Saving Babies' Lives

Care Bundle for reducing stillbirth and early neonatal death

Recommendations report from the four Task and Finish Groups to the Implementation Oversight Group January 2015

Version number: v1.0

First published:

Updated:

Prepared by: Dan O’Connor

Classification: OFFICIAL

Contents

Preface

This report has been written following the development work of four task and finish groups. These consisted of clinical, operational and managerial staff with roles in a variety of maternity stakeholders: Royal Colleges; charities; Strategic Clinical Networks; academic institutions; and government agencies.

The role of these groups was to make recommendations on the content of the care bundle, and identify the enablers, issues for consideration and barriers for its implementation.

These recommendations will be considered by the Implementation Oversight Group set up within NHS England to oversee the development of the care bundle and will be further developed in light of stakeholder feedback, as we move into the early implementation phase.

This document can, however, be used by providers to begin considering implementing the care bundle, on the understanding that the methodology used may necessitate refinements of the bundle content over time.

Introduction

Stillbirth rates in the United Kingdom are among the highest of high income countries. Despite falling to 4.7 per 1,000 total births, in 2013 (making this the lowest stillbirth rate since the early 1990s), the UK still had one of the highest rates of stillbirth in Europe, more than double the rates of the three nations with the lowest rates: Spain and Slovenia (2.3) and Finland (1.9)[1].

In the UK there's about a 33% difference between different regions' rates.[2]
Of the 1 in 200 babies that are stillborn, growth restricted babies are the single largest preventable group. For this group, detection rates in Trusts vary between 12 and 50% across England.

The NHS has made it a priority to reduce stillbirth rates:

- Reducing stillbirth is a Mandate objective from the government to NHS England and is therefore in the NHS England Business Plan 2014-15.
- Reducing deaths in babies and young children; specifically, neonatal mortality and still births is also a key NHS indicator in the NHS Outcomes Framework.
- The Five Year Forward View, published October 2014, has committed to review maternity services.

Work so far on the care bundle

A meeting was held by NHS England in March 2014 to identify work being done on maternity and establish priorities. Many organisations were represented at that meeting: government and its agencies, royal colleges and the charity sector. Still birth reduction was the top of the list of priorities for most of the organisations present.

The approach suggested and agreed at the meeting was for NHS England to develop a Care Bundle that brings together a number of elements likely to impact on still birth rates.

The Care Bundle approach is common in the NHS. Care Bundles typically bring together four to six key, focused elements designed to effect improvement in a particular disease or treatment area. These elements are usually very specific and defined. They often represent known best practice in areas where current practice is unacceptably variable. When implemented as a package, evidence shows that greater benefits are achieved at a faster pace than if those improvements had been implemented as individual components.

The prevailing view was that the care bundle should predominantly focus on fetal growth restriction, but that specific interventions from other important elements should be identified.

[1] Stillbirth statistics - Tommy's http://www.tommys.org/page.aspx?pid=388
[2] Stillbirth statistics - Tommy's http://www.tommys.org/page.aspx?pid=388

Working with four Task and Finish groups consisting of individuals with roles in key clinical, charitable, professional and governmental stakeholders with policy, clinical and operational expertise (see Appendix 1 for full details of stakeholders involved with each element), NHS England has subsequently developed 'Saving Babies Lives': a care bundle designed to reduce stillbirth and early neonatal death. During the development, the draft care bundle has been shared at regular intervals with a stakeholder reference group.

Methodology

Where there is clear evidence for an element or intervention to be included, this has been analysed and cited. Where evidence is less well defined or inconclusive, or there had been no previous practical application of the element, clinical judgment has been used to decide whether the proposed element is likely to have an impact on reducing stillbirth. We have also taken into account the use of methods and interventions in clinical practice that are prevalent in England at the moment.
Improvement science methodology, whereby an intervention will be developed and implemented, and its impact assessed over an agreed period, will be used to evaluate the care bundle elements.

Next steps: early take-up and toolkit to support

Putting a care bundle together on paper is but the first step in its implementation and ultimately in reaping the rewards in terms of improved outcomes.

Following the development of the care bundle, we now need to continue to work with the rest of the NHS system to roll-out the bundle and ensure that maternity service providers are willing and able to take up the bundle, as a means of them achieving reductions in stillbirth and early neonatal death.

These recommendations have been received by the Implementation Oversight Group, which will consider how to best word the released the Care Bundle, particularly for interventions that do not yet have the full evidence base to support their use.

Element 1: Reducing smoking in pregnancy by carrying out Carbon Monoxide (CO) test at booking to identify smokers (or those exposed to tobacco smoke) and referring to stop smoking service/specialist as appropriate

Background and rationale

There is strong evidence that reducing smoking in pregnancy reduces the likelihood of stillbirth and harm to the unborn baby. This element is therefore a potentially high impact activity for reducing stillbirth, and neonatal death and morbidity. The element will impact on other bundle elements, including reducing occurrences of fetal growth restriction and labour complications. Reducing smoking in pregnancy tackles other complications, such as: increased risk of miscarriage; premature birth; low birth-weight; and sudden unexpected death in infancy.

This element reflects the wider prevention agenda and desire for a public health dimension to be in the bundle, enhancing midwives' role in promoting public health messages and interventions.

Comprehensive work is already under way with Public Health England's 'Smoking in Pregnancy' programme, giving opportunities for a reciprocal relationship where national policy to reduce stillbirth can promote wider public health messages.

A number of the Strategic Clinical Networks (SCN) are already working on smoking cessation initiatives, giving an opportunity to align their work with this national policy development.

There is directly relevant NICE guidance, but variable application throughout provider trusts.

Element and interventions

Element
Reducing smoking in pregnancy by carrying out Carbon Monoxide (CO) test at antenatal booking appointment to identify smokers (or those exposed to tobacco smoke) and referring to stop smoking service/specialist as appropriate
Intervention
Carbon monoxide (CO) testing of all pregnant women at antenatal booking appointment and referral, as appropriate, to a stop smoking service/specialist, based on an opt out system. Referral pathway must include feedback and follow up processes.

Essential supporting components

- Referral pathways to include both **feedback** (from the stop smoking service or specialist back to the referring midwife and **follow-up** (so pregnant women are

asked about their smoking at other points during their pregnancy to reinforce or encourage any quit attempts or behaviour change) to ensure midwives have information on activity following referral and further discussions on smoking take place throughout the pregnancy.
- Recording, monitoring and reporting of smoking status and CO reading and referral on to smoking cessation service
- Formal agreement and sign up from all organisations involved in the pathway.
- Reliable (ideally electronic) systems for referral and information exchange, including regular monitoring and review.
- Provision of information on health implications and risk of smoking in pregnancy, including exposure to second hand smoke.

Enablers

- There is clear, relevant and current NICE guidance which will support implementation (includes template referral pathway)
- There are many good local examples of successful implementation at Trust level for introducing CO monitoring. It is important to benefit from learning and experience in other areas.
- The Maternal & Child Dataset potentially offers opportunity to support these activities through data collection
- Training and programmes to support system wide action are available. Commissioners and providers will need to work together to establish current and on-going needs.

Issues for consideration

- Collection of data not consistent across all Trusts at present. Many still not collecting electronically. Local solutions will be required for recording, monitoring and reporting of information on smoking status and CO readings.
- Midwives will need appropriate time and resources to carry out activities. This needs to be considered in commissioning arrangements
- Midwives must have up to date knowledge and skills training to maximise their potential to impact positively on pregnancy outcomes.
- Midwives need to be provided with CO monitors and relevant consumables, which needs to be considered as part of the commissioning arrangements.
- Midwives need to be trained in the use of CO monitors and arrangements put in place to calibrate monitors if required (not all monitors require calibration).
- Template pathways can be provided but logistics of referral systems will need to be negotiated (tested and evaluated) locally.
- Consider systems and pathways for young people, particularly teenagers that may need to be developed with additional/different channels of communication, delivery of key messages and referral pathways.

Proposed next steps

- Determine full range of ‘wrap around’ information and resources needed/available to aid implementation
- Identify and signpost to training opportunities for midwives

- Set out requirements for CO monitoring equipment and training
- Explore ways of capturing data on smoking status
- Explore need for reliable (ideally electronic) systems for referral and information exchange, including regular monitoring and review.
- Explore the issue of time within booking appointment for provision of relevant information, including test & referral (appreciating this is a wider issue than just smoking)
- Influence commissioners of maternity services to allow time and provide equipment for midwives to carry out activities effectively

Process and outcome indicators

Intervention	**Process indicators**	**Outcome indicators**
Carbon monoxide (CO) testing of all pregnant women at booking and referral to stop smoking service/specialist, based on an opt-out system	Recording of smoking status of each pregnant woman Recording of CO reading for each pregnant woman If this identifies exposure to smoke or a high CO reading, referral to stop smoking service (or other action)	Number/rates smoking at booking Number of smokers setting a quit date Number quit at 4 weeks from quit date (CO validated) Number quit at 12 weeks if data available (CO validated) Smoking at time of delivery (SATOD)

Signposting to available resources

Training	Local areas may have systems in place for training practitioners in smoking cessation, brief advice and use of CO monitors. The NCSCT provides free evidence based on-line training for stop smoking practitioners and has a specialty module on *Pregnancy and the Post-Partum Period* designed for intended for anyone who helps pregnant smokers stop smoking. There are also a number of face to face training courses that can be delivered locally. (http://www.ncsct.co.uk/publication_pregnancy_and_the_post_partum_period.php)
Briefing	The NCSCT has produced a briefing for midwifery staff on smoking cessation. This provides expert, concise guidance on how to deliver Very Brief Advice (VBA) to pregnant women who smoke and how to carry out routine carbon monoxide (CO) testing with all pregnant women. It also describes the behavioural support and advice on medication that is available from stop smoking services and how to guide pregnant women who smoke towards these services. (http://www.ncsct.co.uk/publication_briefing_for_midwifery_staff.php)
Key messages	A document has been developed by a multi-agency group (led by ASH and PHE) focussing on the issue of communicating with pregnant women to support the provision of accurate, consistent and evidence based message around smoking in pregnancy. This was originally intended for use in public facing documents or resources (campaigns, press releases, media statements etc.), but may also be a useful tool or background for all those engaging with pregnant women.
babyClear	This package of support involves systematically identifying smokers at time of first booking appointment via CO testing, raising "concern" and automatically referring all smokers into Stop Smoking Services/specialists. This is an intensive, but whole system approach. Region-wide implementation in the North East, case study information provided.

Case study: Implementation of the babyClear approach to routine identification and referral of pregnant smokers across County Durham and Darlington FT

babyClear is a regional approach, supported by Fresh, to tackling the high rates of maternal smoking across the North East of England. It was developed to embed routine identification and referral of pregnant smokers into Stop Smoking Services by midwifery staff. County Durham and Darlington FT was the first Trust to fully roll-out this approach in the North East. This involved locally:

- 120 midwives/midwifery staff trained in a standardised three-minute intervention at booking. As part of this training, they received carbon monoxide monitors and all associated leaflets/resources. CO monitors are uniquely numbered to allow tracking of referral rates.
- 10 SSS administrative staff attended a one-day lead management training session
- 33 stop smoking advisors who work with pregnant smokers attended one/two day skills training
- 15 midwives have been trained to deliver a more intensive risk perception intervention at the 12-week dating scan, highlighting the risk from continued smoking in pregnancy

Implementation involved regular meetings with key strategic partners, including the Head of Midwifery, senior midwifery staff, SSS commissioners and providers. Formal approval also obtained from the FT Chief Executive to adopt this approach across the Trust. The local SSS pregnancy lead has managed the day to day process locally, post-implementation, ensuring that all midwives are routinely using their CO monitors at booking, and providing training updates.

Key early outcomes locally:

- Since full local rollout of babyClear by the end of Quarter 2, 2013/14, the SSS saw a 41% rise in the number of quit dates set by pregnant women, compared to 2012/13 levels
- This converted to a 43% year on year rise in the number of successful, pregnant 4-week quitters over that same period
- Over 2013/14 as a whole, the Durham SSS received over 1,870 referrals of pregnant smokers, which represented 45% of ALL referrals into the service that year
- The risk perception intervention at dating scan (aimed at smokers who declined support previously) has seen 1 in 7 of referred women successfully quitting with SSS support

Newcastle and Teesside Universities are conducting a long-term evaluation of the project which will look at the impact of babyClear on things such as birth outcomes, and the impact on staff attitudes.

Key learning points:

- Securing the highest levels of strategic support within the Trust can help overcome any minor issues, and regular communication between all parties is essential
- Delivery of tailored training sessions for all staff involved in pathway (midwives, advisors, administrative staff) is vital to improving skills and awareness
- Head of Midwifery support is crucial in securing attendance from midwifery staff at training. Basic sessions should last no more than 2 hours
- Standard approach to biochemical intervention at booking is pivotal in making sure that key messages are delivered consistently but quickly. Intervention should last no more than 3 minutes if midwives are to incorporate it into their booking routine
- Genuine opt-out referral process for all women based on agreed CO levels removes any "judgement" call by midwife
- Trained midwives delivering harder-hitting messages at subsequent appointments to those women who have previously declined support can be highly effective
- Importance of over-arching strategic project lead, but also "hands-on" management of process by the SSS pregnancy lead locally.

Element 2: Identification and surveillance of pregnancies with fetal growth restriction

There is strong evidence to suggest that fetal growth restriction (FGR) is the biggest risk factor for stillbirth[3]. This is also a widely held opinion amongst clinicians.

FGR occurs when a fetus fails to reach its growth potential during pregnancy. Babies born with FGR are usually (but not always) also small for gestational age (SGA) which is defined as birthweight <10th centile; this group also naturally includes infants who are constitutionally small, but not FGR. Determining the percentage of infants that are growth restricted is difficult because there is no accepted objective definition of FGR. However, as a result of the high proportion of FGR in any group of SGA infants, the group as a whole has an increased risk of morbidity and mortality, and the association is increased if customised centiles are used to define SGA.

The principal aim of screening and surveillance is to detect FGR and, pragmatically, this is the term used to describe the aims and objectives of this care bundle. However, SGA is used for audit purposes and assessment of performance. Appendix 1 provides a more detailed definition of these terms.

Antenatal detection of FGR (as assessed by SGA birth weight) significantly reduces risk[3] as it prompts further investigation, fetal surveillance and timely delivery. However, at present the majority of pregnancies with SGA are not detected antenatally.

Most instances of FGR are late onset, for which reliable early screening tests are not yet available. Therefore, surveillance of all pregnancies is required throughout pregnancy, and should reflect the level of FGR risk:

- For low risk pregnancies, standardised serial measurement of fundal height at each midwife visit and plotting on customised growth charts which predict the optimal fetal growth in each pregnancy (adjusted for maternal size, ethnicity and parity) has been shown to improve antenatal detection of FGR[4]. Use of customised charts reduces unnecessary referrals and investigations. This allows resources to be targeted on cases where growth does not follow the expected trajectory. Routine single third trimester scans in low risk pregnancies have not been shown to improve detection or outcome.

[3] Gardosi J, Madurasinghe V, Williams M, Malik A, Francis F. Maternal and fetal risk factors for stillbirth: population based study. BMJ:f108 http://www.bmj.com/content/346/bmj.f108

[4] Clifford S, Giddings S, Southam M, Williams M, Gardosi J. The Growth Assessment Protocol: a national programme to improve patient safety in maternity care. MIDIRS Midwifery Digest 23:4: 2013 www.perinatal.org.uk/FetalGrowth/GAP/Resources/GAP_article_MIDIRS_Dec_2013.pdf

- For pregnancies at increased risk (e.g. due to past obstetric history or smoking), RCOG Green Top Guidelines[5] recommend three-weekly ultrasound assessment of fetal growth throughout the third trimester until delivery.

Current ultrasound scanning policies vary between obstetric units primarily because of resource issues and uptake of RCOG recommendations is poor, with on average two ultrasound scans carried out on women at increased risk. Higher ultrasound scan frequency and extending scans to term is associated with improved antenatal detection of FGR.

Care bundle

This element of the 'Saving babies Lives' care bundle is designed to reduce levels of undetected FGR and to target current resources more appropriately by standardising practice in fundal height measurement and recording. The clearly stated requirements of the bundle will help Trusts to determine the ongoing resources and workforce capacity needed sustainably to implement it. The element also seeks to simplify the RCOG guideline[5] and accompanying algorithm in order to help Trusts implement appropriate serial scanning regimes for pregnancies at greater risk. The element will require units to publish their SGA detection rates and identify any barriers to improving detection, thereby driving improvement.

Element and interventions

Element
Identification and surveillance of pregnancies with fetal growth restriction
Interventions
1. Use of customised antenatal growth charts for all pregnant women by clinicians who have gained competence in their use
2. Use of supplied algorithm to aid decision making on classification of risk, and corresponding screening and surveillance of all pregnancies according to their risk
3. Ongoing audit and reporting of Small for Gestational Age (SGA) rates and antenatal detection rates
4. Ongoing case-note audit of selected cases not detected antenatally, to identify barriers

Aim

To improve identification and surveillance of fetal growth restriction (FGR) by:

1. Ensuring all women are assessed for risk of SGA as early as possible during pregnancy
2. Ensuring women who are low risk for SGA and stillbirth receive appropriate fetal growth surveillance throughout pregnancy

[5] RCOG Green-Top Guideline 31: The Investigation and Management of the Small-for-Gestational- Age Fetus. Royal College of Obstetricians and Gynaecologists, 2013 www.rcog.org.uk/womens-health/investigation-and-management-small-gestational-age-fetus-green-top-31

3. Ensuring there is clear guidance on pathways for referral where SGA or FGR is suspected; and where fetal growth is found not to be of concern, women are referred back to the low risk pathway
4. Ensuring women at high risk for SGA and stillbirth are identified early and appropriate surveillance is instituted
5. Where FGR is suspected or diagnosed (either by absent/slow growth of ultrasound EFW or on basis of fetal Doppler studies) - appropriate investigations and management are instituted, according to included algorithm adapted from RCOG SGA guidance.

Essential supporting components

1. Trusts will decide which criteria they use to customise growth charts. For example, if it is the view of a trust that ethnicity is not a characteristic that determines fundal height that trust does not have to use the ethnicity criterion.
2. To ensure that adherence to the algorithm and guidance is captured through an agreed data collection system/audit tool
3. To ensure that data on SGA rates and antenatal detection rates are captured as a baseline prior to implementation of the package
4. To ensure that data on SGA rates and antenatal detection rates are monitored on an ongoing basis following implementation of the element
5. To ensure that a robust training programme and competency assessment is included in any proposed practice change
6. Recommended 10 cases over six months for case note audit

Enablers

- Interpretation of RCOG algorithm for the bundle designed to make enhanced scanning regimes more implementable
- Innovative models and solutions for increasing scanning capacity and trialling training of midwives to undertake 3rd trimester scans
- Work with Health Education England to evaluate scanning workforce capacity being considered, either nationally or via local initiatives
- Currently available GAP programme offers bespoke training around much of the element
- GROW package has data collection capability for detection of SGA and could be used by Trusts, or Trusts' own informatics systems if the capability exists
- Such data will facilitate use of improvement methodology, allowing gathering of evidence as we progress
- Health Education England (HEE) has supported training and implementation in several areas

Issues for consideration

- Significant anecdotal evidence that implementing the RCOG SGA guideline leads to increased scanning requirements and induction rates, meaning similar issues will exist for this bundle element
- Difference of opinion amongst academics and obstetricians over the use of customised and non-customised growth charts. We will be cognisant of emerging evidence related to both approaches during the early implementation phase of the care bundle, and adapt the bundle element as appropriate

- Currently there isn't the required capacity in the ultrasonographer workforce to implement the RCOG guideline, meaning similar issues for implementing this bundle element
- Financial cost of any increase in ultrasound scanning would need to be borne by Trusts
- Some trusts thought to be concerned over cost of GAP training. Debate over use of customised growth charts needs to be acknowledged. We are using improvement methodology, which allows the gathering of evidence as we progress
- Capacity/time issues around need for further training, both for use of customised growth charts and implementing management protocol for increased risk pregnancies
- Issues around capacity/time to produce customised growth charts and enter info after delivery
- Possible conflating of fetal growth surveillance in low risk pregnancy with RCOG guideline on high risk pregnancy: this needs to be clarified to avoid misapprehension
- Patchy and divergent use of maternity informatics systems with inaccurate / incomplete data collection: barrier to publishing detection rate data that is comparable across Trusts
- Lack of capacity to undertake selected case note audit of undetected cases on regular basis (recommended 10 cases / 6 months)

Record of points raised by group members

Evidence

The group was unanimous in that mothers with increased risk of SGA / FGR need an increased level of surveillance. The risk factors reviewed within the RCOG guidelines were discussed as a starting point, but it was acknowledged that they were based on available published evidence which was not all were systematically reviewed and meta-analysed. A pragmatic, easy to follow approach was agreed which would seek to deal with the main / most frequent antecedents of SGA, and correspond to priorities of other care bundle elements, for example, by including all smokers. This approach was agreed on the understanding that it would be likely to highlight capacity and funding issues in the ultrasonographer workforce, but that it was important to set a level of ambition that could drive improvement.

Use of the term 'fetal growth restriction'

There was debate within the group around the use of this term, as it has no accepted objective definition. The term 'small for gestational age' is clearly defined and has been used when we talk about measuring and predicting. However, there remains some conjecture over whether fetal growth restriction or small for gestational age should be used in the element title. The prevailing view of the group is that fetal growth restriction should be used as a pragmatic approach which reflects the aims of the element.

Single supplier

A number of group members have pointed out that the Perinatal Institute is currently the only supplier of a package to generate customised growth charts and provide training in their use. This issue has been noted and is being considered by NHS England.

Conflicts of interest

The related issue of conflict of interest has also been raised and discussed within the group, particularly the involvement of the Perinatal Institute in developing this element of the care bundle. Declarations of interest have been made by the Perinatal Institute in relation to this work. The concerns and declaration have been noted by NHS England.

Amniotic fluid volume

If we are to include liquor volume, there needs to be documentation of the evidence to support this as the RCOG guideline doesn't recommend measurement of amniotic fluid volume. It is used by some clinicians to identify fetuses with FGR. However, due to lack of citable evidence, the group agrees to record this as an unresolved issue for the purposes of its recommendations to the implementation oversight group.

Data

Collected at Trust level:

- Training log of all staff involved in antenatal growth surveillance
- Rate of completed competency assessments
- Proportion of pregnancies that had a customised growth chart generated
- Adherence to antenatal risk assessment and surveillance algorithm
- Regular audit of sample or selection of 'missed' cases (e.g. 10 each 6 months)
- Stillbirth rates, including those that are SGA
- Rates of antenatal detection of babies born SGA

Collected by GAP service (for Trusts and their respective Networks):

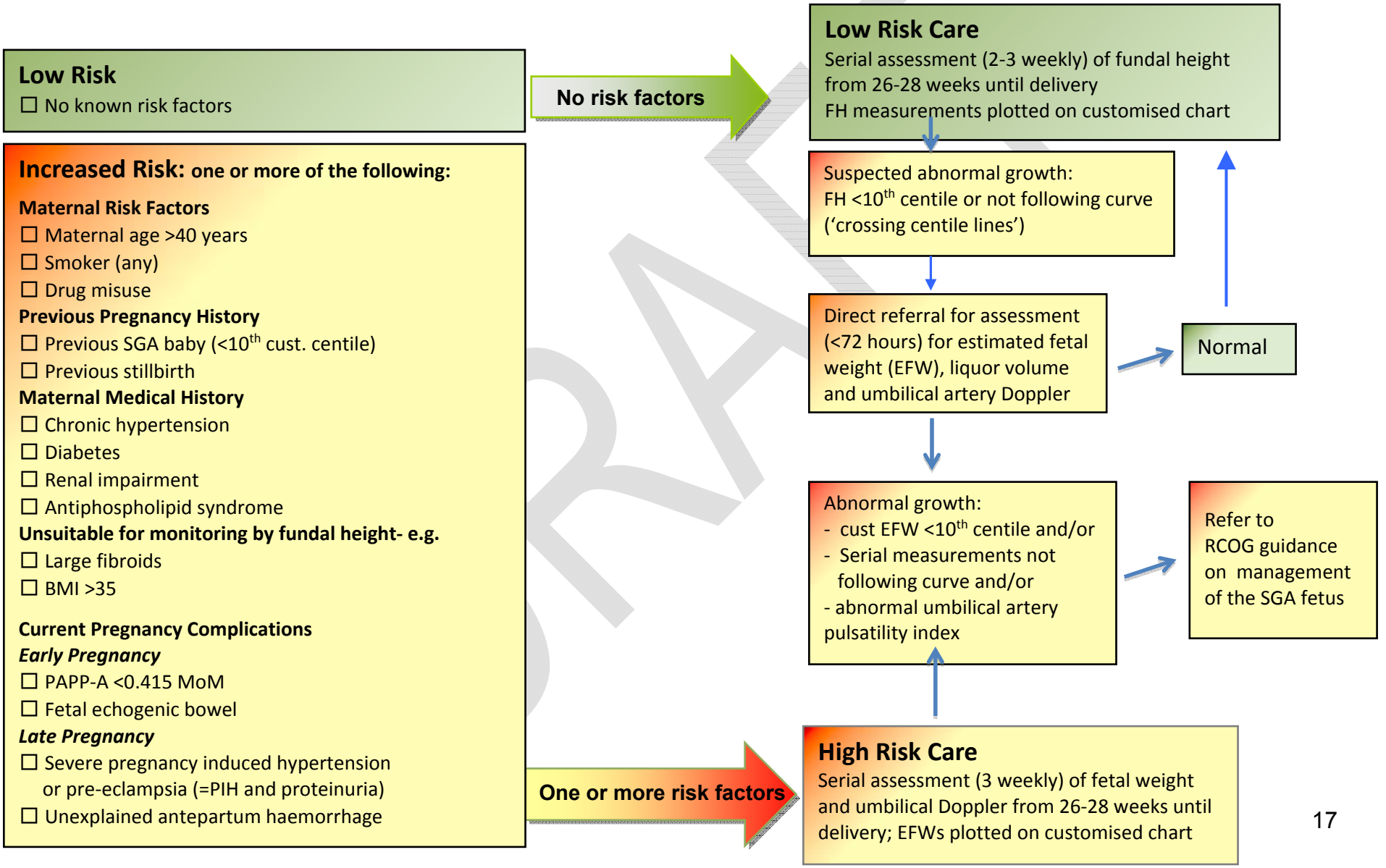
- Customised chart generation rates
- E-learning and competency assessment completion rates
- Rates of completion outcome data (gestation and weight at birth; SGA referral / detection) or alternative
- Stillbirth rates, including those that are SGA
- Rates of antenatal detection of babies born SGA

Process and outcome indicators

Intervention	Process indicators	Outcome indicators
1. Use of customised antenatal growth charts for all pregnant women by clinicians who have gained competence in their use	Customised growth charts implemented Training programme on use of charts in place Fundal height and scan estimated fetal weight measurements plotted	Charts generated for each pregnancy All staff competent in use of customised growth charts, and audited within Trusts e.g. through midwifery supervision/trust based training and competence records

2. Use of supplied algorithm to aid decision making on classification of risk of SGA , and corresponding screening and surveillance of all pregnancies according to their risk	Algorithm to classify risk is part of unit protocol	All staff trained in use of algorithm Proportion of pregnancies appropriately screened / surveilled according to risk
3. Ongoing audit and reporting of Small for Gestational Age (SGA) rates and antenatal detection rates	Completion of postnatal audit using GROW or trust management information systems (MIS)	Increase/decrease of antenatal referral rate and detection rate of babies SGA at birth, including true and false positives Decrease/increase of stillbirths with SGA
4. Ongoing case-note audit of selected cases not detected antenatally, to identify barriers	Appropriate process of selecting for review - e.g. 10 cases each 6 months	Barriers identified; learning from audit is fed back into processes to drive improvement

Algorithm and Risk Assessment Tool:
Screening and Surveillance of fetal growth in singleton pregnancies



Definitions for SGA and FGR and implications for reporting

Definitions

SGA – small for gestational age
FGR – fetal growth restriction (also sometimes referred to as IUGR –intrauterine growth restriction)
EFW - estimated fetal weight

SGA is defined as a weight (fetal or at birth) measurement below the 10th customised centile and can be applied to fundal height, estimated weight or birth weight. Some of these babies are normal (constitutionally small) but if the cut-off limit is customised, most (but not all) constitutional variation has been adjusted for and the smallness is more likely to be pathological (i.e. FGR).

FGR is the term used for babies that have slow or no growth of according to serial fundal height or ultrasound (EFW) measurements (regardless of whether they are already below the tenth centile or not), with or without abnormal umbilical or fetal Doppler flow measurements.

Notes

1. **SGA Rate** [No. with birth weight <10th centile / Total No. of births] is expected to be 10% in a normal ('optimal') population free from pathology, and varies with the prevalence of factors such as smoking, social deprivation, diabetes, congenital anomalies etc.

2. Antenatal suspicion of SGA or FGR leading to referral for further investigation is usually on the basis of a fundal height measurement below the 10th centile line, or sequential measurements suggesting no or slow growth. The rate (%) is calculated as [No. referred antenatally / Total No. SGA at birth].

3. Antenatal detection / diagnosis of SGA [No. detected antenatally / Total No. SGA at birth] indicates an ultrasound estimated fetal weight (EFW) below the tenth centile, or sequential measurements with slow or no growth, and/or one or more abnormal Dopplers.

NB – FGR rate: We have no way to determine the actual number of babies that are FGR at birth. Therefore, the proxy denominator used for calculating the rates of 'referred for suspected FGR' and 'detected' cases is customised SGA birth weight, but this does not include babies that had slow (restricted) growth but were not SGA.

The table below is an example of how these definitions are used in a GAP template unit report

_____(NHS Trust)
Retrospective Baseline Audit
Input dates: Apr - Sept 2014

No. of cases submitted	SGA (birth weight below 10th customised centile)		Referred for suspected SGA/FGR		SGA/FGR detected	
n	n	%	n	%	n	%
754	94	12.5%	31	33.0%	17	18.1%

Element 3: Raising awareness amongst pregnant women of the importance of detecting and reporting reduced fetal movement (RFM), and ensuring providers have protocols in place, based on best available evidence, to manage care for women who report RFM

Background and rationale

Raising awareness amongst pregnant women and their families of the importance of being aware of the movement of the unborn baby is vital to ensuring good outcomes and preventing stillbirth. However, evidence is currently equivocal, awaiting studies yet to report, most notably AFFIRM. Despite this, there is the need to act now to tackle known issues, using clinical guidelines (RCOG Green-top Guideline 57), best available evidence and known good practice.

Information and public messaging on RFM are currently inconsistent and there is variable management practice at trust level when RFM is reported. We need to draw together best available evidence to present clear, consistent messages. Trusts need to provide a service that meets the expectations of women who report RFM.

This has been identified as a potentially high impact intervention which is amenable to practical solutions.

Element and interventions

Element
Raising awareness amongst pregnant women of the importance of detecting and reporting reduced fetal movement (RFM), and ensuring providers have protocols in place, based on best available evidence, to manage care for women who report RFM.
Interventions
1. Information and advice leaflet on reduced fetal movement (RFM), based on current evidence, best practice and clinical guidelines, to be provided to all pregnant women by, at the latest, the 24th week of pregnancy and RFM discussed at every subsequent contact.
2. Use provided checklist to manage care of pregnant women who report reduced fetal movement, in line with RCOG Green-top Guideline 57

Enablers

- RCOG Green-top Guideline 57 provides basis for work
- Awareness leaflet for women already developed and reviewed by Cheshire and Merseyside SCN and further examples that could be drawn on
- Existence of relevant codes will enable monitoring of what Trusts do when RFM is reported

Issues for consideration

- Concern over when messages should be delivered: recommendation is for women to receive leaflet at first booking meeting and RFM discussed at every contact (need to evaluate impact on mothers; potential to increase anxiety)
- Concern that effectiveness of leaflet will be diminished because of glut of other information
- Work needed to encourage pregnant women to overcome any perception/fear of bothering a busy maternity unit with 'unnecessary' concerns
- Need to determine whether current recommendation of a checklist for management of RFM is sufficient or whether we need to develop a management protocol and monitor compliance with the protocol
- Coding: data not currently collected for RFM management, but codes do exist: work needed with Health and Social Care Information Centre (HSCIC)
- Need to monitor impact of element: potential increase in interventions/induction rates
- Analysis will be needed of the acceptability/validity of the leaflet. It is desirable to test assimilation of information by pregnant women. However, it will be challenging to determine the methodology and select an appropriate sample.
- Practical considerations around production and distribution of leaflet
- Need to influence wider public messaging on RFM (through Communications strategy): RFM advice needs to be available and consistent across all pregnancy information providers, especially websites, if we are to gain traction with women

Process and outcome indicators

Intervention	**Process indicators**	**Outcome indicators**
1. Information and advice leaflet on reduced fetal movement (RFM), based on current evidence, best practice and clinical guidelines, to be provided to all pregnant women by, at the latest, the 24th week of pregnancy and RFM discussed at every subsequent contact.	Leaflet given to and discussed with all pregnant women by 24th week of pregnancy Feedback obtained from sample of women to gauge whether messages have been assimilated as intended	
2. Use provided checklist to manage care of pregnant women who report reduced fetal movement, in line with RCOG Green-top Guideline 57	Protocol in place, that follows checklist, for care for pregnant women who report RFM Care for all pregnant women who report RFM managed according to checklist	Stillbirth rate (decrease/increase) Induction rate (increase/decrease) Percentage of women reporting RFM who have 1. further action 2. no

		further action

Further recommendations

Coding

The group recommends that further work is undertaken with the Health and Social Care Information Centre (HSCIC) to identify relevant codes for management of care for women who report RFM. A code for reporting RFM should be identified and codes for each of the resulting interventions when the checklist is used appropriately. This will enable trusts to track, through data collection, the total number of reports of RFM and what was done in response. It will also allow us to monitor whether care to manage RFM improves/becomes more compliant with guidance as a result of the introduction of this element of the care bundle.

Further evidence

Further sources of evidence yet to be published/studies yet to report, particularly the AFFIRM study, should continue to be monitored and used to refine this element of the bundle through implementation, where appropriate.

Signposting to available resources

- RCOG Green-top 57
- AFFIRM study
- Cheshire and Merseyside SCN leaflet and sticker and other leaflets in development

Checklist for Required Management of Reduced Fetal Movements

Based upon RCOG Guideline 57 and Merseyside SCN outline documentation

Needs to be simple 3/5 major points maximum

For women ≥28 weeks gestation

Keep in guidance notes about FMU referral for women <24 weeks gestation

Attendance with Reduced Fetal Movements	Please initial when complete

Ask - Is there maternal perception of reduced fetal movements? ☐

Assess - Are there risk factors for Fetal Growth Restriction or Stillbirth? ☐

Consider - multiple consultations for RFM, known FGR, maternal hypertension, diabetes, extremes of maternal age, primiparity, smoking, obesity, racial/ethnic factors, past obstetric history of FGR or stillbirth) and issues with access to care.

Act - Auscultate fetal heart (hand-held Doppler / Pinnard) ☐

- Perform cardiotocograph to assess fetal heart rate in accordance with national guidelines. ☐

- If risk factors for FGR/Stillbirth, perform ultrasound scan for fetal growth, liquor volume and umbilical artery Doppler within 24 hours. ☐

Advise - Convey results of investigations to the mother. ☐

- Mother should re-attend if further reductions in fetal movements at any time. ☐

Act - Act upon abnormal results promptly. ☐

Element 4: Effective fetal monitoring during labour

Background and rationale

Effective surveillance of fetal wellbeing during the intrapartum period is vital for good neonatal outcomes. It reduces avoidable stillbirth and fetal morbidity. However, practice and levels of competence amongst staff caring for women in labour are variable, and escalation protocols often not in place or unclear.

There is a particularly pressing need to reduce avoidable fetal morbidity related to brain injuries causing conditions such as Hypoxic-Ischemic Encephalopathy (HIE) and Cerebral Palsy. These conditions carry huge emotional and financial cost to families. They also cause significant economic burden on the health and social care system, both through the care needed to support those with a brain injury throughout their lives as well as the cost of litigation brought by families when something goes wrong during labour. The cost to insure maternity units against litigation claims currently stands at over 500 million pounds a year, a figure that is set to rise further over coming years.

This element sets out practical interventions which are based on existing good practice models that have demonstrably improved outcomes. It fulfils the ethos of improving the system through prevention. Money saved through the costs of future care and litigation can be used to improve maternity services instead.

Element and interventions

Element
Effective fetal monitoring during labour
Interventions
1. All staff who care for women in labour are required to undertake an annual training and competency assessment on cardiotocograph (CTG) interpretation and auscultation. No member of staff should care for women in a birth setting without evidence of training and competence within the last year.
2. Buddy system in place for review of cardiotocograph (CTG) interpretation, with a protocol for escalation if concerns are raised. All staff to be trained in the review system and escalation protocol.

Essential supporting components

1. Training and competency assessment for all staff who care for women in labour
    - All staff caring for women in labour undergo an accredited training package on CTG interpretation
    - All staff caring for women in labour undergo an assessment on CTG interpretation following training
    - All staff caring for women in labour must have passed the relevant CTG interpretation assessment to be considered safe to care for women in labour

- All staff caring for women in labour must undertake and pass mandatory annual updates on CTG interpretation.
- Accurate records of compliance with these requirements must be kept.

2. A buddy system for interpretation of CTG recording, with protocol for escalation if concerns are raised
   - Protocol/guidance for buddy system
   - Measurement and documentation of maternal pulse taken at the same time as auscultation; on a minimum of an hourly basis when continuous fetal monitoring is in progress or after any period of loss of contact with the CTG monitoring equipment.
   - Documented evidence of second review
   - Model for escalation and leadership.

Implementation model

- Local champion in each unit (a medical or midwifery lead)
- Regular audit of compliance with agreed guideline
- Minimum monthly audit
- Compliance data fed back to staff
- PDSA cycles of change
- Ongoing measurement
- Review of all admissions to the neonatal unit
- Review of all intrapartum fetal deaths
- Clear alignment with related work streams should be established, to avoid duplication of effort, notably the Each Baby Counts project, reducing term admission project and MBRRACE MNI_CORP.

Enablers

- NICE intrapartum guideline, which includes intrapartum CTG, has now been updated
- Numerous models for buddy systems, including ‘fresh eyes’ initiatives for CTG, are already in use and can be evaluated and adopted locally
- Existing escalation protocols can be evaluated and adapted
- Accredited tools for assessing competence currently available
- Alignment with other work programmes including the Each Baby Counts project, reducing term admission project and MBRRACE MNI_CORP

Issues for consideration

- Concern regarding time resource for training and competence assessment
- A key challenge may be midwives who work in a low risk setting without regular use of CTG, who may have met the criteria but not used CTG for many months and still be eligible to work in intrapartum care. There should be consideration of a system where practitioners identify their own levels of competence if not having practiced CTG for several months, and relating this to the buddy system so that their practice can be refreshed
- Time is needed for staff engagement with required changes and auditing
- Are there the drivers simultaneously to build culture for leadership and escalation?

- There is a need to determine the actions necessary if a midwife is unhappy with a decision following escalation to the consultant: defining the role of the Supervisor of Midwives (SoM) in this situation
- Unit culture: work may need to be done on valuing the role of each team member in raising concerns
- Important to consider means of training other than online, in recognition of people's different learning styles
- Issues around how and by whom training is accredited will need to be considered.

Process and outcome indicators

Intervention	**Process indicators**	**Outcome indicators**
1. All staff who care for women in labour to undertake an annual training and competency assessment on cardiotocograph (CTG) interpretation and auscultation. No member of staff should care for women in a birth setting without evidence of competence within the last year.	Number of staff who have received training on CTG interpretation and auscultation Number of staff who are deemed competent in CTG interpretation and auscultation Number of staff who have successfully completed mandatory annual updates on CTG interpretation and auscultation (denominator for each indicator: total number of labour ward staff at trust whose role includes the care of women in labour.)	Intrapartum stillbirth decreases/increases Number of admissions to neonatal intensive care unit as a result of HIE decreases/increases

2. Buddy system in place for review of cardiotocograph* (CTG) interpretation, with protocol for escalation if concerns are raised. All staff to be trained in review system and escalation protocol.	Buddy system used in all intrapartum CTG interpretation according to local protocol Sticker system used according to guideline for all women in labour undergoing CTG monitoring Escalation protocol in place and used appropriately (documentary evidence required for each indicator)	Intrapartum stillbirth decreases/increases Number of cases of Hypoxic Ischemic Encephalopathy (HIE) where baby requires cooling decreases/ increases Early neonatal death within first seven days decreases/increases

(A number of the suggested indicators will be collected and can be achieved by participation in the Each Baby Counts project)

Signposting to available resources

- Case studies for introduction of buddy systems, including numerous 'fresh eyes' models for CTG interpretation
- Online learning packages for CTG
- Web based platform for uploading resources, stories, case studies.
- Newsletter on how participating units are improving, with links to resources

Contact Details

For further information about the care bundle please contact the central policy team. We are a small central policy team available to answer questions by phone and email. See below for team contact details:

Dan O'Connor
Domain Team Manager
dan.o'connor@nhs.net
07500 954199/0113 8251195

Central team mailbox:
England.stillbirthcb@nhs.net

Appendix 1: List of Stakeholders

Stakeholders involved with element 1 - Smoking Cessation:

Name	Organisation
Ann Hoskins	Public Health England
Cara Taylor	Central Manchester University NHS Foundation Trust
Charlotte Bevan	Sands
Helen Duncan	Public Health England
Hilary Farrow	Yorkshire & The Humber Strategic Clinical Network
Jane Brewin	Tommy's
Janet Fyle	The Royal College of Midwives
Jo Locker	Public Health England
Joanne McCullagh	NHS England
Pat Gould	The Royal College of Midwives
Suzanne Thomas	Central Manchester University NHS Foundation Trust

Stakeholders involved with the element 2 - Fetal Growth Restriction:

Name	Organisation
Anita Dougall	The Royal College of Obstetricians and Gynaecologists
Debby Gould	NHS England
Edward Johnstone	Central Manchester University NHS Foundation Trust
Elizabeth Gomez	The Royal College of Midwives
Jason Gardosi	The Perinatal Institute
Michele Upton	NHS England
Netta Hollings	Health and Social Care Information Centre
Simon Jenkinson	West Midlands Strategic Clinical Network
Steve Robson	The Royal College of Obstetricians and Gynaecologists
Tony Childs	Health and Social Care Information Centre

Stakeholders involved with the element 3 - Reduced Fetal Movement:

Name	Organisation
Alexander Heazell	The University of Manchester
Anita Dougall	The Royal College of Obstetricians and Gynaecologists
Cara Taylor	Central Manchester University NHS Foundation Trust
Devender Roberts	Cheshire & Merseyside Strategic Clinical Network
Hannah Hague	Cheshire & Merseyside Strategic Clinical Network
Jane Munro	The Royal College of Midwives
Michele Upton	NHS England

Stakeholders involved in the element 4 - Fetal Monitoring during Labour:

Name	Organisation
Anita Dougall	The Royal College of Obstetricians and Gynaecologists
Donald Peebles	University College London
Edward Prosser-Snelling	The Royal College of Obstetricians and Gynaecologists
Gail Johnson	The Royal College of Obstetricians and Gynaecologists
Jeanette Beer	NHS Litigation Authority
Michele Upton	NHS England
Tracey Glanville	Leeds Teaching Hospitals NHS Trust