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# Saving Babies' Lives Version Three

A care bundle for reducing perinatal mortality

Version 3.1, July 2023

## SBLCBv3 – Summary of changes

Version	Date	Summary of changes
V3	1 June 2023	Initial publication.
V3.1	6 July 2023	<p>Introduction:</p> <ul style="list-style-type: none"><li>• 'Overseeing implementation' updated to reflect launch of national Implementation Tool.</li></ul> <p>Element 2:</p> <ul style="list-style-type: none"><li>• Update to wording of intervention 2.6.</li><li>• Update to outcome measure 2e.</li><li>• Appendix D: E-cigarette use removed from the moderate risk factor group for additional fetal growth scans. Inclusion of "congenital uterine anomalies" in algorithm for FGR/SGA. Update to definition of FGR in current pregnancy in relation to changes in growth velocity.</li></ul> <p>Element 5:</p> <ul style="list-style-type: none"><li>• Update to process indicators 5b and 5c.</li></ul>

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## Executive summary

The Saving Babies' Lives Care Bundle (SBLCB) provides evidence-based best practice, for providers and commissioners of maternity care across England to reduce perinatal mortality.

The NHS has worked hard towards the national maternity safety ambition, to halve rates of perinatal mortality from 2010 to 2025, and achieve a 20% reduction by 2020 ([DHSC 2017](#)). ONS data showed a 25% reduction in stillbirths in 2020, with the rate rising to 20% in 2021 with the onset of the COVID-19 pandemic. While significant achievements have been made in the past few years, more recent data show there is more to do to achieve the Ambition in 2025.

Version 3 of the Care Bundle (SBLCBv3) has been co-developed with clinical experts including front-line clinicians, Royal Colleges, and professional societies; service users and Maternity Voices Partnerships; and national organisations including charities, the Department of Health and Social Care and a number of arm's length bodies (See Appendix A: Acknowledgements).

Building on the achievements of previous iterations, Version 3 includes a refresh of all existing elements, drawing on national guidance such as from NICE or RCOG Green Top Guidelines, and frontline learning to reduce unwarranted variation where the evidence is insufficient for NICE and RCOG to provide guidance. It also includes a new, additional element on the management of pre-existing diabetes in pregnancy based upon data from The National Pregnancy in Diabetes (NPID) Audit. There are now 6 elements of care:

- **Element 1** focuses on **Reducing smoking in pregnancy** by implementing NHS-funded tobacco dependence treatment services within maternity settings, in line with the [NHS Long Term Plan](#) and [NICE guidance](#). This includes carbon monoxide testing and asking women about their smoking status at the antenatal booking appointment, as appropriate, throughout pregnancy. Women who smoke should receive an opt-out referral for in-house support from a trained Tobacco Dependence Adviser who will offer a personalised care plan and support throughout pregnancy.
- **Element 2** covers **Fetal Growth: Risk assessment, surveillance, and management**. Building on the widespread adoption of mid-trimester uterine artery Doppler screening for early onset fetal growth restriction (FGR) and placental dysfunction, Element 2 seeks to further improve FGR risk assessment by mandating the use of digital blood pressure measurement. It recommends a more nuanced approach to late FGR management to improve the assessment and care of mothers at risk of FGR, and lower rates of iatrogenic late preterm birth.

- **Element 3** is focused on **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.
- **Element 4** promotes **Effective fetal monitoring during labour** through ensuring all staff responsible for monitoring the fetus are competent in the techniques they use (IA and/or CTG) in relation to the clinical situation, use the buddy system, 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, as well as locum, agency or bank staff.
- **Element 5** on **reducing preterm birth** recommends three intervention areas to reduce adverse fetal and neonatal outcomes: improving the **prediction** and **prevention** of preterm birth and **optimising perinatal care** when preterm birth cannot be prevented. All providers are encouraged to draw upon the learning from the existing [BAPM toolkits](#) and the wide range of resources from other successful regional programmes (e.g. PERIPrem resources, MCQIC).
- The new **Element 6** covers the **management of pre-existing diabetes in pregnancy** for women with Type 1 or Type 2 diabetes, as the most significant modifiable risk factor for poor pregnancy outcomes. It recommends multidisciplinary team pathways and an intensified focus on glucose management within maternity settings, in line with the NHS Long Term Plan and [NICE guidance](#). It includes clear documentation of assessing glucose control digitally; using HbA1c to risk stratify and provide additional support/surveillance ([National Diabetes Audit data](#)); and offering consistent access to evidence based Continuous Glucose Monitoring (CGM) technology to improve glucose control (NICE and NHS plan).

In addition to the provision of safe and personalised care, achieving equity and reducing health inequalities is a key aim for all Maternity and Neonatal services and is essential to achieving the National Safety Ambition. Each element in SBLCB v3 has been reviewed to include actions to improve equity, including for babies from Black, Asian and mixed ethnic groups and for those born to mothers living in the most deprived areas, in accordance with the NHS [equity and equality guidance](#).

As part of the [Three Year Delivery Plan for Maternity and Neonatal Services](#), NHS Trusts are responsible for implementing SBLCBv3 by March 2024 and Integrated Care Boards

(ICBs) are responsible for agreeing a local improvement trajectory with providers, along with overseeing, supporting, and challenging local delivery.

SBLCBv3 also sets out a number of important wider principles to consider during implementation. These are not mandated by the care bundle but reflect best practice care and are recommended to be followed in conjunction with the 6 elements.

## Forewords

*ONS data suggests that because of the improvement in the perinatal mortality rate since 2010, at least 900 more babies will return home alive with their families this year. That is a great achievement, and all those who work in Maternity and Neonatal services should be incredibly proud of our progress towards the National Safety Ambition.*

*The recent rise in the perinatal mortality rate is likely to be related to the direct and indirect effects of the COVID-19 pandemic and is a stark reminder that there will always be challenges to reducing stillbirths and neonatal deaths. The trajectory to meet the National Ambition was unlikely to ever be a simple linear progression, particularly as the factors that lead to avoidable perinatal mortality are many and varied. We should all acknowledge that while we have reduced avoidable deaths, there is more to be done.*

*If we are to meet the National ambition for a 50% reduction in the stillbirth and neonatal mortality rates by 2025, we need to address longstanding inequitable outcomes associated with ethnicity and levels of deprivation. While it is clear that some solutions lie beyond the control of the health sector, our services must do everything possible to mitigate against the wider social determinants of health to continue to drive down the perinatal mortality rate.*

*The need to continuously iterate and improve care is why we have developed Version 3 of the care bundle at pace. Clinical experts, professional bodies, charities, service users and national regulators have collaborated to develop national best practice. It is important to remember that the care bundle is just one of a series of interventions to help reduce perinatal mortality and pre-term birth and shouldn't be implemented in isolation. The [Three year delivery plan for maternity and neonatal services](#) describes more broadly how providers should continue to implement best practice care wherever possible and a set of wider principles are included in this version of the Care Bundle.*

*Despite the recent set back in perinatal mortality rates the stillbirth rate was still 19% lower in 2021 than in 2010, and the neonatal mortality rate 30% lower. Thank you to all those who have worked tirelessly to drive improvement in our maternity services, whether they be NHS employees, parents or charities. I am confident that the collaborative approach modelled by the Saving Babies' Lives Care Bundle will continue to deliver improvements in outcomes and reduce the number of parents who have to face the tragedy of perinatal bereavement.*



**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 third version of the Saving Babies' Lives Care Bundle. We continue to support the ambition to achieve a 50% reduction in stillbirths and maternal and neonatal deaths by 2025. The care bundle to date has made a vital contribution to achieving this.*

*The RCM know that 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 continued emphasis on professionals working together and with women to help them to make choices about their care and reduce the risks to their baby.*

*G. Walton.*

**Gill Walton**  
**Chief Executive, Royal College of Midwives**



Royal College  
of Midwives



*As Saving Babies' Lives Care Bundle (SBLCBv3) enters its third edition and its 7<sup>th</sup> year, it continues to innovate and drive forward quality improvement in key areas of maternity care. We welcome the addition of an element covering diabetes in pregnancy and the continued development of the other successful five elements. This version builds on versions 1 and 2, to focus on supporting those caring for pregnant women and to help support women to make choices about their care and reduce unnecessary intervention. Whenever a new guideline is introduced, it will always have limitations and there will be compromises to be made influenced by lack of current evidence and resource requirements to support successful implementation. However, the premise of the bundle is to reduce variation and provide a framework for continuous improvement. This will be supported by ongoing learning from evaluation of the bundle and is key to its success and value.*

*The Saving Babies' Lives Care Bundle is part of a number of initiatives to improve maternity care and safety. However, there are areas that we urgently need to address if we are to ensure a continued reduction in perinatal mortality for all women and babies. We must, therefore, harness the expertise and experience of obstetricians and specialists in fetal and maternal medicine, frontline maternity teams, academics and policymakers to tackle inequality and the social determinants of health in the pregnant population.*

*BMFMS is honoured to have worked closely on all three versions of SBLCB and fully supports the initiatives within this new version and the opportunity to work to deliver improvements in maternity care.*



**Katie Morris**  
**President, British Maternal and Fetal Medicine Society**



*Every day, maternity services support thousands of women and their families through pregnancy and childbirth. The majority of those using maternity services have good outcomes and report a positive experience of care but maternity care is complex and, unfortunately, adverse events occur.*

*Recent public inquiries into maternity care have emphasised the importance of continued learning and action on improving safety. The Royal College of Obstetricians and Gynaecologists warmly welcomes the publication of the third version of the Saving Babies' Lives Care Bundle, which will support further progress towards a 50% reduction in the rate of stillbirths, neonatal mortality and serious brain injury and a reduction of pre term births from 8% to 6% in the UK by 2025, as set in the NHS Long Term Plan.*

*Maternity care is delivered through multi-professional teams working together to support all women, requiring a wide range of skills, knowledge and expertise, and a supportive context in which these can be applied. By implementing the evidence-based, best practice elements of the Saving Babies' Lives Care Bundle, local maternity teams can ensure women receive personalised care that will continue to reduce perinatal mortality.*

*Importantly, each element of the care bundle includes action to improve equity, including for babies from Black, Asian and mixed ethnic groups and for those born to mothers living in the most deprived areas. Maternity systems must continue work to embed these into their local action plans.*

*The care bundle aligns with and complements a range of other important maternity safety initiatives and tools, including wider work being taken forward through the Maternity Transformation Programme as well as initiatives such as the Avoiding Brain Injury in Childbirth (ABC) programme.*

*The Royal College of Obstetricians and Gynaecologists will continue to work with partners, including other Royal Colleges, national policymakers and safety leaders, to support the NHS to implement these together, to improve the quality and safety of care that women and babies receive in the UK.*

*Ranee Thakar*

**Dr Ranee Thakar**  
**President, Royal College of Obstetricians and Gynaecologists**



*Having achieved the first national ambition milestone of reducing by 20% the perinatal mortality rate by 2020 the focus is now on achieving the further 30% reduction by 2025. This will require accelerated progress in the face of having probably dealt with the 'easier' problems to prevent and manage.*

*Activities on multiple fronts are going to be required which is why, amongst other actions, the full implementation in all trusts of the Saving Babies' Lives Care Bundle is needed. This, the third version of the Care Bundle, is a welcome reminder of the five elements from version two and the introduction of a sixth new element to improve diabetic management in pregnancy for women with type 1 and type 2 diabetes.*

*As demonstrated in the National Diabetes in Pregnancy Audit, monitoring and managing tight glycaemic control from pre-pregnancy and throughout pregnancy is key to reducing the risks of adverse outcomes including congenital anomalies and perinatal death. The 2022 MBRRACE-UK maternal confidential enquiry illustrated the risks to both diabetic pregnant women and their babies of poorly managed diabetic ketoacidosis.*

*The steps outlined in element six of the new version of the Care Bundle provide practical advice for service delivery to support improved management for this high-risk group of mothers and babies. Achieving the improvements that could be realised from the full implementation of all six elements of the new version of the Care Bundle will provide some of the essential pieces of the jigsaw of activities still needed to further reduce the national rate of perinatal deaths.*

*Jennifer J. Kurinczuk*

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



*Despite falls in perinatal mortality in recent years, too many parents and families are still devastated by the death of their baby. The exact impact of Covid 19 is as yet unclear but it's very possible that the pandemic has had a significant negative impact not just on women and pregnant people's experiences of maternity, but crucially on outcomes for both them and their babies. Importantly, the government is unlikely to meet the National Ambition to halve stillbirths and neonatal baby deaths by 2025.*

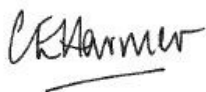
*Coming in the wake of further investigations into poor care such as the Ockenden and East Kent reports, this third version of the Saving Babies' Lives Care Bundle has urgency towards ensuring better, safer care. This new version maintains the focus of version two but adds another crucially important element around caring for women with Type 1 and Type 2 Diabetes who we know to be at 4-5 times increased risk of losing their baby. This version also encourages awareness among those who are pregnant of the importance of early warning signals that something may be wrong, such as noticing and reporting reduced fetal movements (RFM).*

*An innovation in this version is an assurance tool to help Trusts track their progress in implementation, thereby removing the need to have regular implementation surveys.*

*Listening to bereaved parents' experiences is vital in understanding why babies die, and learning from every baby's death is essential 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 updated, third version of the Saving Babies' Lives Care Bundle carries essential knowledge for every healthcare professional who supports and works with those who are pregnant. It helps address inequalities with the same emphasis of continuity of carer, especially for those from black and minority ethnic backgrounds and those living in areas of social deprivation. When the worst happens, it ensures standards in bereavement care, in line with the National Bereavement Care Pathway.*

*We welcome its implementation and believe that it provides an opportunity to protect babies' lives in the future*



**Clea Harmer**  
**Chief Executive, Sands**



*Tommy's work is dedicated to reducing rates of pregnancy complications and baby loss as we know the heartbreak and devastation this causes far too many parents and families. Despite ambitious targets, the rates of stillbirth and preterm birth are not falling as quickly as we would have hoped, and indeed the stillbirth rates sadly rose in 2021. It is also clear that variation in care continues, and not all women and birthing people have the same chance of taking home a healthy baby – the outcome every family deserves. So, we warmly welcome Version 3 of the Saving Babies' Lives Care Bundle as a vital resource for all professionals involved in supporting people to have a safe and healthy pregnancy and birth.*

*Research is continually advancing understanding and growing evidence and it is vital this is translated into improvements in care. While this guidance has been produced before the evaluation of Version 2, we support the fast tracking of new evidence so that everyone can benefit as quickly as possible, and potentially more babies' lives can be saved.*

*We know from the MBRRACE data that some communities continue to experience much poorer outcomes than others. This is unacceptable and we're therefore particularly pleased that Version 3 has been reviewed from an inequity standpoint and highlights the promotion of equity and equality as an important principle to apply when implementing the care bundle. It is also positive to see that continuity of carer is explicitly noted as a key intervention to improve equitable outcomes.*

*A key addition to Version 3 is the management of diabetes in pregnancy. The number of women and birthing people with diabetes is on the rise and perinatal mortality rates for pregnant people with Type 1 and Type 2 diabetes have remained very high for the last five years. This practical guidance should standardise pathways and join these up with other aspects of maternity care to reduce risk.*

*The care bundle also contains a renewed focus on reduced fetal movement (RFM). This is such an important message given the relationship between episodes of RFM and stillbirth, and the vital role of timely hospital attendance and fetal monitoring. Everyone must feel they can and should contact their hospital if they are worried that their baby's movements have changed.*

*This version of the bundle is another important step on the journey to safer pregnancy and birth. We know that when all maternity units follow these actions, fewer families will face the heartbreak and devastation of pregnancy complications and loss.*



**Kath Abrahams, Chief Executive, Tommy's**



*Preterm birth causes 78% of deaths in the neonatal period (first 28 days of life)\*and is also a major contributor to childhood disability and poorer neurodevelopmental outcome. Interventions to reduce the impact of prematurity on morbidity and mortality must therefore be a major focus to move towards the national ambition to halve the rate of stillbirth, neonatal death, maternal death and serious intrapartum brain injury by 2025.*

*BAPM therefore welcomes expansion of element 5 in the SBLCB v3 which aims to reduce preterm birth where possible and optimise perinatal care where preterm birth cannot be prevented. Given the importance of the interventions in improving outcomes, BAPM strongly encourages trusts to ensure that appropriate time is allocated to the neonatal medical and nursing leads of the preterm birth team, in addition to the maternity and obstetric leads, to allow rapid implementation.*

*\*National Child Mortality Database Thematic Report: The contribution of Newborn Health to Child Mortality across England. July 2022*



*Eleri Adams, BAPM President*



**British Association of  
Perinatal Medicine**

# Introduction

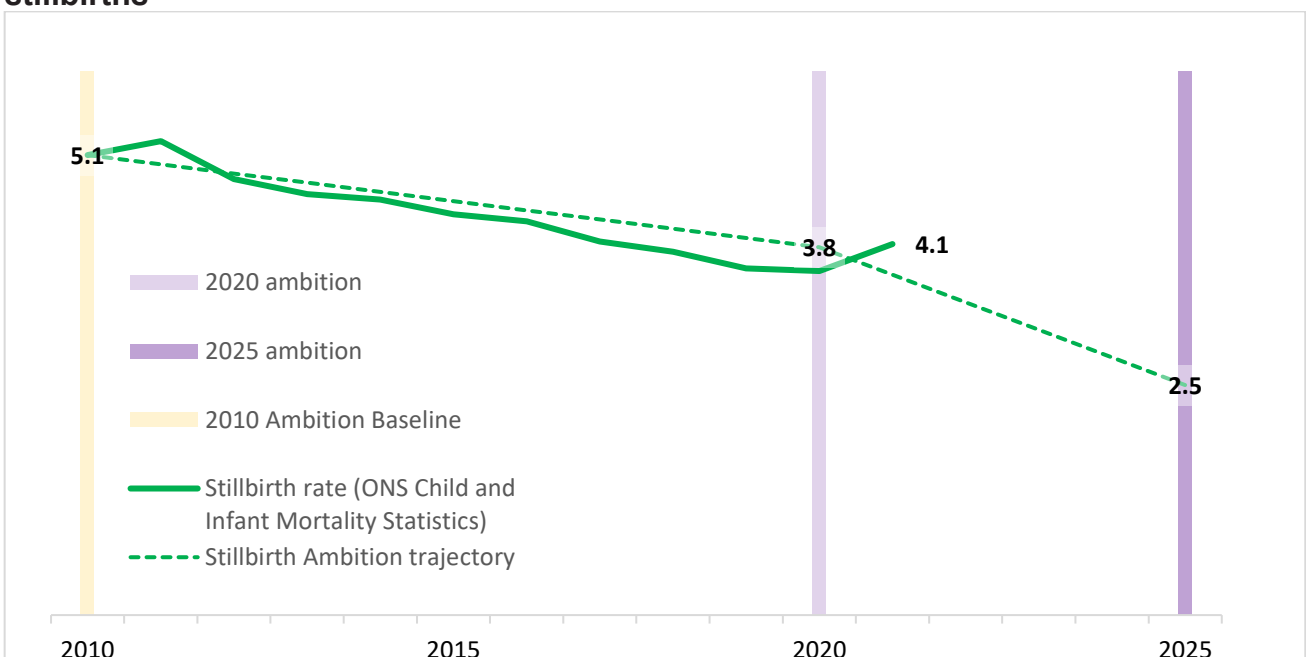
## Progress towards the National Safety Ambition

In 2015, the Secretary of State for Health announced a [national safety ambition](#), to halve the rates of stillbirths, neonatal and maternal deaths and intrapartum brain injuries by 2030, with a 20% reduction by 2020. In 2017, the ambition was extended to include a reduction in the rate of preterm births from [8% to 6%](#), while the date to achieve the ambition was also brought forward to 2025.

[Office for National Statistics \(ONS\) data](#) (shown in **Figure 1**, below) demonstrated a 25% reduction in stillbirths between 2010 and 2020 from 5.1 to 3.8 per thousand births, showing the 2020 milestone had been exceeded for stillbirths. It is not absolutely clear why stillbirth rates increased during the Covid pandemic, but it is likely that the direct effects of the Covid virus as well as the indirect impact of the pandemic on accessing maternity services played a part in the increase of the stillbirth rate from 3.8 per 1000 births in 2020 to 4.1 in 2021. The neonatal mortality rate also increased between 2020 and 2021 from 1.3 to 1.4 per 1000 live births at 24 weeks gestation and over. Despite the significant challenges faced by the NHS, these rates remain 19% and 30% lower (respectively) than in 2010. This equates to more than 900 families returning home with a healthy baby in 2021, than if the rates had remained unchanged from 2010.

The latest data on serious brain injury shows that rate of occurrence during or soon after birth fell by 9% between 2014 and 2019 to 4.25 per 1000 live births. Further reduction in the rate is needed to meet the 2025 ambition, a rate of 2.16 per 1000 live births.

**Figure 1: National Maternity Safety Ambition – Summary of progress on stillbirths**



Despite the achievements of the past few years and in light of the recent setbacks, there is clearly much more to be done to achieve the ambition by 2025. In particular, there is a need to address inequitable outcomes associated with ethnicity and levels of deprivation. MBRRACE-UK Perinatal Mortality Surveillance data show that the lowest stillbirth rates were for babies of White ethnicity from the least deprived areas, at 2.78 per 1,000 total births. The highest stillbirth rates were for babies of Black African and Black Caribbean ethnicity from the most deprived areas, at around 8 per 1,000 total births. The pattern is similar for neonatal deaths. Maternity services must do everything possible to mitigate against the wider social determinants of health in order to continue to drive down the perinatal mortality rate.

## **Progress of the Saving Babies' Lives Care Bundle**

[The first version of the Saving Babies' Lives Care Bundle](#) (SBLCBv1) was published in March 2016, and focused predominantly on reducing the stillbirth rate. An independent evaluation in 2018 showed a decrease in stillbirths in participating Trusts, concluding that despite being one of many concurrent interventions, it was highly plausible that SBLCBv1 had contributed to the reduction.

The evaluation helped inform the development of [version 2](#) of the SBLCB (SBLCBv2). Launched in March 2019, SBLCBv2 aimed to go further in reducing stillbirth while also minimising unnecessary intervention. In answer to the expansion of the national safety ambition in 2017, it introduced Element 5 on reducing pre-term birth, and further decreasing perinatal mortality.

The Care Bundle is now a universal innovation in the delivery of maternity care in England and continues to drive quality improvement to reduce perinatal mortality. It has been included for a number of years in the NHS Long Term Plan, NHS Planning Guidance, the Standard Contract and the CNST Maternity Incentive Scheme, with every maternity provider expected to have fully implemented SBLCBv2 by March 2020.

ONS and MBRRACE-UK data demonstrate the urgent need to continue reducing preventable mortality. Published 4 years after SBLCBv2, Version 3 of the Care Bundle (SBLCBv3) has been developed through a collaboration of frontline clinical experts, service users and key stakeholder organisations. All existing elements have been updated, incorporating learning from the Clinical Negligence Scheme for Trusts: Maternity Incentive Scheme ([CNST MIS](#)) and insights from NHS England's regional maternity teams. SBLCBv3 aligns with national guidance from NICE and the RCOG Green Top Guidelines where available but it aims to reduce unwarranted variation where the evidence is insufficient for NICE and RCOG to provide guidance. SBLCBv3 also includes a new element on optimising care for women with pregnancies complicated by diabetes.

While SBLCBv3 would ideally be informed by the evaluation of SBLCBv2, this has been delayed due to the pandemic. Stakeholders agreed that improvements to best



practice couldn't be delayed when evidence is readily available for improvements to several elements. The evaluation of SBLCBv2 remains a priority and will be published in 2023. Findings will help inform the next iteration of SBLCB, which will also include important innovations from the Avoiding Brain Injury in Childbirth (ABC) collaboration along with anticipated updates to Green Top Guidance. SBLCBv3 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 continue to implement best practice care whenever possible, including by following NICE guidance and using the [National Maternity and Neonatal Recommendations Register](#) to assess their organisations' compliance with recommendations from confidential enquiries and other key national reports.

## Implementing Version 3 of the Care Bundle

As part of the [Three Year Delivery Plan for Maternity and Neonatal Services](#), all NHS maternity providers are responsible for fully implementing SBLCBv3 by March 2024.

### Overseeing implementation

A national Implementation Tool is now available on [the Maternity Transformation Programme's Future NHS platform](#). The tool supports providers to baseline current practice against SBLCBv3, agree a local improvement trajectory with their ICB, and track progress locally in accordance with that trajectory.

To reduce assurance burdens, national implementation surveys are being stepped down. Instead, to comply with [Safety Action 6 of the CNST Maternity Incentive Scheme \(Year 5\)](#), trusts are asked to use the Implementation Tool in 2 ways to ensure local oversight:

1. Track and demonstrate implementation to the Trust Board and ICBs. 'Full implementation' of the care bundle means completing all interventions for all 6 elements. Progress with implementation will therefore be expressed as a percentage of completed interventions for each element, and across all elements. To evidence adequate progress against this deliverable by the submission deadline for the CNST Maternity Incentive Scheme in February, providers are required to demonstrate implementation of 70% of interventions across all 6 elements overall, and implementation of at least 50% of interventions in each individual element.
2. Holding quarterly quality improvement discussions with the ICB. These provider-commissioner discussions should include, at a minimum:
  - Details of element specific improvement work being undertaken including evidence of generating and using the process and outcome metrics for each element.
  - Progress against locally agreed improvement aims.

- Evidence of sustained improvement where high levels of reliability have already been achieved.
- Regular review of local themes and trends with regard to potential harms in each of the six elements.
- Sharing of examples and evidence of continuous learning by individual trusts with their local ICB and neighbouring Trusts.

While there will be no routine, deadline-based submissions of data to the national NHS England team for the purposes of assurance, the maternity team will review data stored on trust Implementation Tools on an ad-hoc basis to assess national progress in implementation.

### **Organisational roles and responsibilities**

Successful implementation of SBLCBv3 requires providers, commissioners, and networks to collaborate successfully. National levers including NHS Planning Guidance, the NHS Standard Contract, and Safety Action 6 in the CNST Maternity Incentive Scheme will be updated in due course to reflect the following organisational responsibilities:

- **Providers** are responsible for implementing SBLCBv3, including baselining current compliance, developing an improvement trajectory, and reporting on implementation with their ICB as agreed locally. They are also responsible for submitting data nationally relating to key process and outcome measures for each element.
- **ICBs** are responsible for agreeing a local improvement trajectory with providers, along with overseeing, supporting, and challenging local delivery. 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 integrated care board. An integral part of ICSs, **LMNSs** are accountable to ICBs and have the system's maternity and neonatal expertise to support planning and provide leadership for improvement, facilitating peer support, and ensuring that learning from implementation and ongoing provision of SBLCBv3 is shared across the System footprint.
- **Clinical Networks and Regional Maternity teams** are responsible for providing support to providers, ICBs and LMNSs to enable delivery and achieve expected outcomes. It is important that specific variations from the pathways described within SBLCBv3 are agreed as acceptable clinical practice by their Clinical Network.

## Principles to be applied when implementing Version Three

It has been necessary to restrict the scope of the SBLCBv3 to ensure it is deliverable. Nevertheless, it is just one of a series of important interventions to help reduce perinatal mortality and preterm birth. The following principles should be considered alongside implementing the Care Bundle.

### Promoting Equity and Equality

Health inequalities are unfair and avoidable differences in health across the population, and between different groups within society. Equity in maternity and neonatal care means that all mothers and babies have a fair and just opportunity to attain the best health outcomes. To achieve equity and reduce inequalities, action must be universal, but with a scale and intensity proportionate to the level of disadvantage; this is known as 'proportionate universalism' ([Marmot 2010](#)).

England is one of the safest countries in the world to give birth. However, stillbirth rates and neonatal death rates are higher for some groups, such as women who are Black, Asian and those living in the most deprived areas. This emphasises the need for a continued focus to address these inequalities when implementing the care bundle. This includes ensuring that services reflect the needs of different groups, with support increasing as health inequalities increase. This requires use of quantitative and qualitative data on the local population and their health needs, along with co-production, to inform pathways and processes during implementation. Maternity and neonatal services also need to respond to each person's unique health and social situation — so that care is safe and personal for all.

Continuous improvement activity related to each element of the care bundle will routinely require consideration of access, experience, and outcomes in relation to protected characteristics and other variables influencing inequalities, such as factors related to deprivation. Pathways and processes should be changed, or additional supportive activity carried out, to address any inequity or inequalities identified.

While most people using maternity and perinatal services are women, the CQC Maternity Survey (2022) found that 0.65% of respondents stated that their gender was not the same as their sex registered at birth. Intersex, transgender, and non-binary people experiencing pregnancy and birth can experience particular health inequalities including poorer access and a lack of information and support in relation to their specific clinical and care needs within maternity services.

### The role of Midwifery Continuity of Carer

Evidence shows that continuity models improve safety and outcomes; women who receive Midwifery Continuity of Carer (MCoC) 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<sup>1</sup>. It is widely acknowledged that it is beneficial for women to know and form a relationship with the professionals caring for them<sup>2</sup>. It is a recurring theme within confidential enquiries that some groups in society struggle to access health care, and/or raise concerns.

The implementation of MCoC has been challenging particularly in the context of the pandemic and staffing shortages. Whilst the ambition remains for MCoC to be the default model of care for all women, currently there is not a national target timeframe for this to be achieved. In September 2022, [NHS England published a letter](#) asking trusts to review their safe staffing levels and decide to either: continue existing MCoC provision and continue to roll out; cease further rollout and continue with current levels of provision; or immediately suspend existing MCoC provision. MCoC remains an important intervention to address higher perinatal mortality rates in Black and Asian women and women from economically disadvantaged groups. In line with the CORE20PLUS5 strategy, Local Maternity and Neonatal Systems, regional and national colleagues will continue to support Trusts with sufficient staffing to focus rollout of MCoC to neighbourhoods with high numbers of women from Black, Asian, and Mixed ethnic groups, and women living in deprived areas, for whom CoC is linked to significant improvements in clinical outcomes<sup>3</sup>.

## **Informed choice and personalised care**

[Evidence shows](#) that better outcomes and experiences, as well as reduced health inequalities, are possible when pregnant women can actively shape their care and support. Personalised care means pregnant women have choice and control over the way their care is planned and delivered, based on best available evidence, 'what matters' to them and their individual strengths, needs and preferences. Pregnant women receiving maternity care make informed decisions. They and their maternity professionals discuss evidence-based options together exploring preferences, benefits, risks, and consequences to enable a safe and positive experience.

For any given situation where a decision needs to be made, women are supported by their maternity professionals to understand their options, the benefits, harms and consequences of each. They have all the information they need for shared decision making and give consent, in line with the [Montgomery ruling](#).

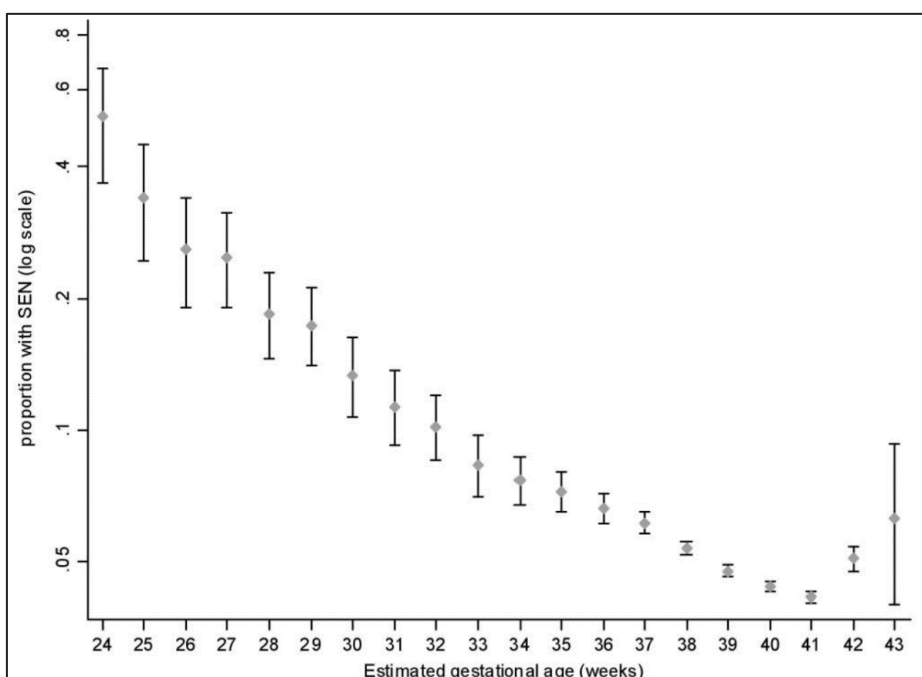
Linked to this principle, the following areas are of particular relevance to implementing a number of Elements in Version 3:

## **Informing women of the long-term outcomes of early term birth**

One of the key interventions in elements 2 and 3 of the SBLCBv3 is offering early birth 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 birth prior to reaching maturity, for example, the baby's brain continues to develop at term<sup>4</sup> Birth 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<sup>4</sup>. 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 birth<sup>4</sup>.



After adjusting for maternal and obstetric characteristics and expressed relative to birth 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<sup>4</sup>. Recent data from the UK Millennium Cohort Study confirmed the finding that children born at early term gestational ages (37 to 38 weeks) were more likely to fail to achieve the expected level of attainment in primary school but, interestingly, there was no association between early term birth and poorer attainment at secondary school<sup>5</sup>. Moreover, as the current data are based on the observed gestational age at birth, the negative associations with later outcome may be explained by the factors that determined early term birth rather than a direct effect of gestational age. However, induction of labour prior to 39 weeks should continue to be considered as a significant medical intervention which requires appropriate justification.

## **Considering how the risks of induction of labour change with gestational age**

For uncomplicated pregnancies [NICE guidance](#) on induction of labour should be followed. 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 birth, fetal morbidity or admission to the neonatal intensive care unit<sup>6</sup>. The [NICE guidance](#) and data from the ARRIVE study<sup>6</sup> 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.

## **Safe and Healthy Pregnancy Information' to enable women and their families to make informed choices regarding their health and reducing risks to their babies.**

It is important that women have access to high quality information before and during their pregnancy to enable them to reduce risks to their baby. The Office for Health Inequalities and Disparities and Sands have developed some key messages:

## Figure 2: Summary of Safe and Healthy Pregnancy key messages

### Pre-pregnancy:

- Choose when to start or grow your family by using contraception.
- Consult with your GP if taking medication for long-term conditions (e.g., diabetes, hypertension, epilepsy) as your medication may have to change prior to pregnancy.
- Eat a [healthy balanced diet](#) and be physically active to enter pregnancy at a healthy weight.
- Take a daily supplement of 400 micrograms (400 µg) folic acid before conception (some women will require a higher dose of 5mg as advised by a healthcare professional).
- Ensure that you are up to date with routine vaccinations e.g., measles, rubella, Coronavirus (Covid 19), flu.
- Find out if you think you or your partner could be a carrier for a genetic disorder.
- Stop smoking and/or exposure to second hand smoke.
- Reduce/stop alcohol consumption.

### During pregnancy:

- Continue to take 400 micrograms (400 µg) folic acid until the 12th week of pregnancy (some women will require a higher dose of 5mg as advised by a healthcare professional).
- Pregnant women should have 10µg of vitamin D a day.
- You may be advised to take aspirin from 12 weeks of pregnancy.
- Alcohol – the safest advice is to not drink alcohol, if you are concerned, talk to your midwife, or doctor and help and advice is available for you.
- Don't smoke and avoid second hand smoke; support is available to help with this.
- Do tell your midwife if you use illegal street drugs or other substances, help is available for you.
- Eat healthily and be physically active to maintain a healthy weight while pregnant.
- Maintain oral hygiene. Free dental care is available to all pregnant women and up to a year after the birth.
- Recommended vaccinations and boosters: seasonal flu; pertussis (whooping cough); Coronavirus (Covid-19)
- Always check with your pharmacist, midwife or doctor about medicines and therapies used in pregnancy, even if you have taken them for a long time on prescription or think they are harmless.
- Avoid contact with people who have infectious illnesses, including diarrhoea, sickness, childhood illnesses or any rash-like illness.
- Reduce the risk of Cytomegalovirus (CMV) Toxoplasmosis, Monkeypox infections etc.,
- Attend all antenatal appointments.
- Contact the maternity service promptly if you are worried about reduced fetal movements, vaginal bleeding, watery or unusual discharge, signs of pre-eclampsia or itching. 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 the [Safer Pregnancy website](#) developed by [Sands](#).

## Working within Networks for more specialist care

In a number of specialist fields, Maternity services are working within networks so that women and babies with complex needs have consistent access to the most specialist care, while also encouraging local expertise, and ensuring that care remains as close as possible to home.

While a networked model has been in place for a number of years in fetal medicine and in neonatal care, NHS England announced the creation of 14 Maternal Medicine Networks, which are now in operation across England.

All providers should be engaging in these networks and contributing to the development of joint protocols and ways of working. In this vein, new elements of

best practice shouldn't be implemented in isolation locally. Providers should consider what implications or opportunities this presents for ways of working agreed within wider Maternal Medicine, Fetal Medicine, or Neonatal Operational Delivery Networks.

## **Implementing relevant NICE guidance**

Integrated Care Systems/ Boards (ICS/ICBs) 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.

Providers and commissioners are encouraged to implement NICE guidance relating to antenatal, intrapartum and postnatal care. In particular, implementation of the NICE guidance on the [management of diabetes in pregnancy](#), [hypertension in pregnancy](#) and [multiple pregnancy](#), along with [service provision for women with complex social factors](#) are key to addressing some of the most significant contributors to perinatal mortality.

## **Best practice care in the event of a stillbirth or neonatal death**

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. A best practice pathway for the clinical management of women experiencing stillbirth is available on the [North West Coast \(NWC\) Strategic Clinical Network website](#).

Sands have developed a National Bereavement Care Pathway (NBCP) to help ensure that all bereaved parents are offered equal, high quality, individualised, safe and sensitive bereavement care when they experience pregnancy loss or the death of a baby. The NBCP is available at [www.nbcpathway.org.uk](http://www.nbcpathway.org.uk).

[The national Perinatal Mortality Review Tool \(PMRT\)](#) is used to support hospital reviews by providing a standardised, structured process so that what happened at every stage of the pregnancy, birth and after, from booking through to bereavement care is carefully considered by staff reviewing care. This online tool may help staff understand why a baby has died and whether there are any lessons to be learned to save future lives.



## Continuous improvement and Maternity and Neonatal Services

As part of the update of SBLCBv3, we are maintaining an approach of continuous improvement. Within each element the focus is on a small number of outcomes with fewer process measures. Implementation of the elements will require a more comprehensive evaluation of each organisation's processes and pathways and an understanding of where improvements can be made.

Each organisation will be expected to look at their performance against the outcome measures for each-element 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 implementation of 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.

## Element 1: Reducing smoking in pregnancy.

Element description	
<b>Reducing smoking in pregnancy by identifying smokers with the assistance of carbon monoxide (CO) testing and ensuring in-house treatment from a trained tobacco dependence adviser<sup>a</sup> is offered to all pregnant women who smoke, using an opt-out referral process.</b>	
Interventions	
1.1	CO testing offered to all pregnant women at the antenatal booking and 36-week antenatal appointment.
1.2	CO testing offered at all other antenatal appointments to groups identified within NICE Guidance <a href="#">NG209</a> .
1.3	Whenever CO testing is offered, it should be followed up by an enquiry about smoking status with the CO result and smoking status recorded.
1.4	Instigate an opt-out referral for all women who have an elevated CO level (4ppm or above), who identify themselves as smokers or have quit in the last 2 weeks for treatment by a trained tobacco dependence treatment adviser (TDA) within an in-house tobacco dependence treatment service.
1.5	Nicotine replacement therapy (NRT) should be offered to all smokers and provision ensured as soon as possible.
1.6	The tobacco dependence treatment includes behavioural support and NRT, initially 4 weekly sessions following the setting of the quit date then regularly (as required, however as a minimum monthly) throughout pregnancy to support the woman to remain smokefree.
1.7	Feedback is provided to the pregnant woman's named maternity health care professional regarding the treatment plan and progress with their quit attempt (including relapse). Where a woman does not book or attend appointments there should immediate notification back to the named maternity health care professional.
1.8	Any staff member using a CO monitor, should have appropriate training on its use and discussion of the result.
1.9	All staff providing maternity care to pregnant women should receive training in the delivery of Very Brief Advice (VBA) about smoking, making an opt-out referral and the processes within their maternity pathway (e.g., referral, feedback, data collection).
1.10	Individuals delivering tobacco dependence treatment interventions should be fully trained to NCSCT standards
Continuous learning	
1.11	When analysing patient safety incidents, maternity care providers should review smoking status throughout pregnancy and determine whether the appropriate pathway of care for this was followed.
1.12	Maternity providers should regularly review (a minimum of quarterly) their smoking-related data to understand performance and develop improvement plans (this list is designed to provide a steer and is not exhaustive): A. Identification of women who smoke – Determine any factors that would optimise CO testing rates and enquiry about smoking status, from both the provider/pathway and

<sup>a</sup> The role of tobacco dependence adviser (TDA) is also known under alternative names, including smoking cessation adviser, stop smoking adviser and smoking cessation practitioner. Irrespective of role name or grade, these roles are underpinned by appropriate training to deliver tobacco dependence treatment interventions (see 1.10).

service-user perspective and make changes to pathways and processes as appropriate.

- B. Training of staff – Ensure all staff involved in identification, referral and treatment of women who smoke, and provision of VBA are appropriately trained.
- C. Engagement – Determine and address any barriers to engagement with treatment services or compliance with treatment interventions from both the provider/pathway and service-user perspective.
- D. Referral – Determine and address any factors that are influencing opt-out referral, from both the provider/pathway perspective and service-user perspective.
- E. Quit rates – Consider the pathway holistically to determine which steps can be optimised to facilitate quit attempts and successful quits.
- F. Relapse – Determine factors that are contributing to relapse and whether additional support or changes to pathways may address these.
- G. Inequalities – Consider all the above by protected characteristics and other variables influencing inequalities, such as factors related to deprivation. Make changes to pathways and processes, or carry out additional supportive activity, to address any inequity or inequalities identified.

1.13 In order to monitor quality and effectiveness of pathways, maternity services should set ambitions for their pathway with regular review (a minimum of quarterly) of data and targeted quality improvement work to ensure they are being achieved.

1.14 Based on highly performing areas, stretching ambitions to achieve effective implementation of the full Element may include:

- A. 95% of women where CO measurement and smoking status is recorded at their booking appointment.
- B. 95% of women where CO measurement and smoking status is recorded at their 36-week appointment.
- C. 95% of smokers have an opt-out referral at booking for treatment by a TDA within an in-house service.
- D. 85% of all women referred for tobacco dependence treatment engage with the programme (have at least one session and receive a treatment plan).
- E. 60% of those referred for tobacco dependence treatment set a quit date.
- F. 60% of those setting a quit date successfully quit at 4 weeks.
- G. At least 85% of quitters should be CO verified.

1.15 Individual providers should examine their outcomes in relation to other providers or systems with similar smoking prevalence or populations. National benchmarking is available through the Maternity Services Dashboard and will be available to ICS/LMS as the Tobacco dependence patient level collection is established.

Process Indicators	Outcome indicators
<p>1a. Percentage of women where there is a recorded of:</p> <ul style="list-style-type: none"> <li>1.a.i. CO measurement at booking appointment</li> <li>1.a.ii. CO measurement at 36-week appointment</li> <li>1.a.iii. Smoking status** at booking appointment</li> <li>1.a.iv. Smoking status** at 36-week appointment</li> </ul> <p>1b. Percentage of smokers* that have an opt-out referral at booking to an in-house/in-</p>	<p>1d. Percentage of smokers* at antenatal booking who are identified as CO verified non-smokers at 36 weeks.</p> <p>1e. Percentage of smokers* that set a quit date and are identified as CO verified non-smokers at 4 weeks.</p>

<p>reach tobacco dependence treatment service.</p> <p>1c. Percentage of smokers* that are referred for tobacco dependence treatment who set a quit date.</p>	
<p>* a “smoker” is a pregnant woman with an elevated CO level (4ppm or above) and identifies themselves as a smoker (smoked within the last 14 days) or has a CO level less than 4ppm but identifies as a smoker (smoked within the last 14 days).</p> <p>** Smoking status relates to the outcome of the CO test (&gt;4ppm) and the enquiry about smoking habits.</p>	

## Rationale

Smoking increases the risk of [pregnancy complications](#), such as stillbirth, preterm birth, miscarriage, low birthweight and sudden infant death syndrome (SIDS). Whether or not a woman smokes during her pregnancy has a [far-reaching impact on the health of a child](#) throughout their life. Whilst a number of studies have found that the risk of a number of poor pregnancy outcomes can be [reduced](#) to that of a non-smoker if a successful quit is achieved [early in pregnancy](#). Others show increased risk with any smoking in [pregnancy](#), and increasing risk with continued smoking. This reinforces the need to support women to quit smoking as early as possible in pregnancy to reduce the risk of poor pregnancy outcomes.

Smoking at time of delivery (SATOD) rates have declined since the release of previous versions of the care bundle, albeit at a slower rate than required to meet the government’s 2022 national ambition of 6% (and ultimately a smokefree generation by 2030). Although there is significant variation, the national SATOD rate was 9.1% in 2021/22, demonstrating that further work to reduce smoking during pregnancy is required.

This element is evidence-based and provides a practical approach incorporating the NHS Long Term Plan pathway for a smokefree pregnancy and core elements of [NICE guidance](#). It builds on the previous version of the care bundle’s focus on CO testing to support identification of smokers, with referral to in-house tobacco dependence treatment services and ensuring that effective treatment is available to all pregnant women who smoke. Research indicates that pregnant women expect to be asked about smoking by their maternity care provider and if the issue is not raised it can be incorrectly interpreted that smoking is not a problem for the pregnancy. Learning from front line services demonstrates a need for a treatment offer that is part of the maternity pathway and the woman’s maternity journey. This should include processes for referral, treatment, and feedback that are timely and optimise engagement, with dedicated leadership within the maternity service that has oversight of the full pathway. To support this, consistent messages should be given from all clinicians who the woman comes into contact with during pregnancy.

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 the health of babies and the long-term outcomes for families and society.

## Implementation guidance

Key factors for effective implementation include:

**In-house pathways:** Clinical leadership, delivery and oversight of the service and its outcomes remains with maternity. Services are considered as in-house when the woman's care for treating their tobacco dependence remains within the maternity service i.e., is not referred out to another provider like a local authority stop smoking service<sup>b</sup>.

**Opt-out referral pathways:** Effective pathways are in place to ensure that as soon as a smoker is identified there is rapid referral to the tobacco dependence adviser on an opt-out basis. Immediate referral and consultation with the tobacco dependence adviser is the ideal, but as a minimum the woman should be contacted within 1 working day and seen (ideally face-to-face) by a TDA within 5 working days.

**Nicotine Replacement Therapy:** Pathways should ensure provision of long and short acting nicotine replacement therapy at the earliest opportunity to facilitate quitting at an optimal time to improve perinatal outcomes and maximise engagement with referral and treatment services. Ideally this should be at the earliest opportunity when maternity care has commenced, even if prior to a formal booking appointment.

**Recent Quitters:** The definition of a smoker includes those who have smoked within the past 2 weeks. However, it is good clinical practice to offer support to all women who have quit smoking since conception given that changes in first trimester pregnancy symptoms may affect smoking habits.

**CO testing:** All pregnant women should be offered CO testing at the antenatal booking and 36-week antenatal appointment, with testing offered at all other antenatal appointments after booking to groups identified within NICE guidance [NG209](#). All staff providing antenatal care should have access to a CO monitor and training in how to use it and interpretation of results. Appropriate procurement processes should be in place for obtaining CO monitors and associated consumables (for example, tubes and batteries).

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<sup>b</sup> In-reach services where a third party, such as the local authority stop smoking service, provide services as part of the maternity team with the patient staying under the care and management of the maternity service would count as in-house.

**CO verified non-smokers at 4 weeks:** this corresponds to the 4-week quit that is regularly captured by stop smoking services and is a comparable indicator that can be used to assess the quality of the intervention.

**CO Levels:** The most common reason for a raised CO level is smoking, however exposure may come from other sources such as second-hand smoke, faulty boilers, faulty heating/cooking appliances or car exhausts (and can happen at home or at the workplace). If women have raised CO levels and are non-smokers environmental exposure from a source in the home should be considered and the women should be advised to contact the Gas Emergency Line on 0800 111 999 for further advice. Referral for further medical advice should be sought if symptoms are consistent with CO poisoning. For NICE guidance on air pollution and vulnerable groups see recommendation 1.7.7. in NICE guidance [NG70](#).

**Tobacco dependence treatment:** Following an initial appointment where a quit is initiated, weekly face-to-face appointments with the tobacco dependence adviser should take place for at least four weeks after the quit date is set followed by regular appointments (as required, but as a minimum monthly) throughout the pregnancy. Treatment includes behavioural support and a combination of long and short acting NRT. A recommended delivery model pathway is available on the Prevention Programme's NHS Futures [webpages](#).

**Recording data:** There should be routine recording of the CO test result and smoking status for each pregnant woman on maternity information systems (MIS), reporting through to the [tobacco dependence patient level collection](#) and, where appropriate, the Maternity Service Data Set (MSDS).

**Review and act upon local data:** Use tools available (for example, the Maternity Services Dashboard's [Clinical Quality Improvement Metrics](#)) 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.

**Vaping:** The Royal College of Midwives [states](#) that "If a pregnant woman who has been smoking chooses to use an e-cigarette (vaping) and it helps her to quit smoking and stay smokefree, she should be supported to do so". There is also more information available via the [Smoking in Pregnancy Challenge Group](#).

**Systemwide action:** Action to help pregnant women stop smoking should be supplemented by wider activity across the local system to reduce smoking rates among women, partners and other household or family members. This includes reducing smoking rates in women pre-conception, in addition to working with neonatal care and health visiting services to ensure there are links with local stop smoking services to support quitting postnatally. Local tobacco control networks alongside LMNSs, ICSs and regional teams should be able to support with integrating activity to reduce smoking prevalence in all population groups which can impact on reducing maternal smoking.

## Implementation resources

**Resources:** The NHS Long Term Plan delivery model for smokefree pregnancy provides details of the pathway and treatment programme that should be delivered in this element. This can be found on the NHS Futures [webpages](#) with additional resources and shared materials.

Information and links to further resources are also available from the [Maternal and Neonatal Health Safety Collaborative](#). [Action on Smoking and Health](#) (ASH) produce annual [briefings for Integrated Care Systems](#) showing the impact of smoking, using data at ICS level. The briefings include national data on maternal smoking and other clinical areas broken down to ICS level, and signpost to current resources and information.

The [Smoking in Pregnancy Challenge Group](#) produces a range of resources and information for health professionals working to reduce maternal smoking. Those with an interest can also join the Smokefree Pregnancy Information Network administered by ASH, which will provide up to date information throughout the year. For more information contact [admin@smokefreeaction.org.uk](mailto:admin@smokefreeaction.org.uk).

**Training - tobacco dependence adviser:** Those providing tobacco dependence treatment interventions are specialist advisers and should have successfully completed NCSCT [stop smoking practitioner training](#) (or local training to the the required [NCSCT Standard](#)) and a [speciality course for smoking in pregnancy \(requires registration and log-in\)](#) including opportunities to observe good practice; to ensure they have the knowledge and skills to deliver the treatment. Tobacco dependence advisers should receive annual refresher training. NCSCT derived competency frameworks are also available on [NHS Futures](#).

**Training - all maternity health professionals:** All multidisciplinary staff providing maternity care for pregnant women should receive training on how to use a CO monitor (see CO testing section), the delivery of Very Brief Advice (VBA) about smoking, making an opt-out referral and the processes within their maternity pathway (e.g., referral, feedback, data collection). Annual refresher training should align with the Core Competency Framework. Very Brief Advice on smoking in pregnancy training can be accessed via [NCSCT e-learning](#) or [HEE eLearning for Health Hub](#).

## Element 2: Fetal Growth: Risk assessment, surveillance, and management

Element description
<b>Risk assessment and management of babies at risk of or with fetal growth restriction (FGR).</b>
Interventions
<p><b>Reduce the risk FGR where possible.</b></p> <p>2.1 Assess all women at booking to determine if prescription of Aspirin is needed using an appropriate algorithm (for example Appendix C) agreed with the local ICSs and regional maternity team</p> <p>2.2 Recommend Vitamin D supplementation to all pregnant women.</p> <p>2.3 Assess smoking status and manage findings as per Element 1.</p> <p><b>Monitor and review the risk of FGR throughout pregnancy.</b></p> <p>2.4 Perform a risk assessment for FGR by 14 weeks gestation using an agreed pathway (for example, Appendix D). In multiparous women risk assessment should include the calculation of previous birthweight centiles. The pathway and centile calculator used should be agreed by both the local ICSs and the regional maternity team.</p> <p>2.5 During risk assessment trusts are encouraged to use information technology platforms to facilitate accurate recording and correct classification of risk by staff. No single provider is recommended, but technology platforms should not prevent compliance with Element 2 guidance and should follow national recommendations on the use of fundal height and fetal growth charts.</p> <p>2.6 As part of the risk assessment for FGR, blood pressure should be recorded using a digital monitor that has been <a href="#">validated for use in pregnancy</a>.</p> <p>2.7 Women who are designated as high risk for FGR (for example see Appendix D) should undergo uterine artery Doppler assessment between 18+0 to 23+6 weeks gestation.</p> <p>2.8 The risk of FGR should be reviewed throughout pregnancy and maternity providers should ensure that processes are in place to enable the movement of women between risk pathways dependent on current risk.</p> <p>2.9 When an ultrasound-based assessment of fetal growth is performed Trusts should ensure that robust processes are in place to review which risk pathway a woman is on and agree a plan of ongoing care.</p> <p>2.10 Women who are at low risk of FGR following risk assessment should have surveillance using antenatal fundal height (FH) measurement before 28+6 weeks gestation. Measurements should be plotted or recorded on charts by clinicians trained in their use.</p> <p>2.11 Staff who perform FH measurement should be competent in measuring, plotting (or recording), interpreting appropriately and referring when indicated. Only staff who perform FH measurement need to undergo training in FH measurement.</p> <p>2.12 Women who are undergoing planned serial scan surveillance should cease FH measurement after serial surveillance begins. FH measurement should also cease if women are moved onto a scan surveillance pathway in later pregnancy for a developing pregnancy risk (e.g., recurrent reduced fetal movements).</p> <p>2.13 Women who are at increased risk of FGR should have ultrasound surveillance of fetal growth at 3-4 weekly intervals until delivery (see RCOG guidance and Appendix D)</p>



**Provide the correct surveillance when FGR is suspected and delivery at the right time.**

- 2.14 When FGR is suspected an assessment of fetal wellbeing should be made including a discussion regarding fetal movements (see Element 3) and if required computerised CTG (cCTG). A maternal assessment should be performed at each contact this should include blood pressure measurement using a digital monitor that has been [validated for use in pregnancy](#) and a urine dipstick assessment for proteinuria. In the presence of hypertension NICE guidance on the use of PIGF/sflt1 testing should be followed.
- 2.15 Umbilical artery Doppler is the primary surveillance tool for FGR identified prior to 34+0 weeks and should be performed as a minimum every 2 weeks. Maternity care providers caring for women with early FGR identified prior to 34+0 weeks should have an agreed pathway for management which includes fetal medicine network input (for example, through referral or case discussion by phone). Further information is provided in Appendix D.
- 2.16 When FGR is suspected, the frequency of review of estimated fetal weight (EFW) should follow the guidance in Appendix D or an alternative which has been agreed with local ICSs following advice from the provider's Clinical Network and/or regional team.
- 2.17 Risk assessment and management of growth disorders in multiple pregnancy should comply with NICE guidance or a variant that must be agreed by both the local ICSs and the regional maternity team.
- 2.18 All management decisions regarding the timing of FGR infants and the relative risks and benefits of iatrogenic delivery should be discussed and agreed with the mother. When the estimated fetal weight (EFW) is <3rd centile and there are no other risk factors (see 2.20), initiation of labour and/or delivery should occur at 37+0 weeks and no later than 37+6 weeks gestation.
- 2.19 In fetuses with an EFW between the 3rd and <10th centile, delivery should be considered at 39+0 weeks. Birth should be achieved by 39+6 weeks. Other risk factors should be present for birth to be recommended prior to 39 weeks (see 2.20)
- 2.20 Fetuses who demonstrate declining growth velocity from 32 weeks' gestation are at increased risk of stillbirth from late onset FGR. Declining growth velocity can occur in fetuses with an EFW >10th centile. Evidence to guide practise is limited and guidance (see Appendix D) is currently based on consensus opinion. In fetuses with declining growth velocity and EFW >10th centile the risk of stillbirth from late onset FGR should be balanced against the risk of late preterm delivery. In infants where declining growth velocity meets criteria (see Appendix D) delivery should be planned from 37+0 weeks unless other risk factors are present. Risk factors that should trigger review of timing of birth are: reduced fetal movements, any umbilical artery or middle cerebral artery Doppler abnormality, cCTG that does not meet criteria, maternal hypertensive disease, abnormal sFlt1: PIGF ratio/free PIGF or reduced liquor volume. Opinion on timing of birth for these infants should be made in consultation with specialist fetal growth services or fetal medicine services depending on Trust availability.

## Continuous learning

### Learning from excellence and error, or incidents

- 2.21 Trusts should determine and act upon all themes related to FGR that are identified from investigation of incidents, perinatal reviews, and examples of excellence.
- 2.22 Trusts should provide data to their Boards and share this with their ICS in relation to the following:
- Percentage of babies born <3<sup>rd</sup> birthweight centile >37+6 weeks' gestation.
  - Ongoing case-note audit of <3<sup>rd</sup> birthweight centile babies not detected antenatally and born after 38+0 weeks, to identify areas for future improvement (at least 20 cases per year, or all cases if less than 20 occur).
  - Percentage of babies born >39+6 and <10<sup>th</sup> birthweight centile to provide an indication of detection rates and management of SGA babies.
  - Percentage of babies >3<sup>rd</sup> birthweight centile born <39+0 weeks gestation
- 2.23 Use the PMRT to calculate the percentage of perinatal mortality cases annually where the identification and management of FGR was a relevant issue. Trusts should review their annual MBRRACE perinatal mortality report and report to their ICS on actions taken to address any deficiencies identified.
- 2.24 Individual Trusts should examine their outcomes in relation to similar Trusts to understand variation and inform potential improvements.
- 2.25 Individual Trusts should provide data on the distribution of FGR outcomes with relation to maternal reported ethnicity.
- 2.26 Maternity providers are encouraged to focus improvement in the following areas:
- Appropriate risk assessment for FGR and other conditions associated with placental dysfunction and robust referral processes to appropriate care pathways following this.
  - Appropriate prescribing of aspirin in line with this risk assessment in women at risk of placental dysfunction.
  - Review of ultrasound measurement quality control. Trusts are encouraged to comply with BMUS guidance on audit and continuous learning with relation third trimester assessment of fetal wellbeing
  - Trusts will share evidence of these improvements with their Trust Board and ICS and demonstrate continuous improvement in relation to process and outcome measures.

Process indicators	Outcome indicators
<p>2a. 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.)</p> <p>2b. Percentage of pregnancies where an SGA fetus (between 3<sup>rd</sup> to &lt;10<sup>th</sup> centiles) is antenatally detected, and this is recorded on the provider's MIS and included in their MSDS submission to NHS Digital.</p>	<p>2d. Percentage of babies &lt;3<sup>rd</sup> birthweight centile born &gt;37+6 weeks (this is a measure of the effective detection and management of FGR).</p> <p>2e. Percentage of live births and stillbirths &gt;3<sup>rd</sup> birthweight centile born &lt;39+0 weeks gestation, where growth restriction was suspected.</p>

2c. Percentage of perinatal mortality cases annually where the identification and management of FGR was a relevant issue (using the PMRT).	
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## Rationale

There is strong evidence linking undiagnosed FGR to stillbirth<sup>7 8</sup>. 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

## Update for version 3

The previous versions of this element have made a measurable difference to antenatal detection of FGR across England. The last version resulted in the widespread uptake of uterine artery Doppler screening for the first time outside of tertiary centres in England and a significant improvement in the quality of care provided to pregnant women in all types of maternity setting. By introducing more nuanced risk assessment we have sought to reduce intervention whilst maintaining the focus on delivering babies at risk. In this version we seek to clarify this further so that all members of staff caring for women have clear, practical guidance. Our new title “**Fetal Growth: Risk assessment, surveillance, and management.**” reflects this.

## Important changes in this update

- Following a review by the Chief Scientific Officer team only digital measurement of blood pressure is now recommended for risk assessment and monitoring of FGR.
- The previous definition of suboptimal fetal growth of <20g/day in the late third trimester has been too didactically interpreted and has therefore been removed. A prospectively tested method of identifying suboptimal fetal growth in babies >10<sup>th</sup> centile remains elusive so suggestion for replacement is contained within Appendix D.
- National guidance from RCOG on FH and EFW charts remains awaited so Trusts may continue to use a range of charts. However, charts that are appropriate for plotting EFW and birthweight are recommended for reporting to reduce discrepancies.

## 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. 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<sup>9</sup> 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<sup>9</sup>

• 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<sup>9</sup>.

• 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

Element 2 recognises that there remains a range of expert opinions on some interventions and allows some flexibility in the choice of pathways. The pathways in Appendix D have been widely implemented but are not mandated. If an alternative pathway is chosen it should be agreed with local ICSs following advice from the provider's Clinical Network and/or regional team as to whether the pathway is acceptable to prevent idiosyncratic care.

To implement this element effectively Trusts should:

- 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 processes designed to detect an FGR fetus, for example measurement of FH, use and interpretation of charts, ultrasound scanning for growth and uterine artery Doppler measurement to detect early onset FGR.
- Agree a plan so that all blood pressure monitors in use with pregnant women are compliant with [Guidance from the Chief Scientific Officer](#). Plans and timescales must be in view of local resources, with priority given to the replacement of analogue/aneroid blood pressure monitors. In the meantime, the use of non-compliant devices should be raised in the service risk register.
- agree which charts will be used antenatally to measure fetal growth and ensure that these charts are based on EFW reference ranges.
- Electronic ultrasound database and MIS suppliers should provide EFW centile charts and birthweight centile charts with reference curves for the 3<sup>rd</sup> and 10<sup>th</sup> centiles. Providers using paper EFW centile charts and birthweight

centile charts should ensure that the charts have reference curves for the 3<sup>rd</sup> and 10<sup>th</sup> centiles. Actual birthweight of the baby should be assessed using the same methodology used antenatally i.e., based on EFW reference, not a birthweight reference scale to ensure consistency.

Although overdue for revision the [RCOG SGA guideline](#) 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) and it is not anticipated that this will change in planned updates. 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), but evidence to guide practise is due in the next 12-24 months and Trusts may wish to consider waiting for this before implementation.

Version two of the MSDS 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 <10<sup>th</sup> centile and <3<sup>rd</sup> 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	
<p><b>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.</b></p>	
Interventions	
3.1	Information from practitioners, accompanied by an advice leaflet (for example, RCOG or Tommy's leaflet available in multiple languages) on RFM, based on current evidence, best practice and clinical guidelines, to be available to all pregnant women by 28+0 weeks of pregnancy and FM discussed at every subsequent contact.
3.2	Use provided checklist (page 40) to manage care of pregnant women who report RFM, in line with national evidence-based guidance (for example, RCOG Green-Top Guideline 57).
Continuous learning	
3.3	Maternity care providers should 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	Maternity care providers should ensure whether inequalities (particularly relating to ethnicity and deprivation) are being adequately addressed when there are incidents relating to presentation with or management of RFM.
3.5	Individual Trusts should examine their outcomes in relation to similar Trusts to understand variation and inform potential improvements.
3.6	Maternity providers are encouraged to focus improvement in the following areas: <ul style="list-style-type: none"> <li>a) Signposting to information regarding RFM to pregnant women by 28+0 weeks of pregnancy.</li> <li>b) Appropriate care according to local guidance in relation to risk stratification and ongoing care for women presenting with RFM.</li> <li>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).</li> </ul>

Process indicators	Outcome indicators
3a. Percentage of women who attend with RFM who have a computerised CTG.	3c. Percentage of stillbirths which had issues associated with RFM

3b. Proportion of women who attend with recurrent RFM* who had an ultrasound scan by the next working day to assess fetal growth.	management identified using PMRT. 3d. Rate of induction of labour when RFM is the only indication before 39+0 weeks' gestation.
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## Rationale

Enquiries into stillbirth have consistently described a relationship between episodes of RFM and stillbirth, ranging from the 8<sup>th</sup> CESDI report published in 2001<sup>10</sup> to the MBRRACE-UK reports into antepartum and intrapartum stillbirths respectively<sup>11 12</sup>. In all 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, including an individual patient data meta-analysis have confirmed a correlation between episodes of RFM and stillbirth<sup>13 14</sup>. This relationship increases in strength when women have multiple episodes of RFM in late pregnancy (after 28 weeks' gestation)<sup>14</sup>. There is no accepted definition of what recurrent RFM means; one region of the UK has successfully adopted a consensus definition of two or more episodes of RFM occurring within a 21-day period after 26 weeks' gestation\*. The relationship between RFM and stillbirth appears to be mediated by placental insufficiency<sup>15,16,17</sup>.

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 2023.

## Implementation

[A systematic review](#) found that interventions for encouraging awareness of fetal movement were associated with a reduction in perinatal death, neonatal intensive care unit admissions and Apgar scores of <7 at 5 minutes of age and were not associated with increases in caesarean births or induction of labour. The effect of encouraging fetal movement awareness or clinical management of RFM on stillbirth is uncertain.

It is possible that altering *clinical management after RFM* will cause an increase in ultrasound scans and obstetric intervention, such as induction of labour and Caesarean birth. 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 births. However, this care pathway reduced the



number of SGA babies born at or after 40 weeks' gestation.<sup>18</sup> Other studies found raised awareness of fetal movements, with no mandated management package, did not increase Caesarean births.<sup>19 20</sup>

There are no trials of computerised CTG (cCTG) following presentation with RFM. However, cCTG is recommended as this provides an objective assessment of fetal wellbeing and may be completed more quickly than conventional CTG. If a cCTG 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, previously in this document, computerised CTGs are recommended over and above visualised CTG due to the potential to reduce the risks of human error.<sup>21</sup> 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 Caesarean birth is associated with small increases in perinatal morbidity and neurodevelopmental delay. Thus, a recommendation for birth needs to be individualised and based upon evidence of fetal compromise (for example, abnormal CTG, EFW <10<sup>th</sup> 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 birth, birth with forceps or ventouse, fetal morbidity or admission to the neonatal intensive care unit. Therefore, expediting birth by induction of labour (to women for whom this is not contraindicated) could be discussed (risks, benefits and mother's wishes) with women presenting with a single episode of RFM after 38+6 weeks gestation. The patient decision aid for timing of induction of labour should be used.

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 expediting birth (by the most appropriate route for them) for RFM alone after 39+0 weeks. Decision to offer birth should consider the timing as to whether this can be achieved within the safe capacity of the unit.

## 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 (if not on an ultrasound surveillance pathway already).

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 only need to be offered on first presentation of RFM if there is an 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 growth scan in the previous two weeks.

In cases of RFM after 38+6 weeks discuss induction of labour with all women and offer birth 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

<b>Element description</b>	
<b>Effective fetal monitoring during labour.</b>	
<b>Interventions</b>	
4.1	All staff who care for women in labour are required to undertake annual training and competency assessment on knowledge and skills required for effective fetal monitoring via Intermittent auscultation (IA) [Midwives] and electronic fetal monitoring [Midwives and Obstetricians].
4.2	At the onset of every labour, there is a structured risk assessment undertaken which informs the clinicians recommendation of the most appropriate fetal monitoring method at the start of labour. This risk assessment should be revisited throughout labour as part of a holistic review.
4.3	Regular (at least hourly) systematic review of maternal and fetal wellbeing should be agreed and implemented. This should be accompanied by a clear guideline for escalation if concerns are raised using this structured process. All staff to be trained in the review system and escalation protocol.
4.4	A buddy system should be used to help provide an objective holistic review for example 'Fresh Eyes' – this should be undertaken at least hourly when CTG monitoring is used and at least four hourly when IA is utilised, unless there is a trigger to provide a holistic review earlier.
4.5	Identify a dedicated lead midwife (minimum of 0.4 WTE) and lead obstetrician (minimum 0.1WTE) with demonstrated fetal monitoring expertise to focus on and champion best practice in fetal monitoring.
<b>Continuous learning</b>	
4.6	Maternity care providers should 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.
4.7	Individual Trusts should examine their outcomes in relation to similar Trusts to understand variation and inform potential improvements.
4.8	Maternity providers are encouraged to focus improvement in the following areas: <ul style="list-style-type: none"> <li>a) Risk assessment of the woman/fetus at the beginning and regularly during labour.</li> <li>b) Interpretation and escalation of concerns over fetal wellbeing in labour.</li> </ul>

Process indicators	Outcome indicators
<p>4a. Percentage of staff who have received training on CTG interpretation and intermittent auscultation, human factors and situational awareness.</p> <p>4b. Percentage of staff who have successfully completed mandatory annual competency assessment.</p> <p>4c. Fetal monitoring lead roles appointed</p>	<p>4d. 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.</p> <p>*Using the severe brain injury definition as used in Gale et al. 2018.</p>

## Rationale

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 birth of a healthy baby, is underlined by data from the RCOG's Each Baby Counts report, 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 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 IA and a failure to recognise transition between the stages of labour.

In the case of a high-risk labour where continuous monitoring is needed, CTG is the best clinical tool available to carry this out as it is a well-established method of confirming fetal wellbeing and identification of potential fetal hypoxia. However, CTG interpretation is a high-level skill and is susceptible to variation in judgement between clinicians and by the same clinician over time<sup>22</sup>. These variations can lead to inappropriate care planning and subsequently impact on perinatal outcomes<sup>23</sup>.

The RCOG's Each Baby Counts report 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

Many of the findings and recommendations from the Each Baby Counts report are echoed in the 2017 MBRRACE-UK Perinatal Confidential Enquiry that focused 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 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 should be able to demonstrate that all qualified staff who care for women in labour are competent to interpret IA [Midwives] and CTG [Midwives and Obstetricians] in relation to the clinical situation, use the Buddy system 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 4.1:** Owing to a lack of validated packages it is not possible to be prescriptive about the exact nature of either training packages or competency assessment. Principles for training packages are included in Appendix E.

However, it is recommended that all trusts mandate annual human factor training for all staff working in a maternity setting; this should include the principles of psychological safety and upholding civility in the workplace, and ensuring staff are enabled to escalate clinical concerns. The content of human factor training must be agreed within the LMNS, [Ockenden, 2022](#)

**Intervention 4.2:** The MBRRACE-UK Perinatal Confidential Enquiry report recommended the national development of a standardised risk assessment tool. As this is not yet available the procedure should comply with fetal monitoring guidelines.

**Intervention 4.3:** The principle underlying this intervention is that fetal wellbeing is assessed regularly (at least hourly) during labour and documented using a structured proforma. This review should be more than recording the fetal heart rate via IA or categorisation of the CTG (Appendix E).

**Intervention 4.4:** A discussion between the midwife caring for the woman and another midwife or doctor should occur at least 4 hourly when undertaking IA and at least hourly when using CTG monitoring. The discussion should include the FHR (IA or CTG), review of antenatal risk factors such as concurrent reduced fetal movements, fetal growth restriction, previous caesarean section; and intrapartum risk factors such as meconium, suspected infection, vaginal bleeding or prolonged labour and should lead to escalation if indicated (Appendix E).

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

**Intervention 4.5:** 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 Leads have dedicated time within their remit to support staff working in intrapartum care to provide high quality intrapartum risk assessments and accurate fetal heart rate interpretation using either IA or CTG. The role should contribute to building and sustaining a safety culture in intrapartum care with all staff committed to continuous improvement.

## Element 5: Reducing preterm births and optimising perinatal care.

Element description		
<p>Reducing the number of preterm births and optimising perinatal care when preterm birth cannot be prevented.</p>		
<p><b>SBLCBv3 Element 5 Reducing Preterm Births and Optimising Perinatal Care</b></p>		
<p><b>Predict</b></p> <ul style="list-style-type: none"> <li>• Assess all women at booking of risk of Preterm birth</li> <li>• Preterm Birth Clinics, Cervical length scanning, Fibronectin</li> </ul>	<p><b>Preterm Birth Lead Team</b></p> <ul style="list-style-type: none"> <li>• Obstetrician</li> <li>• Midwife</li> <li>• Neonatologist</li> <li>• Neonatal Nurse</li> </ul>	
<p><b>Prevent</b></p> <ul style="list-style-type: none"> <li>• Smoking cessation, low dose aspirin, continuity of care</li> <li>• Cervical Cerclage, Progesterone, <u>Arabin</u> pessary</li> <li>• Preterm Birth Clinics, consider aspirin, smoking status</li> <li>• Cervical length scanning</li> </ul>		
<p><b>Perinatal Optimisation</b></p> <table border="0"> <tr> <td> <ul style="list-style-type: none"> <li>• Place of Birth</li> <li>• Antenatal Steroids</li> <li>• Antenatal Magnesium</li> <li>• Intrapartum Antibiotics</li> <li>• Cord Management</li> </ul> </td> <td> <ul style="list-style-type: none"> <li>• Normothermia</li> <li>• Early Maternal Breast Milk</li> <li>• Volume Targeted Ventilation</li> <li>• Caffeine</li> </ul> </td> </tr> </table>		<ul style="list-style-type: none"> <li>• Place of Birth</li> <li>• Antenatal Steroids</li> <li>• Antenatal Magnesium</li> <li>• Intrapartum Antibiotics</li> <li>• Cord Management</li> </ul>
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Interventions		
<p><b>Preterm Birth Lead Team</b></p> <p>5.1 Each provider trust should have.</p> <ol style="list-style-type: none"> <li>An Obstetric Consultant lead for preterm birth, delivering care through a specific preterm birth clinic, or within an existing fetal medicine service.</li> <li>An identified local preterm birth/perinatal optimisation Midwife Lead</li> <li>A Neonatal Consultant lead for preterm perinatal optimisation</li> <li>An identified Neonatal Nursing lead for preterm perinatal optimisation</li> </ol> <p>5.2 Each Preterm Birth Lead team should have clear audit and QI pathways for preterm birth prevention, prediction and perinatal optimisation, and should engage in shared learning and QI with local preterm birth clinical networks, LMNSs and neonatal ODNs.</p>		

## **Prediction**

- 5.3 Assessment of all women at booking for their risk of preterm birth and stratification to low, intermediate and high-risk pathways using the criteria in Appendix F. It is recognised that there are imperfections in the predictability of preterm birth on the basis of history; the use of digital algorithms & tools (for example the Tommy's app) may also be useful to support assessment.
- 5.4 In the assessment of women presenting in suspected preterm labour, evaluated digital tools are now available (QUIDS, QUIPP ) to improve predictive accuracy of triage and enable collaborative decision making.
- 5.5 Networked Trusts should agree on the use of these tools within their ICS/LMNS.
- 5.6 Multiple pregnancy - risk assessment and management in multiple pregnancy should comply with NICE guidance or a variant that has been agreed with the local ICS following advice from the provider's regional maternity team.

## **Prevention**

### **All women:**

- 5.7 Assess smoking status (see Element 1) and implement appropriate intervention to ensure the pregnancy is smoke free before 15 weeks.
- 5.8 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 the local network or ICS following advice from the provider's clinical network.
- 5.9 Symptomatic women require assessment using quantitative fetal fibronectin (qfFN) measurements (and use of decision-assist tools such as the QUIPP and QUIDS apps). The use of TVCS may also be used with or without qfFN. Further advice may be sought from UK Preterm Clinical Network, BAPM, or NICE guidance<sup>55</sup>).

### **Women at intermediate or high risk (Appendix F):**

- 5.10 Assess each woman with a history of preterm birth to determine whether this was associated with placental disease and discuss prescribing aspirin with her.
- 5.11 Test 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<sup>54</sup>.
- 5.12 Asymptomatic women should have access to transvaginal cervix scanning (TVCS) to assess the need for further interventions such as cervical cerclage and progesterone supplementation (Appendix F).
- 5.13 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 are best provided on a supra-regional basis in order to maintain expertise.
- 5.14 Midwifery Continuity of Carer (CoC) models, with a focus on individualised risk assessment and care pathways, may prevent preterm birth and save babies' lives. Ref [B0961 Delivering-midwifery-continuity-of-carer-at-full-scale.pdf](#)



[england.nhs.uk](http://england.nhs.uk)). Local implementation plans for midwifery CoC models should ensure prioritisation of women from the most deprived groups in line with Core20+5. However, [Midwifery CoC must be supported by safe staffing levels to preserve the safety of all pregnant women and families](#)

## Perinatal Optimisation

- 5.15 Women identified to be at increased risk of preterm birth should be made aware of the signs/symptoms of preterm labour and encouraged to attend their local maternity unit early if these occur.
- 5.16 Ensure the neonatal team are involved when a preterm birth is anticipated, so that there is time to meet as a perinatal team to discuss care options with parents prior to birth. This is especially important at earlier gestational ages. In the case of extreme prematurity where complex decision making is required (active survival focused care or comfort care), management should be as outlined in the 2019 BAPM Framework for Practice regarding Perinatal Management of Extreme Preterm Birth before 27 weeks of gestation: *“Conversations with parents should be clearly documented and care taken to ensure that the agreed management plan is communicated between perinatal professionals and staff shifts. Decisions and management should be regularly reviewed before and after birth in conjunction with the parents; plans may be reconsidered if the risk for the fetus/baby changes, or if parental wishes change.”*  
<https://www.bapm.org/resources/80-perinatal-management-of-extreme-preterm-birth-before-27-weeks-of-gestation-2019>
- 5.17 Women identified to be potentially at increased risk of imminent preterm birth, where active survival focused care is planned, should be made aware of optimisation interventions that may be offered. Families should also be offered information and support for families from charities such as Bliss.
- 5.18 Acute tocolysis may be used when short term delay is desirable i.e., in utero transfer, and probably to ensure adequate antenatal exposure to corticosteroid/magnesium sulphate (i.e. no longer than 48 hours). There is no evidence that maintenance tocolysis is beneficial when compared with no tocolysis treatment, oxytocin antagonist and calcium channel blockers appear effective in delaying birth for more than 48 hours. In the absence of any contraindications nifedipine is the preferred agent for tocolysis<sup>2</sup>.
- 5.19 **Place of birth** – Women who have symptoms suggestive of preterm labour or who are having a planned preterm birth:
- less than 27 weeks gestational age (in a singleton pregnancy)
  - less than 28 weeks gestational age (in a multiple pregnancy)
  - any gestation with an estimated fetal weight of less than 800g
- should be managed in a maternity service on the same site as a neonatal intensive care unit (NICU). Maternity services must operate in close perinatal collaboration with neonatal networks to ensure that babies predicted to require a higher level of neonatal care than can be provided in the local delivery unit are moved in utero whenever possible. <https://www.bapm.org/pages/194-antenatal-optimisation-toolkit>

- 5.20 **Antenatal corticosteroids** should be offered to women between 22+0 (where active management is agreed) and 33+6 weeks of pregnancy, optimally at 48 hours prior to birth. A steroid-to-birth interval of greater than seven days should be avoided if possible. and repeat courses of steroids should be avoided where possible. <https://www.bapm.org/pages/194-antenatal-optimisation-toolkit>
- 5.21 **Magnesium sulphate** to be offered to women between 22+0 (where active management is agreed) 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. <https://www.bapm.org/pages/194-antenatal-optimisation-toolkit>
- 5.22 **Intrapartum antibiotics** All women in preterm labour at less than 37 weeks of gestation should receive intravenous intrapartum antibiotic prophylaxis (Benzylpenicillin, where not contraindicated) to prevent early onset neonatal Group B Streptococcal (GBS) infection irrespective of whether they have ruptured amniotic membranes. This excludes planned caesarean births without labour. NB – this intervention should be considered up to 36+6 weeks.
- 5.23 **Cord Management** Babies born at less than 37 weeks gestational age should have their umbilical cord clamped at or after one minute after birth – this can have benefits for all babies. Perinatal multidisciplinary teams should work together to ensure this can reliably be delivered at all births. <https://www.bapm.org/pages/197-optimal-cord-management-toolkit>
- 5.24 **Normothermia** Babies born at less than 37 weeks gestational age should have a first temperature which is both between 36.5–37.5°C and measured within one hour of birth. Neonatal normothermia can have benefits for all babies. <https://www.bapm.org/pages/105-normothermia-toolkit>
- 5.25 **Early maternal breast milk (MBM)** Babies born below 37 weeks gestational age should receive their own mother’s milk, ideally within 6 hours, but aiming always within 24 hours of birth (except in rare situations where there are contraindications to MBM). Perinatal teams should work together to ensure consistent delivery of antenatal advice about MBM, with support (equipment, education, help) for mothers to express within two hours of birth. <https://www.bapm.org/pages/196-maternal-breast-milk-toolkit>
- 5.26 **Volume-Targeted Ventilation** For babies born below 34 weeks’ gestation who need invasive ventilation, use volume-targeted ventilation (VTV) in combination with synchronised ventilation as the primary mode of respiratory support. This reduces the chance of death or bronchopulmonary dysplasia by 27% and intraventricular haemorrhage (grades 3–4) by 47% compared with pressure-limited ventilation modes.  
*\*NB – For preterm babies who do not need invasive ventilation, consider nasal CPAP or nasal high-flow therapy as the primary mode of respiratory support.*  
<https://www.nice.org.uk/guidance/qs193/chapter/Quality-statements>  
<https://www.gettingitrightfirsttime.co.uk/medical-specialties/neonatal-intensive-care/>
- 5.27 **Caffeine** For babies born below 30 weeks’ gestation, caffeine reduces the chance of death or disability. Caffeine should be started within 24 hours of birth  
<https://www.nice.org.uk/guidance/qs193/chapter/Quality-statements>  
<https://www.gettingitrightfirsttime.co.uk/medical-specialties/neonatal-intensive-care/>

## Continuous learning & improvement

- 5.28 All providers are encouraged to draw upon the learning from the four BAPM toolkits and a range of resources from other successful regional current programmes (e.g., PERIPrem resources, MCQIC )
- <https://www.bapm.org/pages/104-qi-toolkits>
  - <https://www.england.nhs.uk/mat-transformation/maternal-and-neonatal-safety-collaborative/>
  - <https://ihub.scot/improvement-programmes/scottish-patient-safety-programme-spsp/spsp-programmes-of-work/maternity-and-children-quality-improvement-collaborative-mcqic/neonatal-care/>
  - <https://www.weahsn.net/our-work/transforming-services-and-systems/periprem/>
- 5.29 Maternity & Neonatal care providers should determine and act upon all themes related to preterm birth that are identified from investigation of incidents, perinatal reviews and examples of excellence, particularly focusing on prediction, prevention, preparation and perinatal optimisation, including:
- Risk assessment of women in their first pregnancy for the risk of preterm birth and timely triage to the appropriate care pathway.
  - Management of women at high risk of preterm birth, including appropriate cervical length surveillance and use of cervical cerclage.
  - Implementation of optimisation interventions as a whole **preterm perinatal optimisation** pathway, including measurement and reporting of overall optimisation pathway compliance
- 5.30 Maternity & Neonatal care providers should demonstrate continuing improvement by regular reassessment of the process and outcome indicators below. These data can be accessed through a number of national and network level data sources including the [National Neonatal Audit Programme \(NNAP\)](#) and Neonatal ODN data. Data completeness via electronic maternity and neonatal record systems is vitally important, and data quality should be monitored frequently. Provider Trusts should seek to support data quality assurance, including support for data clerk or data manager time.
- 5.31 **Benchmarking:** Maternity & Neonatal care providers should examine their process and outcome indicators in relation to similar provider Trusts to understand variation and inform potential improvements.
- 5.32 **Sharing learning & improvement:** The preterm birth teams (see 5.1) within each Maternity & Neonatal care provider setting should:
- Review and share their process and outcome indicator data across the perinatal team on a regular basis (at least quarterly) to drive continual improvement.
  - Share process and outcome indicator data, and evidence of improvement with their Maternity & Neonatal Board level safety champions, LMNS (Local Maternity & Neonatal System) and ICS (Integrated Care System) quality surveillance teams on a quarterly basis.

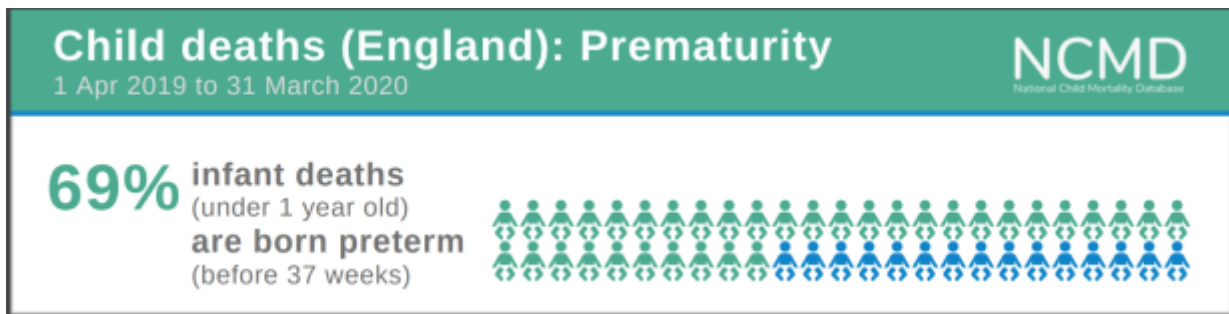
Process indicators	Outcome indicators
<p>5a. Percentage of singleton infants less than 27 weeks of gestation, multiples less than 28 weeks of gestation, or any gestation with an estimated fetal weight of less than 800g, born in a maternity service on the same site as a neonatal intensive care unit (NICU)</p> <p>5b. Percentage of babies born before 34 weeks of gestation who receive a full course of antenatal corticosteroids within 1 week of birth.</p> <p>5c. Percentage of babies born before 30 weeks of gestation who receive magnesium sulphate within the 24 hours prior to birth.</p> <p>5d. Percentage of women who give birth following preterm labour below 34 weeks of gestation who receive IV intrapartum antibiotic prophylaxis to prevent early onset neonatal Group B Streptococcal (GBS) infection.</p> <p>5e. Percentage of babies born below 34 weeks of gestation who have their umbilical cord clamped at or after one minute after birth.</p> <p>5f. Percentage of babies born below 34 weeks of gestation who have a first temperature which is both between 36.5–37.5°C and measured within one hour of birth.</p> <p>5g. Percentage of babies born below 34 weeks of gestation who receive their own mother’s milk within 24 hours of birth.</p> <p>5h. Perinatal Optimisation Pathway Compliance (Composite metric): Proportion of individual elements (5a – 5g above) achieved. Denominator is the total number of babies born below 34 weeks of gestation multiplied by the number of appropriate elements (eligibility according to gestation)</p> <p><i>To minimise the need for local data collection to support these improvements the forma collection of process measure data can be restricted to the seven interventions listed in this section the use of volume targeted</i></p>	<p>5i. <b>Mortality to discharge in very preterm babies</b> (NNAP definition) Percentage of babies born below 32 weeks gestation who die before discharge home, or 44 weeks post-menstrual age (whichever occurs sooner)</p> <p>5j. <b>Preterm Brain Injury</b> (NNAP definition): Percentage of babies born below 32 weeks gestational age with any of the following forms of brain injury:</p> <ul style="list-style-type: none"> <li>a) Germinal matrix/ intraventricular haemorrhage</li> <li>b) Post haemorrhagic ventricular dilatation.</li> <li>c) Cystic periventricular leukomalacia</li> </ul> <p>5k. Percentage of perinatal mortality cases annually (using PMRT for analysis) where the prevention, prediction, preparation or perinatal optimisation of preterm birth was a relevant issue.</p> <p>5l. Maternity care providers will provide outcome data to the Trust Board and share this with the LMNS relating to the incidence of women with a singleton pregnancy giving birth (liveborn and stillborn) as a % of all singleton births:</p> <ul style="list-style-type: none"> <li>a) in the late second trimester (from 16+0 to 23+6 weeks).</li> <li>b) preterm (from 24+0 to 36+6 weeks).</li> </ul>

ventilation and caffeine is recommended but these data are not currently recorded or presented with national datasets In addition, the gestational limits for some of the indicators and/or the groups studies have been adjusted to align with current nationally collected data (e.g. data on babies born only below 34 weeks or data on the number of babies receiving antenatal corticosteroids rather than the number of mothers)

## Rationale

- Preterm birth (PTB), defined as birth at less than 37+0 week’s gestation, is a common complication of pregnancy, comprising around 8% of births in England and Wales<sup>24</sup>. Prematurity is the most significant cause of mortality in children under five and is associated with significant morbidity in surviving infants. PTB is estimated to cost health services in England and Wales £3.4bn per year<sup>24</sup>.

**Figure 5:**



- [The NHS Long Term Plan](#) has an ambitious goal to reduce stillbirth, neonatal mortality and serious brain injury by 25% by 2020, and 50% by 2025. 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<sup>25 26</sup>, 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.

- There are evidence-based perinatal interventions to reduce the risk of preterm mortality or serious brain injury. Perinatal optimisation refers to the process of reliably delivering these evidence-based interventions in the antenatal, intrapartum and neonatal period to improve preterm outcomes.
- [UK audit data](#) show there is variable uptake in these interventions with wide variability between units and networks .
- The British Association of Perinatal Medicine has released a series of [QI toolkits](#) to support implementation of this perinatal optimisation pathway.

## Implementation

All the elements within SBLCBv3 address iatrogenic preterm and early term birth, recognising the need to ensure that any decision for birth is based on evidence of maternal and/or fetal compromise. This element focuses on reducing spontaneous preterm birth via prediction, prevention, and preparation. This will need to be done in the context of a strong perinatal team including neonatology, obstetrics and midwifery. <https://www.bapm.org/resources/building-successful-perinatal-teams-doc>

- The Preterm Birth Lead Team (see 5.1) should provide leadership and oversight of the implementation of Element 5 of SBLCBv3.
- Providers should have provision for care for women at risk of preterm birth ideally within a preterm birth prevention clinic with midwifery support and access to risk assessment 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 should ensure that women are able to access care that guarantees that they are given evidence-based information, access to risk assessment tests and interventions as appropriate and can actively participate in decisions regarding their management.
- Providers should have access to supra-regional prevention services within their care pathways and networks, which include access to high vaginal and transabdominal cerclage.

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

- <https://www.bapm.org/pages/104-qi-toolkits>
- <https://www.england.nhs.uk/mat-transformation/maternal-and-neonatal-safety-collaborative/>
- <https://ihub.scot/improvement-programmes/scottish-patient-safety-programme-spsp/spsp-programmes-of-work/maternity-and-children-quality-improvement-collaborative-mcqc/neonatal-care/>
- <https://www.weahsn.net/our-work/transforming-services-and-systems/periprem/>
- <https://www.bapm.org/resources/80-perinatal-management-of-extreme-preterm-birth-before-27-weeks-of-gestation-2019>.
- [NICE Guideline NG25 'Preterm labour and birth'](#)
- [NICE Diagnostics Guidance DG33 'Biomarker tests to help diagnose preterm labour in women with intact membranes'](#)
- [Ockenden Report \(2022\) Element 9](#)
- [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.

## Element 6: Management of Pre-existing Diabetes in Pregnancy

### **Background and rationale for introducing management of Diabetes in pregnancy into the SBLCB.**

Women with Type 1 and Type 2 diabetes have persistently high perinatal mortality with no improvement over the past 5 years. Contemporary annual data from the mandatory National Pregnancy in Diabetes audit (NHS Digital) (Lancet D&E 2021) in England & Wales shows that perinatal loss in diabetes is 4-5 times higher than the background population: In women with Type 1 diabetes, stillbirth occurs in 10·4 per 1000 livebirths and stillbirths, with neonatal death occurring in 7·4 per 1000 livebirths; In women with Type 2 diabetes it is even higher - stillbirth occurs in 13·5 per 1000 livebirths and stillbirths, with neonatal death occurring in 11·2 per 1000 livebirths. The risk of perinatal mortality is highest in women who are the most socioeconomically deprived (increased 2-fold) and those who have suboptimal glucose control in the third trimester (increased 3 fold). As women with diabetes are more socioeconomically deprived and more likely to be of South Asian and Black ethnicity than pregnant women without diabetes, there is an urgent need to address these inequalities.

Introducing management of Diabetes into the SBLCB allows us to do this in two keyways:

- Ensuring there are standard pathways of care for MDT management of these women throughout pregnancy, with increased access to expert and ‘joined-up’ support for their complex care needs.
- Improving management of glucose control during pregnancy by focusing support on high-risk women who are not achieving safe pregnancy glycaemic targets and by ensuring consistent and high levels of uptake of digital glucose monitoring technology to facilitate this.

The recent Ockenden report has highlighted the need for continuity of experienced staff within Diabetes in Pregnancy teams to reduce poor outcomes in women with diabetes.

The recent MBBRACE report has highlighted the very high risk of fetal death (stillbirth rate 160 per 1,000 births) associated with diabetic ketoacidosis (DKA).



## Element description

Providing multidisciplinary care in a joined-up way for women with type 1 and type 2 diabetes during pregnancy and harnessing technology (e.g. continuous glucose monitoring) to reduce maternal complications of diabetes, including perinatal morbidity and mortality.

## Interventions

- 6.1 Women with a diagnosis of pre-existing diabetes in pregnancy should be offered care in a one stop clinic, providing care to pre-existing diabetes only, which routinely offers multidisciplinary review and has the resource and skill set to address all antenatal care requirements. The multidisciplinary team should consist, as a minimum, of: Obstetric Consultant, Diabetes Consultant, Diabetes Specialist Nurse, Diabetes Dietitian, Diabetes Midwife.
- 6.2 Women with type 1 diabetes should be offered real time continuous glucose monitoring (CGM) and be provided with appropriate education and support to use this.
- 6.3 Women with type 2 diabetes should have an objective record of their blood glucose recorded in their hospital records/EPR and be offered alternatives (e.g., intermittently scanned CGM) to blood glucose monitoring if glycaemic targets are not achieved
- 6.4 Women with diabetes should have an HbA1c measured at the start of the third trimester and those with an HbA1c above 48mmol/mol should be offered increased surveillance including additional diabetes nurse/dietetic support, more frequent face to face review and input from their named, specialist Consultant to plan ongoing care and timing of birth decisions.

Green	HbA1c 43 mmol/mol or less	Continue current care
Amber	HbA1c 44-48 mmol/mol	Consider additional input to improve glucose management
Red	HbA1c more than 48 mmol/mol	MDT discussion required.  Offer additional input to improve glucose management including alternative methods of monitoring treatment.  Offer increased fetal surveillance, and re-discuss increased risk of stillbirth, birth and neonatal complications.

- 6.5 Women with diabetes and retinopathy requiring treatment during pregnancy and/or kidney impairment (CKD 2 with significant proteinuria i.e. PCR>30; or CKD 3 or more) should be managed in a regional maternal medicine centre where care can be delivered in a single MDT clinic. In circumstances where regular travel to a tertiary clinic is not possible, ongoing care should be planned via regular (4-6 weekly) MDT discussion with the MMC centre throughout the pregnancy.
- 6.6 Recognising the very high risk of fetal death (stillbirth rate 160 per 1,000 births) associated with diabetic ketoacidosis (DKA), all pregnant women presenting to secondary care with DKA should have ongoing multidisciplinary Consultant input and be cared for in line with the jointly agreed trust policy.

### Continuous learning

- 6.7 Maternity care providers involved in the care of women with type 1 and type 2 diabetes should examine their outcomes in relation to all themes related to these women. These include risk assessment and management in the antenatal and intrapartum period.
- 6.8 Maternity care providers who look after women with type 1 and type 2 diabetes in pregnancy should submit data to the NPID audit, review their submissions and develop an action plan to address ongoing challenges.
- 6.9 Individual Trusts should examine their outcomes in relation to other Trusts caring for women in pregnancy with type 1 and type 2 diabetes and engage with wider regional and national Diabetes Clinical networks to share examples of good practice and work collaboratively to address challenges.
- 6.10 Individual Trusts should actively gather feedback from service users about their care, and co-produce guidance and proposed care pathways with Maternity Voices Partnerships (MVP) members with 'lived experience'.
- 6.11 All cases of perinatal death in women with diabetes, or where diabetes is considered to be a possible contributory factor, should be reviewed by a multidisciplinary team which includes members with expertise in the care of women with diabetes in pregnancy. Learning from these case reviews should be disseminated as appropriate and an action plan developed to reduce the risk of recurrence.
- 6.12 Any pregnancies where CGM or HbA1C was not offered in line with the recommendations should be subject to case review to determine service-level issues which could be addressed.

Process indicators	Outcome indicators
<p>6a. Demonstrate an agreed pathway for women to be managed in a clinic, providing care to women with pre-existing diabetes only, where usual care involves joined-up multidisciplinary review (The core multidisciplinary team should consist of Obstetric Consultant, Diabetes Consultant, Diabetes Specialist Nurse, Diabetes Dietitian, Diabetes Midwife) and holistic pregnancy care planning – this should be a one stop clinic where possible and include a pathway for the provision/access to additional support (e.g. asylum support, psychology, mental health) either within the clinic or within a closely integrated service (with shared documentation etc).</p> <p>6b. Demonstrate an agreed pathway for referral to the regional maternal medicine for women with complex diabetes.</p> <p>6c. Demonstrate an agreed method of objectively recording blood glucose levels and achievement of glycaemic targets.</p> <p>6d. Demonstrate compliance with CGM training and evidence of appropriate expertise within the MDT to support CGM and other technologies used to manage diabetes.</p> <p>6e. Demonstrate an agreed pathway (between maternity services, emergency departments and acute medicine) for the management of women presenting with DKA during pregnancy. This should include a clear escalation pathway for specialist obstetric HDU or ITU input, with the agreed place of care depending on patients gestational age, DKA severity, local facilities and availability of expertise.</p>	<p>6f. The percentage of women with type 1 diabetes that have used CGM during pregnancy – reviewed via the NPID dashboard (aiming for &gt;95% of women)</p> <p>6g. The percentage of women with type 1 and type 2 diabetes that have had an HbA1c measured at the start of the third trimester (aiming for &gt;95% of women)</p> <p><i>Compliance data for both outcome indicators should be reported by ethnicity and deprivation to ensure focus on at-risk and under-represented groups.</i></p>

## **Reducing perinatal mortality in pregnancies complicated by diabetes.**

This element provides a practical approach to reducing perinatal mortality in pregnancy affected by Type 1 or Type 2 diabetes, by implementing multidisciplinary team pathways and an intensified focus on glucose management within maternity settings in line with the NHS Long Term Plan and NICE guidance. It focuses on demonstrating clear multidisciplinary pathways to provide a dedicated, integrated service for addressing complex needs (and thereby mitigate risk for poor pregnancy outcome). Furthermore, as glucose is the most significant modifiable risk factor for poor pregnancy outcome in pregnancies complicated by diabetes, the element includes: clear documentation of assessing glucose control digitally; using HbA1c to risk stratify and provide additional support/surveillance ([National Diabetes Audit data](#)); and offering consistent access to evidence based Continuous Glucose Monitoring (CGM) technology to improve glucose control (NICE and NHS plan).

## Appendix A: Acknowledgments

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

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### Element 3: Raising awareness of reduced fetal movement (acknowledgments TBC)

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## Element 6: Management of Diabetes in pregnancy

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## Appendix B: Detailed safe and healthy pregnancy messages

There are numerous causes of stillbirth, many of which are poorly understood. [MBRRACE-UK](#) highlights that stillbirth and neonatal mortality rates are higher in women from Black, Asian and minority ethnic backgrounds, those living in areas of deprivation and twin pregnancies. Almost three-quarters of both stillbirths and neonatal deaths occur preterm therefore maternity advice and care should be focused on mitigating risk. Other at-risk groups are women with pre-existing medical conditions especially cardio-vascular disorders; diabetes, psychiatric disorders and maternal age (teenage and older women) and women living with obesity. Health professionals should consider these risk factors (as well as smoking, drinking, recreational drug-taking, oral hygiene and diet) and take appropriate action for individual women. Providing information as 'safe and healthy pregnancy' messages for all women presents an opportunity to raise awareness of pre-term birth as well as stillbirth as an uncommon but possible outcome.

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 and Covid 19 vaccination.

### Background

It is unhelpful to make women feel unnecessarily anxious or judged. Key messages need to be shared sensitively with women to enable them to know what they can do to help themselves and their baby stay safer in pregnancy.

For women who are at increased risk of stillbirth, communication may be a barrier. It is important to provide information in a format and/or language that is easily



accessible and understood. For non-English speaking women, it is imperative that an interpreter/translation service is utilised and family members and/or friends are not used as an alternative.

[Safer Pregnancy](#) is a website developed by Sands that carries safer pregnancy messages with 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.

### Pre-pregnancy

**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. Planning your pregnancy facilitates accessing pregnancy care at the right time and early booking is associated with better outcomes.

**Tip:** Encourage women to speak to a health professional about the range of contraception options available. Some maternity services are now offering contraception from birth (IUCD at Caesarean birth) and/or on the postnatal wards.

**Advice point:** Consult with your GP if taking medication for long-term conditions (e.g., diabetes, hypertension, epilepsy)

**Why is this important?** Some medications may have to change prior to pregnancy e.g. Sodium Valporate is not recommended in pregnancy as it can cause birth defects as well as problems with baby's learning and behaviour. Outcomes are better if conditions such as diabetes; epilepsy; hypertension for example are optimised prior to conception.

**Tip:** GPs to ensure women of childbearing age are aware of their personal status regarding medications and pregnancy as part of medication review appointments.

**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 including an increased risk that their baby will be stillborn.

**Tips:** Encourage women who are overweight or have obesity 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.

**Advice point:** Take a daily supplement of 400 micrograms (400 µg) folic acid before conception and until the 12<sup>th</sup> week of pregnancy (some women will require a higher dose of 5mg as advised by a healthcare professional).

**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.

**Tips:** Encourage women to take folic acid in preparation for pregnancy

**Advice point:** Before pregnancy, ensure that you are protected from **measles, rubella, Coronavirus (Covid 19) and Flu**. Check you are vaccinated if you're thinking of becoming pregnant.

**Why is this important?** Maternal rubella and maternal measles infection in pregnancy may result in fetal loss or congenital rubella syndrome. Coronavirus in pregnancy is associated with a 2-3 times greater risk of pre-term birth and increased risk of stillbirth therefore vaccinations in preparation for pregnancy are strongly recommended. Coronavirus and Flu are also associated with severe illness in pregnant women causing hospital admission.

**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. Coronavirus vaccinations can be given at the same time as seasonal flu vaccines. There are no published studies that demonstrate an increased risk of miscarriage or problems with fertility associated with COVID-19 vaccinations.

**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. Women at risk should be referred for pre-pregnancy counselling with genetic specialist.

**Advice point:** Stop smoking and/or exposure to second hand smoke.

**Why is this important?** Smoking and second-hand smoke can impact on fertility. It can take time to stop smoking so leaving it until pregnancy will be less immediate and can be less successful thus exposing the baby to greater risk. Tobacco smoke contains thousands of chemicals, and many are toxic. They can pass through the placenta to the baby and affect their development. A small baby who doesn't grow healthily has an increased chance of being stillborn. Smoking or exposure to second hand smoke also increases the likelihood of a baby being born prematurely, and that they will have health and development problems in childhood and later life.

**Tips:** The best thing a woman **who smokes** can do is stop. Find out about local stop smoking support available for women and families in your area and adopt an opt out approach to smoking cessation.

**Advice point:** Reduce/stop alcohol consumption in preparation for pregnancy.

**Why is this important?** Drinking to excess can be associated with unplanned pregnancy. Alcohol passes from the mother's blood across the placenta to the developing baby. Alcohol in the baby's blood has a direct effect on the baby and

can lead to birth defects, reduced growth and effects on brain and nervous system with long-term learning and behaviour problems. It can also affect the placenta and interfere with the baby's oxygen and nutrient supply. 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 to drink alcohol at all while planning to become pregnant. There are free and confidential helplines for people concerned about their, or a relative's, drinking. Drinkline 0300 123 1110. [NHS UK](#) (formerly NHS Choices) has additional options.

## During Pregnancy

**Advice point:** Continue to take Folic Acid until the 12<sup>th</sup> week of pregnancy.

**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.

**Tips:** Encourage women to continue to take folic acid until the 12<sup>th</sup> week of pregnancy

**Advice point:** Pregnant women should take 10µg of Vitamin D a day.

**Why is this important?** Pregnant women (and all adults, including breastfeeding women) are also recommended to have 10 µg of vitamin D a day. Vitamin D regulates the amount of calcium and phosphate in the body, which keeps bones, teeth and muscles healthy. Women with BMI >25 have decreased bioavailability of vitamin D which makes these women and their babies at greater risk. Some women are more likely to need vitamin D than others, those who rarely go outside; always cover their skin; use high-factor sun block; have darker skin; have a BMI above 25.

**Tips:** Encourage women to take Vitamin D in pregnancy; particularly women with a greater risk of a deficiency, as above

**Advice point:** You may be advised to take aspirin from 12 weeks of pregnancy.

**Why is this important?** Low dose aspirin (150mg) from 12 weeks of pregnancy is recommended for women who are at high risk of pre-eclampsia. Aspirin is a cyclooxygenase inhibitor with anti-inflammatory and antiplatelet properties. There is no increased risk of adverse fetal or neonatal effects associated with low-dose aspirin exposure.

**Tips:** An accurate risk assessment is required at booking to identify women at increased risk of pre-eclampsia and ensure Aspirin prescribed from 12<sup>th</sup> Week of pregnancy.

**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 has a direct effect on the baby and can lead to birth defects, reduced growth and effects on brain and nervous system with long-term learning and behaviour problems. It can also affect the placenta and interfere with the baby's oxygen and nutrient supply. 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 to drink alcohol at all while pregnant. There are free and confidential helplines for people concerned about their, or a relative's, drinking. Drinkline is a national advice line and can be contacted on 0300 123 1110.

**Advice point:** Stop smoking and/or exposure to second hand smoke. [NHS UK](#) (formerly NHS Choices) has additional options.

**Why is this important?** Smoking and exposure to second hand smoke affects the development of the baby and is associated with complications in pregnancy and poor outcomes. Smoking or exposure to second hand smoke also increases the likelihood of a baby being born prematurely. Also, smoking in pregnancy increases the risk of Sudden Infant Death (SID) <https://www.unicef.org/babyfriendly/baby-friendly-resources/sleep-and-night-time-resources/co-sleeping-and-sids/>. Tobacco smoke contains thousands of chemicals, and many are toxic. They can pass through the placenta to the baby and affect their development. A small baby who doesn't grow healthily has an increased chance of being stillborn or having health and development problems in childhood and later life.

**Tips:** The best way for women to protect themselves and their baby is to stop smoking completely and/or reduce/stop exposure to second hand smoke. Stopping at any time in pregnancy will help, although the sooner the better as it may contribute to a low-birth weight baby. Stopping smoking early in pregnancy can almost entirely prevent any damage to the baby. Stopping smoking in early pregnancy, prior to 15 weeks, can reverse the risk of some adverse perinatal outcomes. 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 women and families in your area and adopt an opt-out approach to smoking cessation.

**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 or Text 82111 and FRANK will text back. Healthcare professionals should support and manage the care of pregnant women who use drugs, alcohol or other substances in conjunction with referral to specialist teams (drug and alcohol) where required.

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

**Why is this important?** Women who are overweight or are living with obesity have an increased risk of complications during pregnancy and birth including an increased risk that their baby will be stillborn. Due to the increased risks associated with obesity, birth is recommended in an obstetric unit which affects choice regarding place of birth.

**Tips:** 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. If they are not used to exercise, then they can build up to daily exercise. If there are health reasons why they shouldn't exercise, advise them to talk to their midwife or GP.

**Advice point:** Maintain oral hygiene.

**Why is this important?** Hormone changes can increase blood flow to gum tissues, causing sensitivity, bleeding or swollen gums. This is known as pregnancy gingivitis, which has been linked to poor pregnancy outcomes, including pre-term birth and low birth weight babies.

**Tips:** Free dental care is available to all pregnant women and up to a year after the birth

**Advice point:** Have the seasonal Flu vaccination, it's safe, effective and free of charge to pregnant women.

**Why is this important?** Influenza is more likely to cause severe illness in pregnant women than in women of reproductive age who are not pregnant. Changes to the immune system, heart, and lungs during pregnancy make women more susceptible to influenza severe enough to cause hospitalisation throughout pregnancy and up to two weeks postpartum. A common influenza symptom, e.g., fever, may be associated with neural tube defects and other adverse outcomes for a developing baby such as perinatal mortality, prematurity and lower birth weight. Parental vaccination also can help protect a baby from influenza after birth (because antibodies are passed to a developing baby during pregnancy)

**Tips:** Getting an influenza (flu) vaccine is the first and most important step in protecting against flu. Vaccination has been shown to reduce the risk of flu-associated acute respiratory infection in pregnant women by up to one-half and reduces a pregnant person's risk of being hospitalized with flu by an average of 40 percent. Pregnant women who get a flu vaccine also are helping to protect their babies from flu illness for the first several months after their birth, when they are too young to get vaccinated. Reassure women and their families that Flu vaccinations have been given to millions of people over many years with an excellent safety record.

**Advice point:** Have the pertussis (whooping cough) vaccination.

**Why is this important?** It's safe, effective and free of charge to pregnant women. 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 gives 90% protection against the disease and 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.

**Advice point:** Have the Coronavirus (COVID-19 vaccination/booster

**Why is this important?** Women who are pregnant or were recently pregnant, are more likely to get severely ill from COVID-19 compared to people who are not pregnant. Pregnancy causes changes in the body that can make it easier to get very sick leading to increase hospital admissions, the need for ventilation in intensive care units and the requirement of extracorporeal membrane oxygenation (ECMO). There is also a higher rate of stillbirth in infected women and an increase in babies born pre-term with its associated complications. Other factors can further increase the risk of getting very sick with COVID-19: women from Black Asian and Mixed Ethnic Groups with underlying medical conditions; being older than 25 years; and living/working in communities with high numbers of COVID-19 cases/low levels of COVID-19 vaccination.

**Tips:** Getting a COVID-19 vaccination/ booster is the first and most important step in protecting against COVID-19. Vaccination has been shown to reduce the risk to babies born to vaccinated women of admission to neonatal units and intrauterine fetal death. There are no published studies that demonstrate an increased risk of miscarriage or problems with fertility.

**Advice point:** Always check with your pharmacist, midwife or doctor about medicines and therapies used in pregnancy, even if you have taken them for a long time on prescription or think they are harmless.

**Why is this important?** A medicine or therapy may have different effects on your body if you're pregnant. As a result, familiar medicines and therapies may not always be safe for pregnant women or their developing baby.

**Tips:** If medications are via prescription they should be checked by the pharmacists or doctor who prescribed it. If they are over-the-counter medications, then they should be checked with the pharmacist or midwife. If it's a complimentary or alternative therapy, check with the therapist. Not all therapies are considered safe in pregnancy e.g., some essential oils are not recommended for use while pregnant.

**Advice 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 infections 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 seek advice from their GP or midwife if they have been in contact with someone who has rash-like illnesses, or if they develop a rash-like illness themselves.

**Advice point:** Reduce the risk of CMV (cytomegalovirus) and Toxoplasmosis infections.

**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. Toxoplasmosis is a common infection that is usually harmless. However, if pregnant women get toxoplasmosis for the first time when they are pregnant, or a few months before they conceive, there's a small risk the infections could cause miscarriage or stillbirth.

**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](#).

To prevent toxoplasmosis, it is recommended that gloves are worn during gardening and when emptying cat litter trays/dealing with excrement.

**Advice point:** Attend all antenatal appointments.

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

**Tips:** The first midwife appointment (sometimes called ‘booking appointment’) should happen before 10 weeks. 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 government website

[https://youtu.be/\\_afr5o1lpTM](https://youtu.be/_afr5o1lpTM)\*\* and there are [leaflets](#) also available in 12 languages <http://www.gov.uk/government/publications/screening-tests-for-you-and-your-baby-description-in-brief>

**Tip:** Maternity services are staffed 24/7, and there is always someone who can speak to women on the phone.

**Advice point:** Contact the maternity service promptly if you are worried. Don’t wait!

**Tip:** Maternity services are staffed 24/7, and there is always someone who can speak to women on the phone

[Leaflets](#) are also available in 12 languages

<http://www.gov.uk/government/publications/screening-tests-for-you-and-your-baby-description-in-brief>

**Why is this important?** Timely action is sometimes needed (see below). Women should be aware of who to contact/when if they have concerns as it may be an acute issue that requires a prompt response for the wellbeing of the woman and/or baby. [Leaflets](#) are also available in 12 languages

<http://www.gov.uk/government/publications/screening-tests-for-you-and-your-baby-description-in-brief>

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 different to usual.
- 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.
- Itching, particularly on the hands and feet, can be a sign of the liver disorder called intrahepatic cholestasis of pregnancy (ICP); women should contact a midwife within 24 hours if they experience itching.

**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. Find out more information about sleep positions on the Tommy's website.

**Advice point:** Talk to your midwife about the benefits of breastfeeding.

**Why is this important?** There is overwhelming evidence on the benefits of breastfeeding for babies for a wide range of different health outcomes.

<https://www.unicef.org.uk/babyfriendly/baby-friendly-resources/breastfeeding-resources/off-to-the-best-start/>

**Tips:** Maternity services have specially trained staff to provide you with advice and support with any questions, there is always someone to talk to

## 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). 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 pregnant women for treatment with aspirin. NICE recommends Aspirin<sup>°</sup> reduces the risk of pregnancy complications related to placental dysfunction, particularly preeclampsia<sup>26</sup>. Thus, it is important to take a full history from pregnant women who have had a previous baby with FGR and/or a preterm birth 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.

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<sup>°</sup> Although this use is common in UK clinical practice, at the time of publication, 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.

## Dosage

There is evidence from randomised controlled trials that the dose of aspirin should be 150mg<sup>27</sup> from 12 weeks' gestation and may be more effective if taken at night<sup>28</sup>. In some circumstances this may not be appropriate and lower doses (60-75mg) may be used (for example, pregnant women with hepatic or renal disease). Predictive algorithms that combine a variety of risk factors to identify pregnant 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<sup>29</sup>. Any other algorithm must be agreed with local commissioners (ICBs) following advice from the provider's Clinical Network.

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

Risk level	Risk factors	Recommendation
<b>High</b>	<ul style="list-style-type: none"> <li>• Hypertensive disease during a previous pregnancy</li> <li>• Chronic kidney disease</li> <li>• Autoimmune disease such as systemic lupus erythematosus or antiphospholipid syndrome</li> <li>• Type 1 or type 2 diabetes</li> <li>• Chronic hypertension</li> <li>• Placental histology confirming placental dysfunction in a previous pregnancy</li> </ul>	Recommend low dosage aspirin if the woman has $\geq 1$ of these high-risk factors
<b>Moderate</b>	<ul style="list-style-type: none"> <li>• First pregnancy</li> <li>• Are 40 years or older at booking.</li> <li>• Pregnancy interval of more than 10 years</li> <li>• Body mass index (BMI) of 35kg/m<sup>2</sup> or more at first visit</li> <li>• Family history of preeclampsia in a first degree relative</li> <li>• Multiple pregnancy</li> </ul>	Consider aspirin if the woman has two or more moderate risk factors

There are a few absolute contraindications to aspirin therapy<sup>30</sup>. Pregnant 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 pregnant 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 pregnant 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 marginally increased risk of stillbirth. Trusts may wish to follow other pathways, but these should be agreed with their local ICSs and for some deviations specified in the guidance the regional maternity team.

### Definition of FGR within SBLCBv3

FGR is difficult to diagnose representing those fetuses that have failed to reach their growth potential. A Delphi consensus-based definition has been used in research for both early (defined in the Delphi consensus as <32 weeks) and late onset FGR<sup>31</sup>, but 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 challenge.

The following definitions are suggested to address these challenges and remain practical for most providers. It highlights that absent or reversed end diastolic flow in the umbilical artery is a feature of early onset FGR, importantly even in the absence of this feature (for example, a normal umbilical artery Doppler) after 32 weeks of gestation does not exclude growth restricted or fetal compromise.

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

- birthweight <3<sup>rd</sup> centile
- early onset placental dysfunction necessitating birth <34 weeks.
- birthweight <10<sup>th</sup> 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) <3<sup>rd</sup> centile

- EFW or AC <10<sup>th</sup> centile with evidence of placental dysfunction (either):
- Abnormal uterine artery Doppler (mean pulsatility index >95<sup>th</sup> centile<sup>38</sup>) earlier in pregnancy (20 – 24 weeks) and/or
- Abnormal umbilical artery Doppler (absent or reversed end diastolic flow or pulsatility index >95<sup>th</sup> centile).

### **Suboptimal fetal growth:**

- When assessing fetal growth, a pattern of slowing growth velocity (i.e., a downward trend in the percentile) indicates an increased risk of morbidity and stillbirth and should necessitate review. This review should include assessment of all fetal biometry measurements since the anomaly scan to identify potentially erroneous single measurements and also the presence or absence of other risk factors for FGR. **Particular attention should be paid to a downward trend in abdominal circumference growth velocity.** FGR is rare >20<sup>th</sup> centile, so early delivery (<39+0 weeks) should only be considered following senior review, ideally by a dedicated fetal growth restriction assessment and monitoring service.

### **Risk assessment and screening**

Early onset FGR is rare (~0.5%<sup>73</sup>). Most cases are associated with abnormal uterine artery Doppler indices or already present estimated fetal weight (EFW) <10<sup>th</sup> centile in the early third trimester. Thus, uterine artery Doppler can be used in the second trimester (18+0 – 24+0 weeks) to facilitate determining the risk of placental dysfunction and risk of hypertensive disorders or early onset FGR.

For pregnant women with a normal uterine artery Doppler pulsatility index (mean measurement ≤95<sup>th</sup> centile) the risk of these disorders is low and thus serial scanning for fetal biometry can be routinely planned from 32 weeks gestation.

Pregnant 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 from 32 weeks.

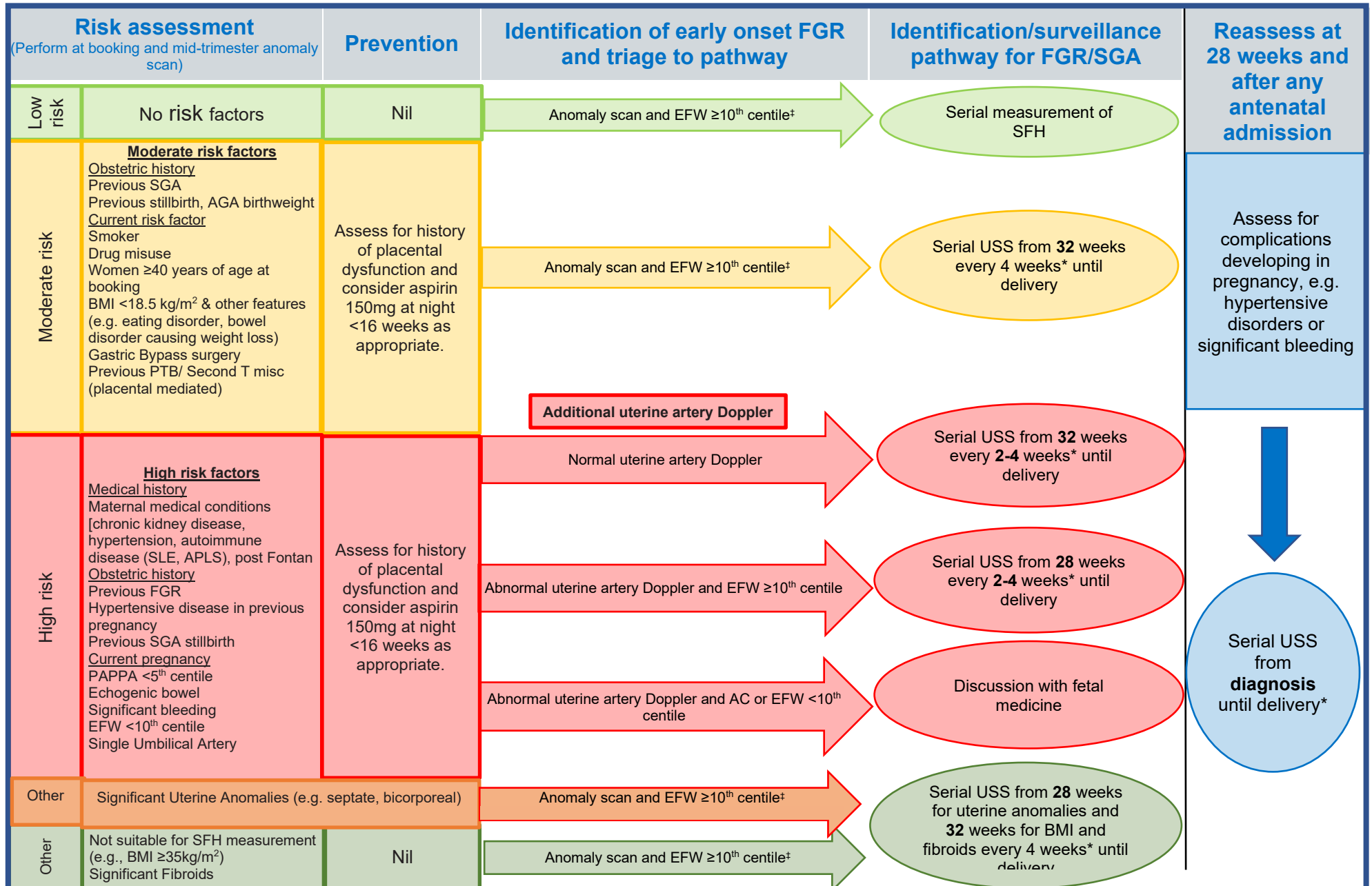
Ongoing surveillance of fetal growth should be performed at intervals between 21 – 28 days whilst fetal growth remains >10<sup>th</sup> centile. For many pregnancies in the moderate risk category or in those unsuitable for SFH measurements, an interval of four weeks is appropriate. For pregnant women in the high-risk category the scan interval should be confirmed following the first assessment for fetal growth, but routine growth assessment should not occur <14 days.

Trusts are encouraged to invest in training of Ultra sonographers 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<sup>32</sup> 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<sup>33</sup>.

Figure 6 provides an algorithm for using uterine artery Doppler as a screening tool for risk of early onset FGR. Note the use of <10<sup>th</sup> centile EFW calculated at the time of the routine anomaly scan is preferred over <10<sup>th</sup> centile AC. ([Ref](#))

**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.

## **Management of FGR**

The RCOG<sup>34</sup> provides detailed recommendations for the monitoring of SGA when EFW is <10<sup>th</sup> centile and Trusts should either follow this guidance or a similar protocol which has been agreed with local commissioners (ICBs) 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 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.

### **FGR diagnosed before 34 weeks' gestation.**

Prior to 34+0 weeks, management of the FGR fetus requires regional network specialist fetal medicine input to determine the most appropriate monitoring for fetal wellbeing and timing of birth where fetal compromise is demonstrated.

Trusts caring for such pregnant 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 (i.e., not 365 days/year), then computerised CTG must be provided for monitoring and a pre-established referral pathway should be present to enable assessment of pregnant women by a specialist fetal medicine service within 72 hours.

Pregnant women with early onset FGR should give birth in a unit with neonatal facilities able to deal with the increased risks of FGR preterm infants. Timing should be determined in collaboration with neonatal colleagues, sub-speciality fetal medicine input, steroid administration and magnesium sulphate administration and be guided by current RCOG guidance and findings from the [Truffle 2 study](#)

### **FGR diagnosed after 34 weeks' gestation.**

For fetuses with an EFW <3<sup>rd</sup> centile diagnosed later in pregnancy birth should be initiated at 37+0 weeks' gestation. If other risk factors are present, then involvement of a specialist fetal growth service or fetal medicine service is required to plan birth.

In fetuses with an EFW between the 3<sup>rd</sup> and <10<sup>th</sup> centile, other risk factors must be present for birth to be recommended prior to 39 weeks. These are reduced fetal

movements, any umbilical artery or MCA Doppler abnormality, cCTG that does not meet criteria, maternal hypertensive disease, abnormal sFlt1: PIGF ratio/free PIGF or reduced liquor volume. If FGR cannot be excluded, then birth after 37 weeks should be discussed with the mother and an ongoing management plan individualised.

For all fetuses with an EFW or AC <10<sup>th</sup> centile, birth or the initiation of induction of labour should be offered at 39+0 weeks after discussion with the mother.

Evidence on the use of MCA Doppler in the management of late onset FGR is awaited and this is not mandated for use in the management of FGR in this version of SBLCB.

For pregnant women who decline induction of labour or birth 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 birth/induction at this gestation ([REF](#)) and that there is no evidence to determine how fetuses with SGA/FGR should be monitored if pregnancy continues  
SGA = 3<sup>rd</sup> to <10<sup>th</sup> centile.



## Appendix E: Risk assessment at the onset of labour

### 4.1 Multidisciplinary Training – Principles:

Include multidisciplinary and scenario-based training – this should involve all medical and midwifery staff who care for pregnant women in birth settings.

All staff to be competent in the use of fetal monitoring equipment.

Teaching about fetal responses to labour including changes in fetal heart rate (FHR). In addition, the impact of factors antenatal risk factors such as fetal growth restriction and intrapartum risk factors such as maternal pyrexia.

Effective fetal monitoring in low-risk pregnancies using IA, the role of IA in initial assessment, in established labour and indications for changing from IA to CTG.

Interpretation of CTG including:

- normal FHR parameters
- impact of intrapartum fetal hypoxia on the FHR
- classification of CTG
- holistic interpretation of fetal monitoring in specific clinical circumstances (such as previous caesarean sections, breech and multiple pregnancy).

Channels of communication to follow in response to a deteriorating CTG trace, and escalation.

Application of local fetal monitoring guideline (NICE, FIGO or Physiological)

Multi-disciplinary training must integrate the local handover tool (such as SBAR) into teaching programme at all trusts ([IEA 7, Ockenden Report](#))

Provision of adequate training is a Trust priority – as a minimum all staff should receive a full day of multidisciplinary training (including the principles outlined above) each year with reinforcement from regular attendance at fetal monitoring review events.

The training and assessment should be agreed with local commissioners (ICBs) based on the advice of the Clinical Network.

Competency assessment: all staff will have to pass an annual competency assessment that has been agreed by the local commissioner (ICBs) 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). Trusts should agree a procedure with their ICB for how to manage staff who fail this assessment.

No member of staff should care for pregnant women in a birth setting without evidence of training and assessment within the last year.

### 4.2 Start of labour risk assessment.

All pregnant women should undergo a full clinical assessment when presenting in early or established labour. This should include a review of any risk factors and consideration of whether any complicating factors have arisen which might change recommendations about place of birth. This assessment should be agreed with local commissioners (ICBs) based on the advice of the Clinical Network and reflect fetal monitoring guidelines. This should be shared with woman and her birth partner to enable an informed decision re place of birth.

### 4.3 Ongoing labour risk assessments

To include: start of labour risk assessment; intrapartum risk factors; consideration of fetal heart rate parameters when using Intermittent auscultation (IA) or cardiotocograph (CTG),

and whether the woman and her birth partner have any concerns. This information is used to inform the whole clinical picture and inform care and escalation if required.

#### **4.4 Buddy system/Fresh Eyes**

There is no evidence to inform the optimal frequency of a buddy system for IA or CTG and/or its effectiveness. However, the concept was introduced to enable a fresh eyes perspective of maternal and fetal wellbeing therefore has the potential to be beneficial and supportive.

IA is predominantly used in low-risk labours where the incidence of hypoxia is very low and therefore an hourly fresh eyes process can be distracting from care in labour without conferring benefit. A four hourly review may be more beneficial\*

CTG is predominantly used in labour where there are risk factors and therefore the risk of sepsis and fetal hypoxia is greater; therefore, fresh eyes review at least hourly may be more beneficial\*

\*Timeframe for Fresh Eyes should be decided within maternity services should be agreed with local commissioners (ICBs) based on the advice of the Clinical Network.

#### **4.5 Fetal monitoring expertise**

The dedicated hours for midwifery and obstetric fetal monitoring leads will be dependent on the size of the maternity unit and agreed with local commissioners (ICBs) based on the advice of the Clinical Network.

## 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 pregnant women at risk of preterm birth. It has been designed with reference to NICE guidance<sup>35</sup> 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<sup>36 37 38</sup>

### **Prevention**

All pregnant women should be assessed at booking for risk factors for preterm birth. This assessment should include modification of population-based risk factors acknowledging that the majority of preterm births occur in pregnant women not appropriate for care in a preterm prevention clinic.

**Smoking cessation:** Smoking doubles the risk of preterm birth<sup>39</sup> and therefore all pregnant 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).

**Maternal age:** Young women (<18 years) have an increased risk of preterm birth<sup>40</sup>. Appropriate referral to teenage pregnancy teams should be offered to provide adequate support and advice throughout the pregnancy and may help prevent preterm birth.

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

**Urinary tract infection (UTI):** As indicated in [NICE guidance](#) A midstream urine sample (MSU) should be taken and sent for culture and sensitivity in all high or intermediate risk pregnant women at booking. Culture positive samples, even in symptom-free pregnant 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.

**Vaginal infection:** Pathogens such as *Neisseria Gonorrhoeae* and *Chlamydia Trachomatis* are associated with preterm birth, and screening should be offered to at-risk pregnant 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 identification and treatment in at-risk pregnant 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**

The risk assessment should identify a group of high-risk pregnant women who require management in a preterm birth prevention clinic where further tests may be offered as part of the surveillance pathway. This assessment 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 pregnant women at risk of preterm birth

<b>Risk factor</b>	<b>Pathway</b>
<p><b><u>High risk</u></b></p> <ul style="list-style-type: none"> <li>• Previous preterm birth or mid-trimester loss (16 to 34 weeks gestation).</li> <li>• Previous preterm prelabour rupture of membranes &lt;34/40.</li> <li>• Previous use of cervical cerclage.</li> <li>• Known uterine variant (i.e., unicornuate, bicornuate uterus or uterine septum).</li> <li>• Intrauterine adhesions (Ashermann's syndrome).</li> <li>• History of trachelectomy (for cervical cancer).</li> </ul>	<p><b><u>Surveillance</u></b></p> <ol style="list-style-type: none"> <li>1. Referral to local or tertiary Preterm Prevention (PP) clinic by 12 weeks.</li> <li>2. Further risk assessment based on history +/- examination as appropriate in secondary care with identification of pregnant women needing referral to tertiary services.</li> <li>3. All pregnant women to be offered transvaginal cervix scanning every 2-4 weeks between 16 and 24 weeks as a secondary test to more accurately quantify the risk of preterm birth.</li> <li>4. Additional use of quantitative fetal fibronectin in asymptomatic pregnant women may be considered where centres have this expertise.</li> </ol> <p><b><u>Management</u></b></p> <ol style="list-style-type: none"> <li>5. Interventions should be offered to pregnant women as appropriate, based on either history or additional risk assessment tests by clinicians able to discuss the relevant risks and benefits according to up to date evidence and</li> </ol>

	<p>relevant guidance, for example, <a href="#">UK Preterm Clinical Network guidance</a> and NICE<sup>41</sup> guidance. These interventions should include cervical cerclage, pessary and progesterone as appropriate.</p>
<p><b><u>Intermediate risk</u></b></p> <ul style="list-style-type: none"> <li>• Previous birth by caesarean section at full dilatation.</li> <li>• History of significant cervical excisional event i.e., LLETZ where &gt;15mm depth removed, or &gt;1 LLETZ procedure carried out or cone biopsy (knife or laser, typically carried out under general anaesthetic).</li> </ul>	<p><b><u>Surveillance</u></b></p> <ol style="list-style-type: none"> <li>1) Refer to preterm birth prevention clinic by 12 weeks.</li> <li>2) Further risk assessment based on history +/- examination as appropriate in secondary care with discussion of option of additional risk assessment tests, including: <ol style="list-style-type: none"> <li>a) A single transvaginal cervix scan between 18-22 weeks as a minimum.</li> <li>b) Additional use of quantitative fetal fibronectin in asymptomatic pregnant women can be considered where centres have this expertise.</li> </ol> </li> </ol> <p><b><u>Management</u></b></p> <ol style="list-style-type: none"> <li>3) Interventions should be discussed with pregnant women as appropriate based on either history or additional risk assessment 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.</li> <li>4) Pregnant women at intermediate risk should be reassessed at 24 weeks for consideration of transfer back to a low-risk pathway.</li> </ol>

### **Risk assessment**

Pregnant 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 risk assessment tool, quantitative fetal fibronectin, is currently being evaluated in symptomatic pregnant women in clinical studies. In asymptomatic

pregnant 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 pregnant women. It can also be used in high-risk pregnant 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 risk assessment tools in asymptomatic pregnant 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<sup>41</sup>.

### **Prevention**

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

Several interventions have been assessed for pregnant 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 pregnant women<sup>42</sup>. At present the evidence base cannot determine precisely in which pregnant women, and in what circumstances, each intervention will be most effective. Care should, therefore, always be individualised, taking into account the pregnant 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:

#### **Pregnant 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 pregnant women having ultrasound surveillance, discuss intervention when cervix is <25mm, either cervical cerclage<sup>42</sup>, Arabin pessary or prophylactic progesterone (vaginal or intramuscular).
- **Pregnant 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<sup>43</sup>.

- **Pregnant 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 pregnant 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.

Pregnant women with an intervention (cerclage, pessary or progesterone) should remain under the care of the preterm birth prevention clinic until birth. Pregnant women undergoing transvaginal cervix scanning risk assessment should continue this until 24 weeks, when this monitoring pathway is complete and if no intervention is recommended, pregnant 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  
**BME** – Black 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  
**LMNS** – Local maternity and neonatal 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



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