NHS England

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

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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.

Working with four Task and Finish groups consisting of individuals with roles in key clinical, charitable, professional and governmental stakeholders with policy, clinical

[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

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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.

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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.

- 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.

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[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

[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

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
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.

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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

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- 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

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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

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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

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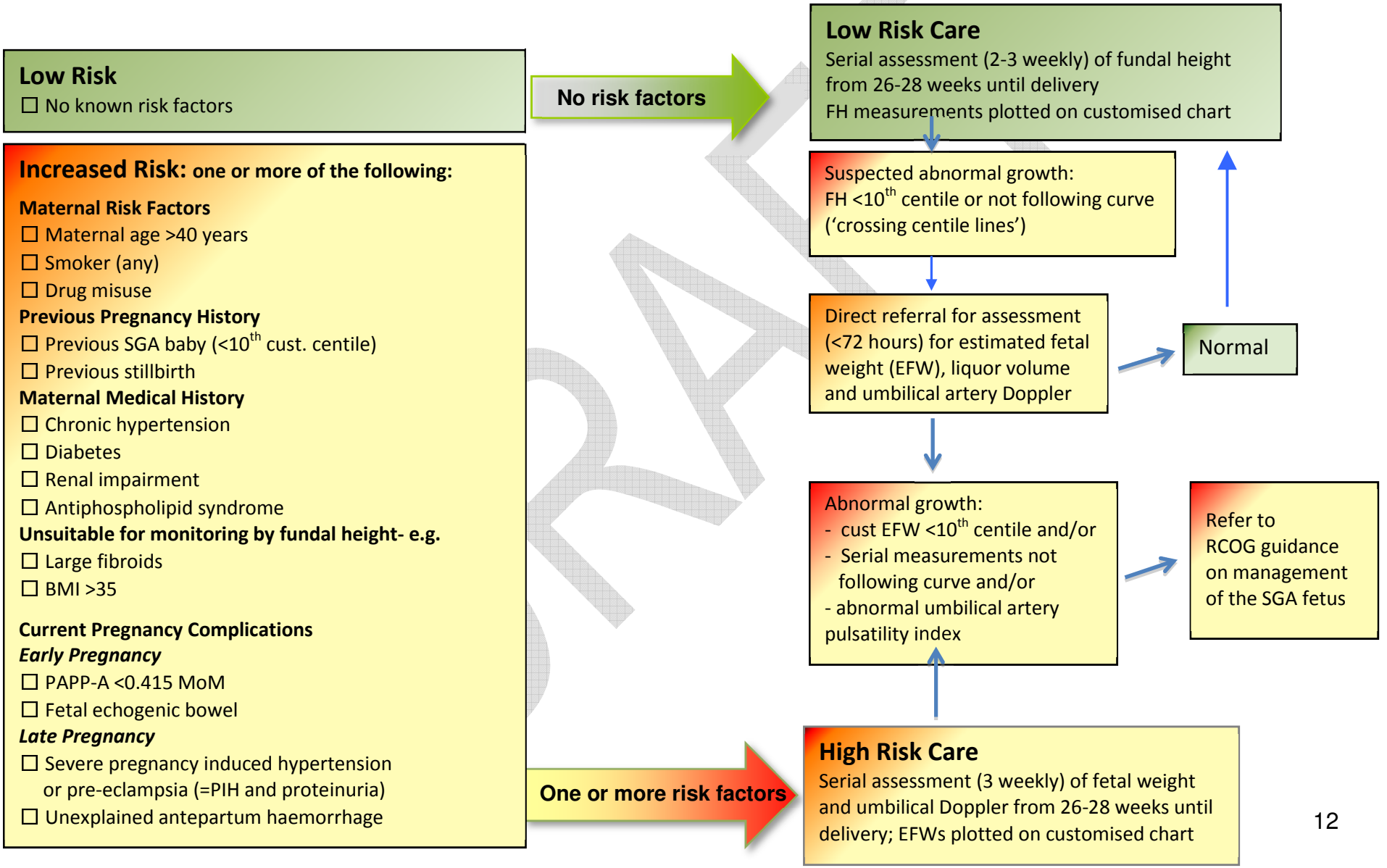
Algorithm and Risk Assessment Tool:
Screening and Surveillance of fetal growth in singleton pregnancies



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%

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Appendix 1: List of Stakeholders

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

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