement by reassessment of the elements of the care pathway involved.

5.15 Maternity care providers will provide outcome data to the Trust Board and share this with the LMS relating to the incidence of women with a singleton pregnancy giving birth (liveborn and stillborn) as a % of all singleton births:

a. in the late second trimester (from 16+0 to 23+6 weeks).
b. preterm (from 24+0 to 36+6 weeks).

5.16 Use the PMRT to calculate the percentage of perinatal mortality cases annually where the prevention or prediction of or preparation for preterm birth was a relevant issue.

5.17 Individual Trusts must examine their outcomes in relation to similar Trusts to understand variation and inform potential improvements.

5.18 Maternity providers are encouraged to focus on the following areas:

a. Risk assessment of women in their first pregnancy for the risk of preterm birth and timely triage to the appropriate care pathway.
b. Management of women at high risk of preterm birth, including appropriate cervical length surveillance and use of cervical cerclage.
c. Optimisation of women with suspected preterm labour, including effective use of antenatal corticosteroids and magnesium sulphate.
d. Appropriate place of birth for women at risk of preterm birth.

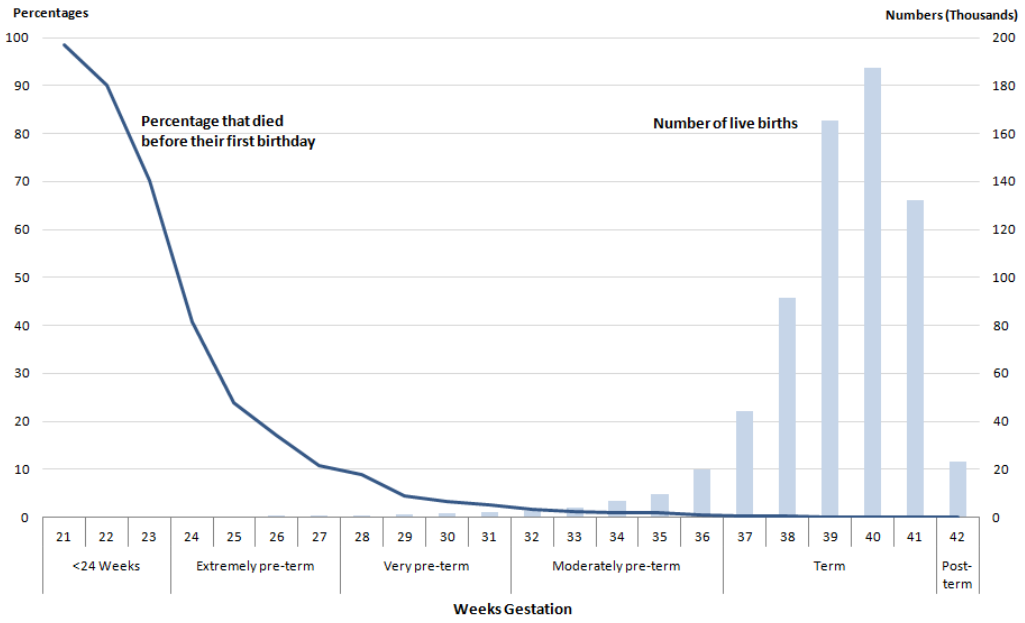
5.19 Maternity providers will share evidence of these improvements with their Trust Board and LMS and demonstrate continuous improvement in relation to process and outcome measures.

Process indicators	Outcome indicators
i. Percentage of singleton live births (less than 34+0 weeks) receiving a full course of antenatal corticosteroids, within seven days of birth. ii. Percentage of singleton live births (less than 34+0 weeks) occurring more than seven days after completion of their first course of antenatal corticosteroids. iii. Percentage of singleton live births (less than 30+0 weeks) receiving magnesium sulphate within 24 hours prior to birth. iv. Percentage of women who give birth in an appropriate care setting for gestation (in accordance with local ODN guidance).	i. The incidence of women with a singleton pregnancy giving birth (liveborn and stillborn) as a % of all singleton births: a. In the late second trimester (from 16+0 to 23+6 weeks). b. Preterm (from 24+0 to 36+6 weeks).

Rationale

Preterm birth (PTB), defined as delivery at less than 37+0 week's gestation, is a common complication of pregnancy, comprising around 8% of births in England and Wales[56]. It is the most important single determinant of adverse infant outcome with regards to survival and quality of life[57]. Babies born preterm have high rates of early, late, and post-neonatal mortality and morbidity. PTB is estimated to cost health services in England and Wales £3.4bn per year[58].

Figure 5: Percentage of infant deaths and number of live births by week gestation (2013)[59].



The 2015/16 Outcomes Framework outlined objectives to:

- reduce deaths in babies and young children
- improve the safety of maternity services (admission of full-term babies to neonatal care)

This has been further developed in 'Safer Maternity Care: The National Maternity Safety Strategy – Progress and Next Steps' where the Government made it clear that 'we will not achieve the national Maternity Safety Ambition [to halve the rates of stillbirths, neonatal and brain injuries that occur during or soon after birth by 2030] unless the rate of preterm births is reduced' and set an additional ambition to reduce the national rate of preterm births from 8% to 6%. The current scope of NICE preterm guidelines is limited to principally to acute presentation[60 61], and this document specifies those at-risk populations who should be targeted for additional referral and management to meet this ambition. It is anticipated that the rapidly expanding evidence base in this field will contribute to these evolving guidelines, and the UK Preterm Clinical Network guidance document will be updated periodically and this will be an open access document.

Implementation

All the elements within SBLCBv2 address iatrogenic preterm and early term birth, recognising the need to ensure that any decision for delivery is based on evidence of maternal and/or fetal compromise. This element focuses on reducing spontaneous preterm birth via prediction, prevention, and optimisation of care when preterm birth is imminent.

It highlights the following for provision of care within networks:

- Providers should identify a clinical lead for preterm birth prevention to oversee development of clinical guidelines and pathways of care, responsibility for quality, governance and training, involvement in research studies and registries and involvement regionally within the local preterm birth network.
- Providers must have provision for care for women at risk of preterm birth ideally within a preterm birth prevention clinic with midwifery support and access to screening tests, including transvaginal cervix scanning and quantitative fetal fibronectin and potential interventions, for example, cervical cerclage, pessary and progesterone. Where preterm birth prevention clinics are not available providers must ensure that women are able to access care that guarantees that they are given evidence-based information, access to screening tests and interventions as appropriate and can actively participate in decisions regarding their management.
- Providers must have access to supra-regional prevention services within their care pathways and networks, which include access to high vaginal and transabdominal cerclage.

Trusts are encouraged to implement these changes using strategies recommended by the Maternal and Neonatal Health Safety Collaborative.

Further guidance regarding the care of women and their babies at risk of preterm birth can be found at:

- NICE Guideline NG25 'Preterm labour and birth'
- NICE Diagnostics Guidance DG33 'Biomarker tests to help diagnose preterm labour in women with intact membranes'

- UK Preterm Clinical Network 'Reducing Preterm Birth: Guidelines for Commissioners and Providers'

Appendix F includes a suggested risk assessment and management algorithm that providers may wish to adopt.

Appendix A: Acknowledgments

NHS England would like to thank the following contributors to the development of the elements of this care bundle:

Saving Babies' Lives Care Bundle Oversight Group

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Element 1: Reducing smoking in pregnancy

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Element 2: Risk assessment, prevention and surveillance of pregnancies at risk of fetal growth restriction

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Element 3: Raising awareness of reduced fetal movement

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Element 4: Effective fetal monitoring during labour

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Element 5: Reducing preterm births

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Appendix B: Detailed ‘safe and healthy pregnancy’ messages

There are numerous causes of stillbirth, many of which are poorly understood. Surveillance work by *MBRRACE-UK* highlights that BAME women, older women, teenagers and those living in poverty are at increased risk[62]. Health professionals should consider these risk factors (as well as smoking, drinking and diet) and take appropriate action for individual women. Providing information as ‘safe and healthy pregnancy’ messages presents an opportunity to raise awareness of stillbirth as an uncommon but possible occurrence.

This section looks at how women can help themselves and their baby. It also includes some pre-pregnancy advice, and a note on whooping cough vaccination.

Background

Women with no experience of stillbirth or perinatal death don’t want to be made to feel unnecessarily anxious, but do want to know what they can do to help themselves and their baby stay safer in pregnancy.

Women whose baby has died may feel guilt and that their behaviour was to blame for what happened. ‘Safe and healthy pregnancy’ messages risk amplifying these feelings if not delivered and managed with sensitivity.

www.saferpregnancy.org.uk is a website developed by Sands that carries safer pregnancy messages together with short information films and links to national guidance and further information.

Safe and healthy pregnancy messages

The section below contains additional information which may support conversations with women around these ‘safe and healthy pregnancy’ messages.

Advice point: Choose when to start or grow your family by using contraception.
Why is this important? Worse outcomes are linked to unplanned pregnancies. Also, getting pregnant again after a baby is born can happen sooner than many people realise, and too short a gap between babies is known to cause problems.
Tip: Encourage women to speak to a health professional about the range of contraception options available.

Advice point: Eat healthily and be physically active to enter pregnancy at a healthy weight and maintain a healthy weight while pregnant.

Why is this important? Women who are overweight or obese before they conceive have an increased risk of complications during pregnancy and birth. They also face an increased risk that their baby will be stillborn.

Tips: Encourage women who are overweight or obese to:

- speak to a health professional about how to lose weight and sustain the weight loss to enter pregnancy at a healthy weight
- eat a balanced diet, control portion sizes and swap unhealthy food for healthier options (the Eatwell Guide may be helpful)
- be fit and healthy, try to be active daily and do at least 150 minutes of weekly physical activity, including both aerobic and strength exercises

While pregnancy isn't the time for a weight-loss diet, it is a good time to adopt a healthy diet, so encourage women to swap unhealthy foods for healthier options and try to keep active. Reassure women that, even during the last few months of pregnancy, they only need an extra 200 calories a day (for example, two slices of wholemeal toast or an apple and a banana). Also encourage women to do 30 minutes or more of moderate physical activity, such as walking, every day right up until the baby is born.

Advice point: Take a daily supplement of 400 micrograms (400 µg) folic acid before conception and until the 12th week of pregnancy (some women will require a higher dose as advised by a healthcare professional). Pregnant women (and all adults, including breastfeeding women) are also recommended to have 10 µg of vitamin D a day. Women should not take vitamin A supplements, or any supplements containing vitamin A (retinol) during pregnancy as a build-up of this vitamin in the body can harm your baby. Always check the label of supplements for vitamin A.

Why is this important? Folic acid (also known as vitamin B9) is very important for the development of a healthy fetus, as it can significantly reduce the risk of neural tube defects (NTDs), such as spina bifida. A high proportion of women are still unaware of the recommendation to take folic acid and do not take supplements. Vitamin D regulates the amount of calcium and phosphate in the body, which keeps bones, teeth and muscles healthy.

Tips: Encourage women to take a vitamin supplement before conception and during pregnancy as appropriate.

Advice point: Before pregnancy, ensure that you are protected from rubella. Check you are vaccinated if you're thinking of becoming pregnant.

Why is this important? Maternal rubella infection in pregnancy may result in fetal loss or congenital rubella syndrome.

Tips: Encourage women to check with their GP that they have had two documented doses of MMR vaccine. If not, they can catch up on missing doses before becoming pregnant, but should take steps to avoid pregnancy for one month following the MMR vaccination.

(Encourage women not fully vaccinated but pregnant to check their MMR immunisation status with their GP after the birth.)

Advice point: Find out about screening if you think you or your partner could be a carrier for a genetic disorder.

Why is this important? Some disorders can be passed from parents to their children through their genes, and these can be more common in some groups of people.

Tip: Encourage women to speak to their GP to see if they and/or their partners should be screened before becoming pregnant.

Advice point: Go to all antenatal appointments. By doing this, you'll have support and advice throughout your pregnancy.

Why is this important? Some of the tests and measurements have to be done at specific times, and the midwife needs to give information as the pregnancy progresses.

Tips: Make sure women know where the dates and times of appointments are written and what to do if they miss an appointment or can't attend.

There's an animation that describes antenatal and newborn screening for pregnant women, new mums and their families on the NHS UK website (formerly NHS Choices). Leaflets are also available in 12 languages.

Advice point: Contact the maternity service promptly if there is a concern. Don't wait until the next day. Maternity services are staffed 24/7, and there is always someone who can speak to you on the phone. Reasons to get in touch promptly include:

- Baby's movements have reduced, slowed down or changed
- Bleeding from the vagina
- Watery, clear or coloured discharge from the vagina which seems abnormal
- Signs of pre-eclampsia, such as obvious swelling, especially affecting the hands and face or upper body; severe headache that won't go away, sometimes with vomiting; problems with vision (blurring, flashing lights or spots, difficulty in focusing); and severe pain just below the ribs in the middle of the abdomen

Why is this important? Timely action is sometimes needed, but women may be worried about contacting the service directly.

Tip: Also talk about how itching, particularly on the hands and feet, can be a sign of the liver disorder called intrahepatic cholestasis of pregnancy; women should get in touch within 24 hours if they experience itching.

Advice point: Stop smoking. Smoking affects the development of the baby and is associated with complications in pregnancy and poor outcomes Smoking can also impact on fertility. The best way for women to protect themselves and their baby is to stop smoking completely.

Why is this important? Tobacco smoke contains thousands of chemicals, and many are toxic. They can pass through the placenta to the baby and affect his or her development. A small baby who doesn't grow healthily has an increased chance of being stillborn. Smoking

also increases the likelihood of a baby being born prematurely, and that he or she will have health and development problems in childhood and later life.

Tips: The best thing a woman can do is stop. Stopping at any time in pregnancy will help, though the sooner the better. If her partner or other household members smoke, they can support her by making efforts to give up smoking too and have a smoke-free home. Find out about local stop smoking support available for pregnant women and families in your area.

Advice point: The safest way to ensure baby is not damaged by alcohol is not to drink while pregnant. Advice about alcohol in pregnancy can get confusing – the simplest line is to not drink alcohol at all when pregnant.

Why is this important? Alcohol passes from the mother's blood across the placenta to the developing baby. Alcohol in the baby's blood can interfere with his or her oxygen and nutrient supply, leading to birth defects, reduced growth and long-term learning and behaviour problems. Stillbirths are also more common in women who drink heavily. Drinking alcohol at critical times in the baby's development, heavy ('binge') drinking and frequent drinking increase the likelihood that the baby will be affected

Tips: The simplest and safest advice for women is not drink alcohol at all while pregnant. Drinkline is a free and confidential helpline for people concerned about their, or a relative's, drinking and can be contacted on 0300 123 1110. NHS UK (formerly NHS Choices) has additional options.

Advice point: If you currently use or have used illegal street drugs or other substances, it is important to tell your midwife.

Why is this important? Street drugs and other substances can be harmful to the baby during pregnancy.

Tips: A woman may be worried about sharing this information – reassure her that it will be treated in strict confidence and will only be shared with relevant health professionals if that's in the best interest of the baby.

Women can contact FRANK for friendly and confidential drugs advice, including information on the different types of help available. The FRANK helpline 0300 123 6600 is open every day, 24 hours a day.

Advice point: Have the seasonal flu vaccine; it's safe, effective and free of charge to pregnant women.

Why is this important? Pregnant women have a much higher risk of serious illness as a result of flu compared with the general population. In addition, influenza during pregnancy may also be associated with perinatal mortality, prematurity, smaller neonatal size and lower birth weight. The flu vaccine is safe to have at any stage of pregnancy and women who've had the vaccine when pregnant also pass some protection onto their babies, which lasts for the first few months of the baby's life.

Tip: You can be reassuring about vaccination during pregnancy. Routine inactivated flu vaccine programmes for pregnant women have been running in a large number of

developed countries for many years, with no reported safety issues relating to inactivated flu vaccination.

Action point: Have the pertussis (whooping cough) vaccination. It's safe, effective and free of charge to pregnant women.

Why is this important? Pertussis can lead to the death of a young baby. Pregnant women can have a pertussis vaccine from 16 weeks gestation – the best time is at 16 to 32 weeks. Women may still be immunised after week 32 of pregnancy but this may not offer as high a level of passive protection to the baby. The aim of the maternal pertussis immunisation programme is to provide the baby with passive immunity to pertussis until the baby starts routine immunisations from 8 weeks of age.

Tips: You can be reassuring that vaccine containing pertussis can be safely given to pregnant women from 16 weeks gestation. It is 97% effective in preventing death from pertussis in babies less than 3 months. The mother's antibodies that are generated in response to the vaccine help protect the baby until they have their immunisations from 8 weeks of age.

The baby should also complete their routine childhood immunisations on time at 8, 12 and 16 weeks of age.

Action point: Wherever possible, avoid contact with people who have infectious illnesses, including diarrhoea, sickness and childhood illnesses, such as chickenpox or parvovirus (slapped cheek) or any rash-like illness.

Why is this important? The immune system becomes weaker in pregnancy, so pregnant women are more at risk of infections. Some can increase the risk of stillbirth and/or maternal and perinatal complications.

Tips: Encourage women to:

- be strict about good hygiene – washing hands before and after handling food, after going to the toilet and after sneezing and blowing their nose
- know which foods to avoid
- urgently see their midwife or GP if they have been in contact with someone who has rash-like illnesses, or if they develop a rash-like illness themselves.

Action point: Remember the importance of handwashing to reduce the risk of CMV (cytomegalovirus) infection

Why is this important? CMV is a common virus, similar to the herpes virus that causes cold sores and chickenpox. Infection can be dangerous during pregnancy as it can cause problems for unborn babies, such as hearing loss, visual impairment or blindness, learning difficulties and epilepsy. CMV is particularly dangerous to the baby if the pregnant mother has not had the infection before.

Tips: it is not always possible to prevent a CMV infection, but you can reduce the risk by:

- washing your hands regularly with soap and hot water, particularly if you have been changing nappies, or work in a nursery or day care centre

- not kissing young children on the face – it is better to kiss them on the head or give them a hug
- regularly wash toys or other items that get young children's saliva or urine on them
- not sharing food or cutlery with young children, and not drinking from the same glass as them.

These precautions are particularly important if you have a job that brings you into close contact with young children. In this case, you can have a blood test to find out whether you have previously been infected with CMV. Find out more about CMV on the CMV Action website.

Advice point: In later pregnancy (after 28 weeks), it is safer to go to sleep on your side than on your back.

Why is this important? For pregnant women, the blood flow going to the baby may be reduced or interrupted if they spend a long time lying on their back. Research has linked this with an increased risk of stillbirth.

Tips: Encourage women to settle on their side when they go to sleep or have a day-time nap, rather than on their back. A woman who wakes up on her back shouldn't worry, but should settle to sleep again on her side.

Appendix C: Medication to reduce the risk of pregnancy complications

All women should take a daily supplement of 400 micrograms (400 µg) folic acid before conception and until the 12th week of pregnancy (some women will require a higher dose as advised by a healthcare professional). Pregnant women (and all adults, including breastfeeding women) are also recommended to have 10 µg of vitamin D a day.

Elements 2 and 5 of this care bundle include the assessment of women for treatment with aspirin. NICE recommends Aspirin* reduces the risk of pregnancy complications related to placental dysfunction, particularly preeclampsia[63]. Thus, it is important to take a full history from women whom have had a previous baby with FGR and/or a preterm delivery to determine whether placental dysfunction was a contributory factor. Aspirin as a preventative medication appears to be safe in pregnancy and therefore there is a substantial net benefit of daily aspirin use to reduce the risk for preeclampsia and associated preterm birth. Aspirin is therefore recommended from the first to the third trimester of pregnancy in women, following risk assessment at their pregnancy booking visit.

Dosage

There is evidence from randomised controlled trials that the dose of aspirin should be 150mg[64] from 12 weeks' gestation, and may be more effective if taken at night[65]. In some circumstances this may not be appropriate and lower doses (60-75mg) may be used (for example, women with hepatic or renal disease). Predictive algorithms that combine a variety of risk factors to identify women at risk for preeclampsia are available. Providers should use an algorithm such as the one included in Table 1 which is based on the NICE pregnancy hypertension guideline[66]. Any other algorithm must be agreed with local commissioners (CCGs) following advice from the provider's Clinical Network.

* Although this use is common in UK clinical practice, at the time of publication (June 2019), aspirin did not have a UK marketing authorisation for this indication. Community pharmacies cannot legally sell aspirin as a Pharmacy Only Medicine for prevention of pre-eclampsia in pregnancy in England. Aspirin for this indication must be prescribed. The prescriber should see the Summary of Product Characteristics for the manufacturer's advice on use in pregnancy. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information.

Table 1: Clinical risk assessment for preeclampsia as indications for aspirin in pregnancy

Risk level	Risk factors	Recommendation
High	• Hypertensive disease during a previous pregnancy • Chronic kidney disease • Autoimmune disease such as systemic lupus erythematosus or antiphospholipid syndrome • Type 1 or type 2 diabetes • Chronic hypertension • Placental histology confirming placental dysfunction in a previous pregnancy	Recommend low dosage aspirin if the woman has ≥1 of these high risk factors
Moderate	• First pregnancy • Are 40 years or older at booking • Pregnancy interval of more than 10 years • Body mass index (BMI) of 35kg/m² or more at first visit • Family history of preeclampsia in a first degree relative • Multiple pregnancy	Consider aspirin if the woman has two or more

There are a few absolute contraindications to aspirin therapy[67]. Women with a history of aspirin allergy (for example, urticaria) or hypersensitivity to other salicylates are at risk of anaphylaxis and should not receive aspirin. There is significant cross-sensitivity between aspirin and other nonsteroidal (NSAIDS) drugs, thus aspirin is contraindicated in women with known hypersensitivity to NSAIDs. Relative contraindications to aspirin include a history of gastrointestinal bleeding, active peptic ulcer disease, other sources of gastrointestinal or genitourinary bleeding, and severe hepatic dysfunction. The decision to continue aspirin in the presence of obstetric bleeding or risk factors for obstetric bleeding should be considered on a case-by-case basis.

Appendix D: Risk assessment, surveillance pathway and management of FGR

This appendix describes a risk assessment and surveillance pathway for women at increased risk of FGR and a management pathway when a fetus has been found to be growth restricted, recognising that prior to 34 weeks this will require input from fetal medicine services. It has been designed to optimise effectiveness and minimise the scan burden on providers and recognise the potential harm caused by increased intervention in infants at only marginal increased risk of stillbirth. Providers may wish to instead use the RCOG Green-Top Guideline[68], Growth Assessment Protocol (GAP) or another pathway which has been agreed with local commissioners (CCG) following advice from the provider's Clinical Network as to whether the variation is acceptable.

Definition of FGR within SBLCBv2

FGR is difficult to diagnose representing those fetuses that have failed to reach their growth potential. A recent Delphi consensus based definition has been suggested for use in research for both early (defined in the Delphi consensus as <32 weeks) and late onset FGR[69], but this has not yet been shown to be useful in improving outcomes through intervention. Diagnosing FGR in a current pregnancy and risk assessing whether FGR existed in a previous pregnancy also present different challenges.

The following definitions are suggested to address these challenges and remain practical for the majority of providers. It highlights that absent or reversed end diastolic flow in the umbilical artery is a feature of early onset FGR, but importantly that absence of this feature (for example, a normal umbilical artery Doppler) after 32 weeks of gestation does not mean that the fetus is not growth restricted nor that there is no evidence of fetal compromise.

Definition of FGR in a previous pregnancy as a risk factor: defined as any of the following:

- birthweight <3rd centile
- early onset placental dysfunction necessitating delivery <34 weeks
- birthweight <10th centile with evidence of placental dysfunction as defined below for current pregnancy.

Definition of FGR in a current pregnancy: defined as either of the following:

- EFW or abdominal circumference (AC) <3rd centile
- EFW or AC <10th centile with evidence of placental dysfunction (either):
    - Abnormal uterine artery Doppler (mean pulsatility index >95th centile[70]) earlier in pregnancy (20 – 24 weeks) and/or
    - Abnormal umbilical artery Doppler (absent or reversed end diastolic flow or pulsatility index >95th centile).

Suboptimal fetal growth:

- Increase in EFW <280g over 14 days (20g per day) from 34 weeks [71 72].

Risk assessment and screening

Early onset FGR is rare (~0.5%[73]). The vast majority of cases are associated with abnormal uterine artery Doppler indices or already present estimated fetal weight (EFW) <10th centile in the early third trimester. Thus, uterine artery Doppler can be used in the second trimester (20 – 24 weeks alongside routine fetal anomaly scan) to further determine the risk of placental dysfunction and therefore risk of hypertensive disorders or early onset FGR for women at high risk. For women with a normal uterine artery Doppler pulsatility index (mean ≤95th centile) the risk of these disorders is low and thus serial scanning for fetal biometry can be commenced in the third trimester.

Women at moderate risk of FGR do not require uterine artery Doppler assessment but are still at risk of later onset FGR so require serial ultrasound assessment of fetal growth at 32 weeks.

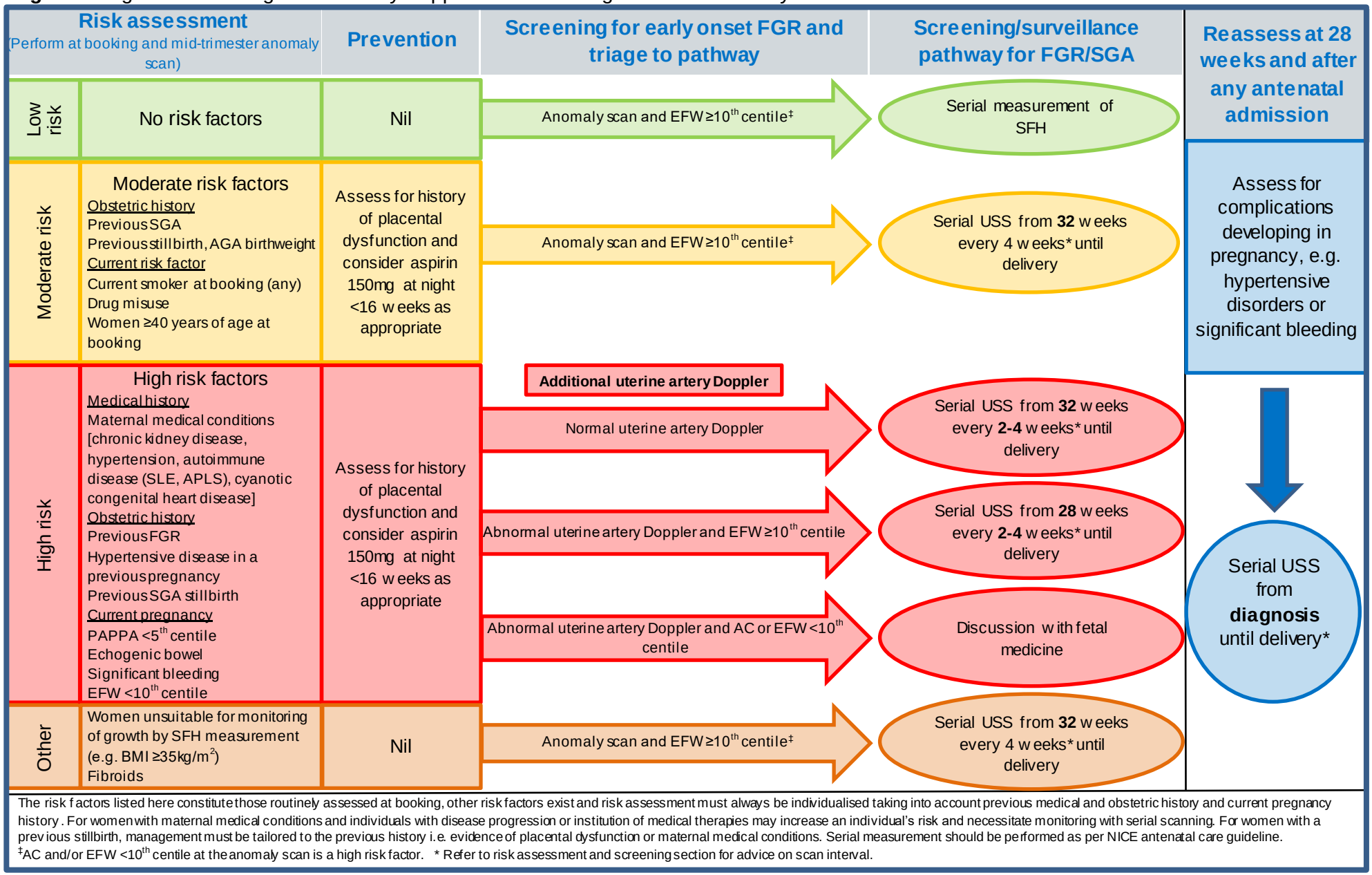
Ongoing surveillance for fetal growth should be performed at intervals of at least 14 days, with optimum assessment for growth velocity being 21 – 28 days. For the vast majority of pregnancies in the moderate risk category or in those unsuitable for SFH measurements, an interval of four weeks is appropriate. For women in the high risk category the scan interval should be confirmed following the first assessment for fetal growth.

Therefore, Trusts may decide to invest in training ultrasonographers to perform uterine artery Doppler alongside the fetal anomaly scan with the opportunity to reduce the number of serial scans for growth that a woman would require during the pregnancy.

It should be noted that there are reference ranges available for uterine artery Doppler PI throughout pregnancy[74] and thus while offering at the time of the fetal anomaly scan is appropriate (for resource use and convenience), the measurement may be performed at any time during pregnancy[75].

Figure 6 provides an algorithm for using uterine artery Doppler as a screening tool for risk of early onset FGR.

Figure 6: Algorithm for using uterine artery Doppler as a screening tool for risk of early onset FGR



The risk factors listed here constitute those routinely assessed at booking, other risk factors exist and risk assessment must always be individualised taking into account previous medical and obstetric history and current pregnancy history. For women with maternal medical conditions and individuals with disease progression or institution of medical therapies may increase an individual's risk and necessitate monitoring with serial scanning. For women with a previous stillbirth, management must be tailored to the previous history i.e. evidence of placental dysfunction or maternal medical conditions. Serial measurement should be performed as per NICE antenatal care guideline.
‡AC and/or EFW <10th centile at the anomaly scan is a high risk factor. * Refer to risk assessment and screening section for advice on scan interval.

Management of FGR

The RCOG[76] provides detailed recommendations for the monitoring of SGA when EFW is <10th centile and Trusts should either follow this guidance or a similar protocol which has been agreed with local commissioners (CCGs) following advice from the provider's Clinical Network as to whether the variation is acceptable.

This appendix describes further recommendations for management of fetuses with FGR supported by randomised controlled trial evidence[77] and highlights important features for management:

- Absent or reversed end diastolic flow in the umbilical artery is a feature of FGR prior to 32 weeks.
- Ductus venosus (DV) Doppler is less predictive after 32 weeks in the management of the FGR fetus.
- A normal umbilical artery Doppler after 32 weeks of gestation does not mean that the fetus is not growth restricted, nor that there is no evidence of fetal compromise.
- After 34 weeks providers with capacity may wish to use assessment of Middle Cerebral Artery (MCA) Doppler pulsatility indices (PI) to help identify and act upon potential fetal compromise in later pregnancy.

Thus, prior to 34 weeks, management of the FGR fetus will require network specialist fetal medicine input to determine the most appropriate monitoring for fetal wellbeing and timing of delivery where fetal compromise is demonstrated.

Trusts caring for such women should have access to personnel who can carry out DV Doppler assessment and computerised CTG. If Trusts do not have access to DV Doppler or access that is intermittent then computerised CTG must be provided for monitoring and a pre-established referral pathway should be present to enable assessment of women by a specialist fetal medicine service within 72 hours.

For fetuses with an EFW <3rd centile in later pregnancy delivery should be initiated at 37+0 weeks' gestation (or earlier if there are other concerning features present depending on the protocol).

In fetuses with an EFW between the 3rd and 10th centile, other features must be present for delivery to be recommended prior to 39 weeks, as described above, for the definition of FGR (for example, fetal [based on Doppler assessment] or maternal [maternal medical conditions or concerns regarding fetal movements]). If FGR cannot be excluded, then delivery after 37 weeks should be discussed with the mother and an ongoing management plan individualised.

For all fetuses with an EFW or AC <10th centile where FGR has been excluded, delivery or the initiation of induction of labour should be offered at 39+0 weeks after discussion with the mother.

For women who decline induction of labour or delivery after 39+0 weeks, counselling must include a discussion regarding evidence that there is no increase in risk for the baby or for the mother from delivery/induction at this gestation and that there is no evidence to determine how fetuses with SGA/FGR should be monitored if pregnancy continues.

Appendix E: Risk assessment at the onset of labour

This guidance is based on NICE intrapartum care for healthy women and babies guidance. Any variations of this pathway should be agreed with local commissioners (CCGs) following advice from the provider's Clinical Network.

Carry out an initial assessment to determine if midwifery led care in any setting is suitable for the woman, irrespective of any previous plan. The assessment should comprise the following:

- Observations of the woman:
  - Review the antenatal notes (including all antenatal screening results) and discuss these with the woman.
  - Ask her about the length, strength and frequency of her contractions.
  - Ask her about any pain she is experiencing and discuss her options for pain relief.
  - Record her pulse, blood pressure and temperature, and carry out urinalysis.
  - Record if she has any vaginal loss.
- Observations of the unborn baby:
  - Ask the woman about the baby's movements in the last 24 hours.
  - Palpate the women's abdomen to determine the fundal height, the baby's lie, presentation, position, engagement of the presenting part, and frequency and duration of contractions.
- Auscultate the fetal heart rate for a minimum of 1 minute immediately after a contraction. Palpate the woman's pulse to differentiate between the heartbeats of the woman and baby.

In addition:

- If there is uncertainty about whether the woman is in established labour, a vaginal examination may be helpful after a period of assessment, but is not always necessary.
- If the woman appears to be in established labour, offer a vaginal examination.

Appendix F: Risk assessment, surveillance pathway and management of women at risk of preterm birth

This appendix describes a risk assessment, surveillance and management pathway for women at risk of preterm birth. It has been designed with reference to NICE guidance[78] and the UK Preterm Clinical Network guidance. It does not address administration of corticosteroids, magnesium sulphate and use of tocolytics for which there is evidence based guidance[79] [80] [81].

Prevention

All women should be screened at booking for risk factors for preterm birth. This screening should include modification of population based risk factors acknowledging that the majority of preterm deliveries occur in women not appropriate for care in a preterm prevention clinic.

1. **Smoking cessation**: Smoking doubles the risk of preterm delivery[82] and therefore all women should be asked about smoking, and cessation advice and/or referral should be provided. Women who have experienced a previous preterm birth, who stopped smoking early in the pregnancy, modify their risk back to that of a non-smoker. If smoking cessation is delayed until the third trimester this modifiable benefit is lost. The importance of promoting smoking cessation is therefore one of the most important prevention strategies to implement (see Element 1 for more detail).

2. **Maternal age**: Young women (<18 years) have an increased risk of preterm birth[83]. Appropriate referral to teenage pregnancy teams should be offered to provide adequate support and advice throughout the pregnancy and may help prevent preterm birth.

3. **Domestic violence**: Women experiencing domestic violence and/or other social pressure should be directly counselled and referred for specific support through local pathways.

4. **Urinary tract infection (UTI)**: As indicated in NICE guidance[84], midstream urine sample (MSU) should be taken and sent for culture and sensitivity in all pregnant women at booking. Culture positive samples, even in symptom-free women (asymptomatic bacteriuria), should be promptly treated. Following any positive culture and treatment, a repeat MSU to confirm clearance is recommended. Those who have a recurrent episode require review in secondary care.

5. **Vaginal infection**: Pathogens such as *Neisseria Gonorrhoeae* and *Chlamydia Trachomatis* are associated with preterm birth, and screening should be offered to at-risk women. In particular, healthcare professionals should inform pregnant women under the age of 25 years about the high prevalence of chlamydial infection in their age group, and give details of their local National Chlamydia Screening Programme.

   The role of organisms found in bacterial vaginosis (BV) remains controversial; the

presence of BV is linked with preterm birth, but the varying methods used to ascertain its presence, and the timing and means of treatment in several studies have meant that no consensus currently exists as to its screening and treatment in at-risk women. The presence of Group B Streptococci in a vaginal swab is not an indication to treat until in labour unless also isolated from a midstream urine specimen.

Risk assessment

A further risk assessment should be performed identifying a high risk group of women who require screening and management in a preterm birth prevention clinic. This screening should take place at the booking appointment with referral by 12 weeks.

Table 2 is a suggested risk assessment and management tool.

Table 2: Risk assessment and management tool for women at risk of preterm birth

Risk factor	Pathway
High risk • Previous preterm birth or mid-trimester loss (16 to 34 weeks gestation). • Previous preterm prelabour rupture of membranes <34/40. • Previous use of cervical cerclage. • Known uterine variant (i.e. unicornuate, bicornuate uterus or uterine septum). • Intrauterine adhesions (Ashermann's syndrome). • History of trachelectomy (for cervical cancer).	**Surveillance** 1. Referral to local or tertiary Preterm Prevention (PP) clinic by 12 weeks. 2. Further risk assessment based on history +/- examination as appropriate in secondary care with identification of women needing referral to tertiary services. 3. All women to be offered transvaginal cervix scanning as a secondary screening test to more accurately quantify risk every 2-4 weeks between 16 and 24 weeks. 4. Additional use of quantitative fetal fibronectin in asymptomatic women may be considered where centres have this expertise. **Management** 5. Interventions should be offered to women as appropriate, based on either history or additional screening tests by clinicians able to discuss the relevant risks and benefits according to up to date evidence and relevant guidance, for example, UK Preterm Clinical Network guidance and NICE[85] guidance. These interventions should include cervical cerclage, pessary and progesterone as appropriate.

Intermediate risk • Previous delivery by caesarean section at full dilatation. • History of significant cervical excisional event i.e. LLETZ where >10mm depth removed, or >1 LLETZ procedure carried out or cone biopsy (knife or laser, typically carried out under general anaesthetic).	**Surveillance** 1) Refer to preterm birth prevention clinic by 12 weeks. 2) Further risk assessment based on history +/- examination as appropriate in secondary care with discussion of option of additional screening tests, including: a) A single transvaginal cervix scan between 18-22 weeks as a minimum. b) Additional use of quantitative fetal fibronectin in asymptomatic women can be considered where centres have this expertise **Management** 3) Interventions should be discussed with women as appropriate based on either history or additional screening tests by clinicians able to discuss the relevant risks and benefits according to up to date evidence and relevant guidance. These interventions should include cervical cerclage, pessary and progesterone as appropriate. 4) Women at intermediate risk should be reassessed at 24 weeks for consideration of transfer back to a low risk pathway.

Screening tests

Women with any of the additional high risk factors should be reviewed in a preterm birth prevention clinic where a detailed history should be obtained and an individualised plan made. Additional tests for ascertaining risk should be offered; as a minimum this should include transvaginal cervix scan between 18 and 22 weeks. Some providers may wish to schedule this as part of the anomaly scan. Additional cervical length scans should be performed at the discretion of the lead clinician and are likely to be more frequent than the minimum outlined above.

The addition of a second screening tool, quantitative fetal fibronectin, is currently being evaluated in symptomatic women in clinical studies. In asymptomatic women, this additional tool may be used from 18 weeks to ascertain risk of second trimester miscarriage or preterm birth in conjunction with cervical length measurement and support discussions of potential interventions with women. It can also be used in high risk women in late second/early third trimester to determine timing of preparation for preterm birth, for example, administration of steroids and magnesium sulphate. In current clinical practice the use of additional screening tools in asymptomatic women should be at the discretion of the lead clinicians and where there is expertise and clear guidance for use.

The use of other near-patient tests, such as placental alpha macroglobulin-1 (PAMG-1,

PartoSure) and insulin-like growth factor binding protein-1 (IGFBP-1, Actim Partus), has recently been examined by NICE and these are currently not recommended for routine use outside research settings[86].

Prevention

After assessment within the preterm birth prevention clinic, women on the basis of history and/or additional screening should be offered treatment to prevent second trimester miscarriage and preterm birth.

Several interventions have been assessed for women at high risk of preterm birth: cervical cerclage, progesterone and pessaries. Cervical cerclage is an established procedure, progesterone is recommended in certain situations by NICE, and there are randomised trials suggesting benefit in the use of Arabin pessaries in at-risk women[87]. At present the evidence base cannot determine precisely in which women, and in what circumstances, each intervention will be most effective. Care must, therefore, always be individualised, taking into account the women's wishes, and following a discussion with a clinician able to discuss the potential risks and benefits of each intervention. The following evidence and guidance should be discussed:

- **Women with a history of spontaneous preterm birth or late miscarriage (16-34 weeks)**:
  - Offer a history-indicated (planned, prophylactic, elective) cervical cerclage or transvaginal ultrasound surveillance of the cervix within the second trimester.
  - History-indicated cerclage should be placed by the end of the first trimester where possible, however often it may be prudent to wait until after the dating scan and aneuploidy screening has been performed, so that significant fetal malformations can be excluded.
  - For women having ultrasound surveillance, discuss intervention when cervix is <25mm, either cervical cerclage[88], Arabin pessary or prophylactic progesterone (vaginal or intramuscular).
- **Women with a previous failed transvaginal suture**:
  - The circumstances of the failed suture and other clinical factors should be considered prior to placement, and appropriately experienced clinicians should be involved in the decision making and surgery. High vaginal or transabdominal cerclage may be considered. Transabdominal placement during pregnancy should be undertaken prior to 14 weeks. Guidelines regarding laparoscopic placement have previously been published by NICE[89].
- **Women with no history of spontaneous preterm birth or midtrimester loss in whom a transvaginal cervix scan has been carried out between 16+0 and 26+0 weeks of pregnancy and the cervix is less than 25mm***:*
  - Care for these women should be individualised. Counselling should include options of continued surveillance or intervention with clinicians able to discuss the relevant risks and benefits according to up to date evidence and relevant guidance. These interventions should include cervical cerclage, pessary and progesterone as appropriate.

Women with an intervention (cerclage, pessary or progesterone) should remain under the care of the preterm birth prevention clinic until delivery. Women undergoing transvaginal cervix scanning screening should continue this until 24 weeks, when this screening pathway is complete and if no intervention is recommended, women may be transferred to

routine pathways of care. Midwifery-led care is appropriate if no other additional risk factors are identified.

Abbreviations

AC – Abdominal circumference
BAME – Black, Asian and Minority Ethnic
CCG – Clinical Commissioning Group
CI – Confidence interval
CO – Carbon monoxide
CTG – Cardiotocograph
DV – Ductus venosus
EFW – Estimated fetal weight
FGR – Fetal growth restriction
FHR – Fetal heart rate
HCP – Healthcare professional
HEE – Health Education England
IA – Intermittent auscultation
LLETZ - Large loop excision of the transformation zone
LTP – NHS Long Term Plan
LMS – Local maternity system
MCA – Middle Cerebral Artery
MIS – Maternity information system
MSDS – Maternity services data set
MSU – Midstream urine
MSW – Maternity Support Worker
NSAIDS – Nonsteroidal anti-inflammatory drugs
NHS – National Health Service
NICE – National Institute for Health and Care Excellence
ODN – Operational delivery networks
ONS – Office for National Statistics
PI – Pulsatility index
PMRT – Perinatal mortality review tool
PHE – Public Health England
RCM – Royal College of Midwives
RCOG – Royal College of Obstetricians and Gynaecologists
RFM – Reduced fetal movements
SBLCB – Saving Babies' Lives Care Bundle
SEN – Special educational needs
SFH – Symphysis fundal height
SGA – Small for gestational age
SIDS – Sudden infant death syndrome
TVCS – Transvaginal cervix scanning
VBA – Very brief advice
WHO – World Health Organisation

References

1. Widdows K., Roberts SA., Camacho EM., Heazell AEP. (2018). *Evaluating the implementation of Saving Babies' Lives care bundle in NHS Trusts in England: stillbirth rates, service outcomes and costs*. Manchester: Maternal and Fetal Health Research Centre, University of Manchester.
2. Widdows K., Roberts SA., Camacho EM., Heazell AEP. (2018). *Evaluating the implementation of Saving Babies' Lives care bundle in NHS Trusts in England: stillbirth rates, service outcomes and costs*. Manchester: Maternal and Fetal Health Research Centre, University of Manchester.
3. Department for Health (2015). *New ambition to halve rate of stillbirths and infant deaths* [press release], 13 November.
4. NHS England (2016). *Saving Babies' Lives: a care bundle for reducing stillbirth*. Available from: https://www.england.nhs.uk/wp-content/uploads/2016/03/saving-babies-lives-car-bundl.pdf [Information accessed 25 January 2019].
5. Department of Health and Social Care (2017). *Safer Maternity Care: Progress and Next Steps*. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/662969/Safer_maternity_care_-_progress_and_next_steps.pdf [Information accessed 25 January 2019].
6. Office for National Statistics. (2018). *Births in England and Wales, 2017*. London: Office for National Statistics.
7. Draper ES., Gallimore ID., Kurinczuk JJ., Smith PW., Boby T., Smith LK., Manktelow BN., on behalf of the MBRRACE-UK Collaboration (2018). *MBRRACE-UK Perinatal Mortality Surveillance Report, UK Perinatal Deaths for Births from January to December 2016*. Leicester: The Infant Mortality and Morbidity Studies, Department of Health Sciences, University of Leicester.
8. McParland P LC., Latham J. on behalf of MBRRACE-UK. *Diagnosis of the stillbirth and intrapartum care*. In Draper ES, Kurinczuk JJ, Kenyon S (Eds.) on behalf of MBRRACE-UK. (2015). *MBRRACE-UK Perinatal Confidential Enquiry: Term, singleton, normally formed, antepartum stillbirth*. Leicester: The Infant Mortality and Morbidity Studies, Department of Health Sciences, University of Leicester:36-42.
9. Widdows K., Roberts SA., Camacho EM., Heazell AEP. (2018). *Evaluating the implementation of Saving Babies' Lives care bundle in NHS Trusts in England: stillbirth rates, service outcomes and costs*. Manchester: Maternal and Fetal Health Research Centre, University of Manchester.
10. Tommy's (2016). Leaflet: *Feeling your baby move is a sign that they are well*. Available from: https://www.tommys.org/sites/default/files/RFM-Infographic_0.pdf [Information accessed 25 January 2019].
11. Widdows K., Roberts SA., Camacho EM., Heazell AEP. (2018). *Evaluating the implementation of Saving Babies' Lives care bundle in NHS Trusts in England: stillbirth rates, service outcomes and costs*. Manchester: Maternal and Fetal Health Research Centre, University of Manchester.
12. NHS England (2016). *National Maternity Review: Better Births – Improving outcomes of maternity services in England – A Five Year Forward View for maternity care*. Available from: https://www.england.nhs.uk/publication/better-

births-improving-outcomes-of-maternity-services-in-england-a-five-year-forward-view-for-maternity-care/ [Information accessed 25 January 2019].
13. NHS England (2016). *National Maternity Review: Better Births – Improving outcomes of maternity services in England – A Five Year Forward View for maternity care*. Available from: https://www.england.nhs.uk/publication/better-births-improving-outcomes-of-maternity-services-in-england-a-five-year-forward-view-for-maternity-care/ [Information accessed 25 January 2019].
14. Sandall, J., Soltani, H., Gates, S., Shennan, A. & Devane, D. (2016). *Midwife-led continuity models versus other models of care for childbearing women*. Cochrane Database of Systematic Reviews, Issue 4. Art. No.: CD004667. DOI: 10.1002/14651858.CD004667.pub5. .
15. Homer, C., Leap, N., Edwards, N. and Sandall, J. (2017). *Midwifery continuity of carer in an area of high socio-economic disadvantage in London: A retrospective analysis of Albany Midwifery Practice outcomes using routine data (1997–2009)*. Midwifery. 48, 1-10. Available from: https://doi.org/10.1016/j.midw.2017.02.009 [Information accessed 25 January 2019].
16. NHS England (2017). *Implementing Better Births: Continuity of Carer.* Available from: https://www.england.nhs.uk/publication/implementing-better-births-continuity-of-carer/ [Information accessed 30 January 2019].
17. MacKay DF, Smith GCS, Dobbie R, Pell JP (2010). *Gestational Age at Delivery and Special Educational Need: Retrospective Cohort Study of 407,503 Schoolchildren*. PLoS Med 7(6): e1000289. Available from: https://doi.org/10.1371/journal.pmed.1000289 [Information accessed 25 January 2019].
18. MacKay DF, Smith GCS, Dobbie R, Pell JP (2010). *Gestational Age at Delivery and Special Educational Need: Retrospective Cohort Study of 407,503 Schoolchildren*. PLoS Med 7(6): e1000289. Available from: https://doi.org/10.1371/journal.pmed.1000289 [Information accessed 25 January 2019].
19. MacKay DF, Smith GCS, Dobbie R, Pell JP (2010). *Gestational Age at Delivery and Special Educational Need: Retrospective Cohort Study of 407,503 Schoolchildren*. PLoS Med 7(6): e1000289. Available from: https://doi.org/10.1371/journal.pmed.1000289 [Information accessed 25 January 2019].
20. National Institute for Health and Care Excellence (2008). *Inducing labour (NICE Guideline 70)*. Available from: https://www.nice.org.uk/guidance/cg70 [Information accessed 25 January 2019].
21. Grobman WA. (2018). *A randomized trial of elective induction of labor at 39 weeks compared with expectant management of low-risk nulliparous women*. American Journey of Obstetrics and Gynecology; 218: S601.
22. National Institute for Health and Care Excellence (2008). *Inducing labour (NICE Guideline 70)*. Available from: https://www.nice.org.uk/guidance/cg70 [Information accessed 25 January 2019].
23. Grobman WA. (2018). *A randomized trial of elective induction of labor at 39 weeks compared with expectant management of low-risk nulliparous women*. American Journey of Obstetrics and Gynecology; 218: S601.
24. Gaffney G., Sellers S., Flavell V., Squier M., Johnson A. (1994). *Case-control study of intrapartum care, cerebral palsy, and perinatal death*. BMJ; 308: 743-750.

25. Marufu TC., Ahankari A., Coleman T. and Lewis S. (2015). *Maternal smoking and the risk of still birth: systematic review and meta-analysis*. BMC Public Health: 15:239. doi:10.1186/s12889-015-1552-5. Available from: http://www.biomedcentral.com/1471-2458/15/239 [Information accessed 25 January 2019].
26. Royal College of Physicians (2010). *Passive smoking and children. A report by the Tobacco Advisory Group*. London: RCP.
27. Marufu TC., Ahankari A., Coleman T. and Lewis S. (2015). *Maternal smoking and the risk of still birth: systematic review and meta-analysis*. BMC Public Health: 15:239. doi:10.1186/s12889-015-1552-5. Available from: http://www.biomedcentral.com/1471-2458/15/239 [Information accessed 25 January 2019].
28. National Institute for Health and Care Excellence (2018). *Smoking: stopping in pregnancy and after childbirth (Public Health Guideline 26)*. Available from: https://www.nice.org.uk/guidance/ph26 [Information accessed 25 January 2019].
29. Bunch KJ., Allin B., Jolly M., Hardie T. and Knight M. (2018). *Developing a set of consensus indicators to support maternity service quality improvement: using Core Outcome Set methodology including a Delphi process*. BJOG: Nov;125(12):1612-1618. doi: 10.1111/1471-0528.15282.
30. MacKay DF, Smith GCS, Dobbie R, Pell JP (2010). *Gestational Age at Delivery and Special Educational Need: Retrospective Cohort Study of 407,503 Schoolchildren*. PLoS Med 7(6): e1000289. Available from: https://doi.org/10.1371/journal.pmed.1000289 [Information accessed 25 January 2019].
31. Gardosi J, Madurasinghe V, Williams M, Malik A, Francis A. Maternal and fetal risk factors for stillbirth: population based study. BMJ. 2013;346(January): f108. Available from: http://www.bmj.com/content/346/bmj.f108 [Information accessed 30 January 2019].
32. Blencowe H, Cousens S, Jassir FB, Say L, Chou D, Mathers C, Hogan D, Shiekh S, Qureshi ZU, You D, Lawn JE (2016). *National regional and worldwide estimates of stillbirth rates in 2015, with trends from 2000: a systematic analysis*. The Lancet Global Health 2016;4(2):e98-e108.
33. Stock SJ, Ferguson E, Duffy A, Ford I, Chalmers J, Norman JE (2012). *Outcomes of elective induction of labour compared with expectant management: population based study*. BMJ: 344: e2838.
34. Stock SJ, Ferguson E, Duffy A, Ford I, Chalmers J, Norman JE (2012). *Outcomes of elective induction of labour compared with expectant management: population based study*. BMJ: 344: e2838.
35. Stock SJ, Ferguson E, Duffy A, Ford I, Chalmers J, Norman JE (2012). *Outcomes of elective induction of labour compared with expectant management: population based study*. BMJ: 344: e2838.
36. Royal College of Obstetricians and Gynaecologists (2013). *RCOG Green-Top Guideline 31: The Investigation and Management of the Small for Gestational Age Fetus*. London: RCOG. Available from: https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg31/ [Information accessed 30 January 2019].
37. Royal College of Obstetricians and Gynaecologists (2011) *RCOG Green-Top Guideline 57: Reduced Fetal Movement*. London: RCOG. Available from:

https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg57/ [Information accessed 30 January 2019].
38. Confidential Enquiry into Stillbirths and Deaths in Infancy (1997). *4th Annual Report, 1 January–31 December 1995*. London: Maternal and Child Health Research Consortium.
39. Stacey T, Thompson JM, Mitchell EA, Zuccollo J and McCowan LM (2011). *Maternal perception of fetal activity and late stillbirth risk: findings from the Auckland Stillbirth Study*. Birth: Dec;38(4):311-6.
40. Heazell AEP, Budd J, Minglan L, Cronin R, Bradford B, McCowan LME, Mitchell EA, Stacey T, Martin B, Roberts D and Thompson JMD (2018). *Alterations in maternally perceived fetal movement and their association with late stillbirth: findings from the Midland and North of England stillbirth case-control study*. BMJ Open: Jul 6;8(7): e020031.
41. O'Sullivan O, Stephen G, Martindale E and Heazell AE (2009). *Predicting Poor Perinatal Outcome in Women who Present with Decreased Fetal Movements - A Preliminary Study*. Journal of Obstetrics and Gynaecology: 29(8):705-10.
42. Scala C, Bhide A, Familiari A, Pagani G, Khalil A, Papageorghiou A, Thilaganathan B. (2015). *Number of episodes of reduced fetal movement at term: association with adverse perinatal outcome*. American Journal of Obstetrics and Gynaecology: 213(5):678 e1-6. doi: 10.1016/j.ajog.2015.07.015.
43. Heazell AEP, Budd J, Minglan L, Cronin R, Bradford B, McCowan LME, Mitchell EA, Stacey T, Martin B, Roberts D and Thompson JMD (2018). *Alterations in maternally perceived fetal movement and their association with late stillbirth: findings from the Midland and North of England stillbirth case-control study*. BMJ Open: Jul 6;8(7): e020031.
44. Scala C, Bhide A, Familiari A, Pagani G, Khalil A, Papageorghiou A, Thilaganathan B. (2015). *Number of episodes of reduced fetal movement at term: association with adverse perinatal outcome*. American Journal of Obstetrics and Gynaecology: 213(5):678 e1-6. doi: 10.1016/j.ajog.2015.07.015.
45. Norman J, Heazell AEP, Rodriguez A, Weir CJ, Stock SJE and Calderwood CJ (2018). *Awareness of fetal movements and care package to reduce fetal mortality (AFFIRM): a stepped wedge, cluster-randomised trial*. Lancet: Sep 27. pii: S0140-6736(18)31543-5. doi: 10.1016/S0140-6736(18)31543-5.
46. Norman J, Heazell AEP, Rodriguez A, Weir CJ, Stock SJE and Calderwood CJ (2018). *Awareness of fetal movements and care package to reduce fetal mortality (AFFIRM): a stepped wedge, cluster-randomised trial*. Lancet: Sep 27. pii: S0140-6736(18)31543-5. doi: 10.1016/S0140-6736(18)31543-5.
47. National Institute for Health and Care Excellence (2017). *Intrapartum care for healthy women and babies (Clinical Guideline 190)*. Available from: https://www.nice.org.uk/guidance/cg190 [Information accessed 11 December 2018].
48. Gale C, Statnikov Y, Jawad S, Uthaya SN, Modi N (Brain Injuries expert working group) (2018). *Neonatal brain injuries in England: population-based incidence derived from routinely recorded clinical data held in the National Neonatal Research Database*. Archives of Disease in Childhood Fetal and Neonatal Edition: Jul;103(4): F301-F306.
49. Alfirevic Z, Devane D and Gyte GML (2013). *Continuous Cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour (Review)*. The Cochrane Collaboration. John Wiley & Sons Ltd.
50. Murphy KW, Johnson P, Moorcraft P, Pattinson R, Russel V, Turnball A (1990). *Birth asphyxia and the intrapartum cardiotocograph*. British Journal of Obstetrics and Gynaecology: 97: 470-479.

51. Royal College of Obstetricians and Gynaecologists (2017). *Each Baby Counts: 2015 Full Report*. London: RCOG.
52. Draper ES, Kurinczuk JJ, Kenyon S (Eds.) on behalf of MBRRACE-UK (2017). *MBRRACE-UK 2017 Perinatal Confidential Enquiry: Term, singleton, intrapartum stillbirth and intrapartum-related neonatal death*. Leicester: The Infant Mortality and Morbidity Studies, Department of Health Sciences, University of Leicester: Leicester.
53. National Institute for Health and Care Excellence (2017). *Intrapartum care for healthy women and babies (Clinical Guideline 190)*. Available from: https://www.nice.org.uk/guidance/cg190 [Information accessed 11 December 2018].
54. Schneeberger C, Geerlings SE, Middleton P and Crowther CA (2015). *Interventions for preventing recurrent urinary tract infection during pregnancy*. Cochrane Database Syst Rev: Jul 26;(7):CD009279. doi: 10.1002/14651858.CD009279.pub3.
55. National Institute for Health and Care Excellence (2015). *Preterm labour and birth (NICE Guideline 25)*. Available from: https://www.nice.org.uk/guidance/ng25 [Information accessed 11 December 2018].
56. National Institute for Health and Care Excellence (2015). *Preterm Labour and birth (NICE Guideline 25)*. Available from: https://www.nice.org.uk/guidance/ng25 [Information accessed 11 December 2018].
57. Saigal S, Doyle LW (2008). *An overview of mortality and sequelae of preterm birth from infancy to adulthood*. Lancet: 371(9608): 261-9.
58. National Institute for Health and Care Excellence (2015). *Preterm Labour and birth (NICE Guideline 25)*. Available from: https://www.nice.org.uk/guidance/ng25 [Information accessed 11 December 2018].
59. Office for National Statistics, (2013). *Pregnancy and ethnic factors influencing births and infant mortality*. London: Office for National Statistics.
60. National Institute for Health and Care Excellence (2015). *Preterm labour and birth (NICE Guideline 25)*. Available from: https://www.nice.org.uk/guidance/ng25 [Information accessed 11 December 2018].
61. National Institute for Health and Care Excellence (2018). *Biomarker tests to help diagnose preterm labour in women with intact membranes (Diagnostics guidance 33)*. Available from: https://www.nice.org.uk/guidance/dg33 [Information accessed 11 December 2018].
62. Draper ES., Gallimore ID., Kurinczuk JJ., Smith PW., Boby T., Smith LK., Manktelow BN., on behalf of the MBRRACE-UK Collaboration (2018). *MBRRACE-UK Perinatal Mortality Surveillance Report, UK Perinatal Deaths for Births from January to December 2016*. Leicester: The Infant Mortality and Morbidity Studies, Department of Health Sciences, University of Leicester.
63. National Institute for Health and Care Excellence (2011). *Hypertension in pregnancy: diagnosis and management (Clinical Guideline 107)*. Available from: https://www.nice.org.uk/guidance/cg107 [Information accessed 11 December 2018].
64. Rolnik DL, Wright D, Poon LC, O'Gorman N, Syngelaki A, de Paco Matallana C, Akolekar R, Cicero S, Janga D, Singh M, Molina FS, Persico N, Jani JC, Plasencia W, Papaioannou G, Tenenbaum-Gavish K, Meiri H, Gizurarson S,

Maclagan K, Nicolaides KH (2017). *Aspirin versus Placebo in Pregnancies at High Risk for Preterm Preeclampsia*. New England Journal of Medicine, 377(7):613-622.

65. Ayala DE, Ucieda R and Hermida RC (2012). *Chronotherapy with Low-Dose Aspirin for Prevention of Complications in Pregnancy*. Chronobiology International, 30:1-2, 260-279.
66. National Institute for Health and Care Excellence (2011). *Hypertension in pregnancy: diagnosis and management (Clinical Guideline 107)*. Available from: https://www.nice.org.uk/guidance/cg107 [Information accessed 11 December 2018].
67. Elsevier. *Clinical pharmacology* [database online]. Available at: http://www.clinicalpharmacology.com/. Retrieved March 20, 2018.
68. Royal College of Obstetricians and Gynaecologists (2013). *RCOG Green-Top Guideline 31: The Investigation and Management of the Small for Gestational Age Fetus*. London: RCOG. Available from: https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg31/
69. Gordijn SJ, Beune, IM, Thilaganathan B, Papageorghiou A, Baschat AA, Baker PN, Silver RM, Wynia K and Ganzevoort W (2016). *Consensus definition of fetal growth restriction: a Delphi procedure*. Ultrasound in Obstetrics and Gynecology: 48: 333-339. doi:10.1002/uog.15884.
70. Gómez O, Figueras F, Fernández S, Bennasar M, Martínez JM, Puerto B (2008). *Reference ranges for uterine artery mean pulsatility index at 11-41 weeks of gestation*. Ultrasound in Obstetrics and Gynecology: 32(2):128–32. Available from: http://doi.wiley.com/10.1002/uog.5315 [Information accessed 30 January 2019].
71. Mongelli M, Benzie R, Condous G (2016). *Average fetal weekly weight gain: a novel measure of growth velocity*. Journal of Maternal, Fetal and Neonatal Medicine: 29(4): 676-9.
72. Owen P, Donnet ML, Ogston SA, Christie AD, Howie PW, Patel NB (1996). *Standards to ultrasound fetal growth velocity*. British Journal of Obstetrics and Gynaecology: 103: 60-69.
73. Dall'Asta A, Brunelli V, Prefumo F, Frusca T, Lees CC (2017). *Early onset fetal growth restriction*. Maternal Health Neonatology Perinatology: 3(1):2. Available from: http://mhnpjournal.biomedcentral.com/articles/10.1186/s40748-016-0041-x [Information accessed 30 January 2019].
74. Gómez O, Figueras F, Fernández S, Bennasar M, Martínez JM, Puerto B (2008). *Reference ranges for uterine artery mean pulsatility index at 11-41 weeks of gestation*. Ultrasound in Obstetrics and Gynecology: 32(2):128–32. Available from: http://doi.wiley.com/10.1002/uog.5315 [Information accessed 30 January 2019].
75. Royal College of Obstetricians and Gynaecologists (2013). *RCOG Green-Top Guideline 31: The Investigation and Management of the Small for Gestational Age Fetus*. London: RCOG. Available from: https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg31/ [Information accessed: 30 January 2019].
76. Royal College of Obstetricians and Gynaecologists (2013). *RCOG Green-Top Guideline 31: The Investigation and Management of the Small for Gestational Age Fetus*. London: RCOG. Available from:

https://www.rcog.org.uk/en/guidelines-research-services/guidelines/gtg31/ [Information accessed: 30 January 2019].
77. Lees CC, Marlow, N, Wassenaer-Leemhuis A, Arabin B, Bilardo C, Brezinka C, Calvert S, Derks JB, Diemert A, Duvekot J, Ferrazzi E, Frusca T. Ganzevoort W, Hecher K, Martinelli P, Ostermayer E, Papageorghiou AT, Schlembach D, Schneider K, Rigano S (2015). *2 year neurodevelopmental and intermediate perinatal outcomes in infants with very preterm fetal growth restriction (TRUFFLE): a randomised trial*. The Lancet: 10.1016/S0140-6736(14)62049-3.
78. National Institute for Health and Care Excellence (2015). *Preterm labour and birth (NICE Guideline 25)*. Available from: https://www.nice.org.uk/guidance/ng25 [Information accessed 11 December 2018].
79. Roberts D, Brown J, Medley N, Dalziel SR (2017). *Antenatal corticosteroids for accelerating fetal lung maturation for women at risk of preterm birth*. Cochrane Database of Systematic Reviews: Issue 3. Art. No.: CD004454. DOI: 10.1002/14651858.CD004454.pub3.
80. Crowther CA, McKinlay CJ, Middleton P, Harding JE (2015). *Repeat doses of prenatal corticosteroids for women at risk of preterm birth for improving neonatal health outcomes*. Cochrane Database Systematic Reviews: Jul 5;(7):CD003935. doi: 10.1002/14651858.CD003935.pub4.
81. Chang E (2015). *Preterm birth and the role of neuroprotection*. BMJ: 350: p. g6661.
82. Andres RL, Day MC (2000). *Perinatal complications associated with maternal tobacco use*. Seminars in Neonatology: **5**(3): 231 – 41.
83. UK Preterm Clinical Network (2018). *Reducing preterm birth: Guidelines for Commissioners and Providers*. UK: Preterm Clinical Network.
84. National Institute for Health and Care Excellence (2018). *Urinary tract infection (lower): antimicrobial prescribing (NICE Guideline 109))*. Available from: https://www.nice.org.uk/guidance/ng25 [Information accessed 11 December 2018].
85. National Institute for Health and Care Excellence (2015). *Preterm labour and birth (NICE Guideline 25)*. Available from: https://www.nice.org.uk/guidance/ng109 [Information accessed 06 February 2019].
86. National Institute for Health and Care Excellence (2018). *Biomarker tests to help diagnose preterm labour in women with intact membranes (Diagnostics guidance 33)*. Available from: https://www.nice.org.uk/guidance/dg33 [Information accessed 11 December 2018].
87. UK Preterm Clinical Network (2018). *Reducing preterm birth: Guidelines for Commissioners and Providers*. UK: Preterm Clinical Network.
88. Berghella V. and Mackeen AD (2011). *Cervical length screening with ultrasound-indicated cerclage compared with history-indicated cerclage for prevention of preterm birth: a meta-analysis*. Obstetrics and Gynecology: 118(1): p. 148-55.
89. National Institute for Health and Care Excellence (2007). *Laparoscopic cerclage for prevention of recurrent pregnancy loss due to cervical incompetence (Interventional Procedures Guidance 228)*. Available from: https://www.nice.org.uk/guidance/ipg228 [Information accessed 14 January 2019].