MANCHESTER 1824
The University of Manchester

SPARE

Evaluation of the implementation of the Saving Babies' Lives Care Bundle in early adopter NHS Trusts in England

July 2018

Tommy's

Funding

The Saving Babies' Lives Project Impact and Results Evaluation (SPiRE) was commissioned by NHS England and delivered by the Tommy's Centre for Stillbirth Research within the Faculty of Biology, Medicine and Health Sciences at the University of Manchester.

The study was adopted into the National Institute for Health Research (NIHR) Clinical Research Network (CRN) portfolio.

ISBN number: 978-1-5272-2716-3

This report should be cited as:

Widdows K, Roberts SA, Camacho EM, Heazell AEP. Evaluation of the implementation of the Saving Babies' Lives Care Bundle in early adopter NHS Trusts in England. Maternal and Fetal Health Research Centre, University of Manchester, Manchester, UK. 2018.

Foreword

The authors of this evaluation were presented with a very difficult challenge and this report is testament to their knowledge and skill in producing such valuable feedback. I am grateful to the Tommy's Stillbirth Research Centre and their co-workers at the University of Manchester for their hard work and thank you to all the NHS staff who have contributed to the implementation of the Saving Babies' Lives Care Bundle.

The Care Bundle was born out of a response by the Strategic Clinical Networks to England's poor stillbirth rate, and in particular the disappointing international ranking published in the two Lancet Stillbirth series. The project gained momentum through the Maternity Transformation Programme and the ambition to halve the stillbirth rate. The Care Bundle has focussed upon the effective implementation of best practice care such as the RCOG green top guidelines on reduced fetal movements and the small for gestational age fetus.

Neither the 20% reduction in stillbirth rates nor the increased obstetric intervention with associated costs can be unequivocally attributed to the implementation of the Care Bundle but it is highly likely that these are related. Furthermore, the wider uptake of the Care Bundle in England during 2017 correlates with a fall in the stillbirth rate to 4.1 per 1,000 live births. This is a 5.1% decrease from the rate in 2016, and an 18.8% decrease since 2010.

The Care Bundle appears to work to reduce stillbirth rates, but the evaluation suggests there is room for improvement in both the Care Bundle and the guidelines the Care Bundle sign posts. The introduction of any new pathway carries a risk of 'intervention creep' and the increases in induction of labour, pre-term birth and caesarean section suggest that there is an opportunity to better target obstetric intervention.

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

The projected costs of the Care Bundle equates to 2.8% of the overall spend on maternity services. Much of these costs relate to increased obstetric intervention for which Trusts have been reimbursed through the Maternity Payment Pathway (MPP). The greatest cost pressure has been in relation to ultrasound scanning. One of the challenges for the future is to use this resource in a more targeted fashion.

The Maternity Transformation Programme is also reviewing the MPP which may help address this issue.

The SPiRE project has provided invaluable evidence to guide our next steps to halve the stillbirth rate and reduce one of the worst tragedies too many parents sadly have to face.

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

Foreword

We welcome the result of this evaluation which has shown that the stillbirth rate reduced following the implementation of the Saving Babies' Lives Care Bundle (SBLCB); the rate of decline achieved was greater than the underlying national decline.

This report is an independent evaluation of the SBLCB which sought to implement four practical interventions to reduce stillbirth in nineteen NHS maternity units. The initiative was launched by NHS England, bringing together medical experts and patient representatives in response to the Government's ambition to halve stillbirth by 2025 and keeps us on target to deliver that goal.

It is good practice to evaluate the impact of changing care in the NHS and this study reminds us that there are often consequences of making changes - some of which are inevitable but place extra demands on scare resources in maternity units. Some of the consequences cause concern, most notably the increase in preterm birth; which is associated with morbidity for babies. It is to be welcomed that the Government has now added a target for reduction of preterm birth and future iterations of the Care Bundle must address these twin objectives in tandem.

Parents welcome the implementation of evidence-based research into clinical practice as many parents have supported and contributed to this research in the hope that other parents will not have to experience the devastating loss of their baby. Parents also welcome being involved in improving their own care; giving them the opportunity and support to give up smoking cigarettes and the knowledge to monitor their baby's movements and report when they had concerns, knowing they would be taken seriously and their concerns acted upon.

Despite notable and laudable improvements there was obvious variation between units in implementing the interventions, and disappointingly not everyone was using up to date clinical guidelines. There is potential to deliver even greater reductions in stillbirth if more complete implementation and adherence to the Care Bundle and clinical guidelines was achieved.

On behalf of all parents, their babies and parents-to-be, I want to thank everyone who has contributed to the SBLCB; its initiation, development, implementation and evaluation - let's hope this gives us the impetus to accelerate the implementation of evidence based best practice so that this country is the safest place in the world to have a baby.

Jane Brewin,
Chief Executive, Tommy's

Tommy's

Foreword

The Saving Babies' Lives Care Bundle (SBLCB) has been implemented in England alongside a substantial number of other initiatives focused on achieving the national ambition to halve the rates of stillbirth, neonatal deaths and brain injury by 2025. Starting the evaluation just as the Care Bundle was launched was not ideal, so the team from Manchester took the only practical approach possible within the time constraints, of a before and after analysis. Conducting this comprehensive evaluation to the required timetable and within the resources was nothing less than heroic and I would like to congratulate the team on their achievements.

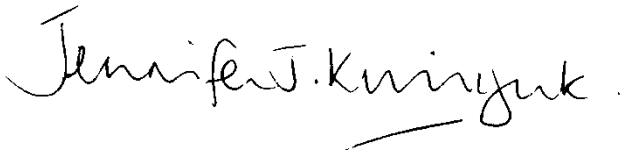
In assessing the results and generalising from them we do need to bear in mind that it is still early days in terms of implementation; there was no demonstrable relationship between stillbirth rates and the overall implementation score of the care bundle. Those Trusts who participated are early adopter sites and are not necessarily representative of all Trusts, and that other initiatives are simultaneously underway. The evaluation team carefully took these contextual issues into account in their interpretation and are quite rightly cautious in saying that they cannot unambiguously attribute the reduction in the stillbirth rate in the participating Trusts directly and wholly to the Care Bundle. Nevertheless, the fact that there was reduction in stillbirth rates is very encouraging.

Likewise, on the same basis, we must also be cautious in wholly attributing the increase in scanning, inductions and emergency caesarean sections seen over the same period to the Care Bundle implementation. However, it is highly plausible that the focus on growth (element 2) and the increase in the number of ultrasound scans performed is a consequence of the focus on the identification of small for gestational age babies, and that the increase in inductions is also partly a consequence of the response to the resulting increase in identifying these at risk babies. In contrast there seems to have been very little impact of the first element of the bundle aimed at smoking cessation. Smoking at delivery most plausibly seems to have been decreasing generally with little effect of the care bundle and in the face of anecdotal evidence of the withdrawal of smoking cessation services generally.

Although some information was not available the evaluation team attempted to estimate the cost of the Care Bundle implementation across England. They concluded that implementation across all trusts in England will cost about £94 million. Importantly most of these costs will be ongoing.

When the SBLCB was launched the findings of the recent MBRRACE-UK confidential enquiry had identified similar findings to the CESDI enquiry 20 years earlier. However, there had been little discernible impact of the CESDI findings on subsequent stillbirth rates raising the question: how are we going to do better this time? The findings from the evaluation give me cause for cautious optimism that we are now on the right track. One further important consequence of the Care Bundle has been to raise the profile of stillbirths in Trusts as deaths they should be concerned to prevent.

This is crucial, if we are to achieve better outcomes for all mothers, babies and families and realise the national ambition by 2025.



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

Executive Summary

Background

This report presents the findings from the Saving Babies Lives Project Impact and Results Evaluation (SPiRE) conducted by the Tommy's Stillbirth Research Centre at the University of Manchester, commissioned by NHS England in May 2016. The report describes the results of a comprehensive evaluation involving nineteen NHS Trusts in England that have been implementing the Saving Babies' Lives Care Bundle (SBLCB) since April 2015, which aims to reduce the incidence of stillbirth by implementing best practice in four aspects of maternity care[1]. This report describes the degree of implementation, the clinical and service outcomes and the economic impact(s) following a maximum two year implementation period in these early adopter Trusts and crucially, whether implementation of SBLCB translates into fewer stillbirths.

Reducing stillbirth is at the core of the UK's National Maternity Ambition. The SBLCB is a central element of NHS England's Maternity Transformation Programme and a key metric of the Government's ambition to reduce the number of stillbirths in the UK by half by 2030[2], with a view to making the UK one of the safest places in Europe to give birth. Although the SBLCB was derived from national evidence-based clinical guidelines and accepted best practice, the purpose of this evaluation was to gather primary data to assess the effectiveness of the Care Bundle at reducing stillbirth rates and associated costs. It is anticipated that the findings will inform future iterations of the SBLCB.

Methods

Nineteen NHS Trusts in England took part in the evaluation, they were located across 9 clinical networks and the evaluation included both secondary and tertiary centres. In response to the commissioning brief, which identified that the evaluation should minimise the burden of data collection on participating organisations, the evaluation employed a pragmatic before and after study design to determine whether stillbirth rates and other outcome measures altered over time. Data was obtained retrospectively from a number of sources. Longitudinal birth data was obtained from Trust's electronic records encompassing a two-year period before and after the SBLCB implementation date in the early adopter Trusts on 1 April 2015. Data on stillbirths (defined as a baby delivered at or after 24+0 weeks gestation showing no signs of life, irrespective of when the death occurred) was primarily collected from clinical audit. Intervention outcomes and resource use associated with SBLCB were collected from clinical audit and surveys with patients and healthcare professionals. Information on implementation levels was obtained from surveys with organisational leads at each Trust.

Analysis

Stillbirth rates, clinical and service outcomes, element outcomes, estimated costs relating to SBLCB implementation and local guideline appraisal are reported. Information about the impact of

implementation of the SBLCB on staff and services is described. Participating trusts were assigned a letter for anonymization in the analysis.

Rates before (April 2013) and after (April 2017) implementation of SBLCB on the nominal date of April 2015 were estimated and the relative risk ratio (RR) between these two time points was estimated. For audit or questionnaire data, rates before and/or after SBLCB implementation were computed as simple averages of the available data, and (where we have pre- and post-implementation data) a risk-ratio was estimated.

Results

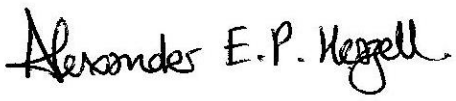
All elements of the SBLCB were implemented to some degree in the early adopter Trusts. Screening for cigarette smoking using carbon monoxide monitors was almost universally accepted, facilitating referrals to smoking cessation services. Structured screening for small for gestational age (SGA) babies increased the proportion of SGA infants detected antenatally from 33.8 to 53.7%. The majority of women were given and read information regarding reduced fetal movements, with almost all women monitoring their movements. A buddy system to improve interpretation of fetal heart rate traces in labour is in place in almost all units.

During the time period analysed in the early adopter Trusts there was a statistically significant reduction in stillbirth of 20%; this reduction was also seen in term stillbirths. Due to variations in the timing and level of implementation of the various elements of the SBLCB this reduction cannot be unambiguously related to its implementation. However, it is highly plausible that the SBLCB contributed to the fall in stillbirths. There was an increase in the number of ultrasound scans and in the proportion of women having interventions at or around the time of birth including induction of labour (by 19.4%) and emergency caesarean section (by 9.5%). Such increases would be an expected consequence of increased detection rates of SGA and compromised fetuses and are likely to be related in some degree to implementation of the SBLCB. During the time period analysed there was an increase in the rates of preterm birth (by 6.5%), admission to a neonatal unit and in the number of elective caesarean sections (by 19.5%). These changes may be the result of other changes in population or policies as the SBLCB does not include guidance which recommends preterm birth (except in the case of SGA) or elective caesarean section. Nevertheless, these changes in practice have resource implications. The key findings are summarised in the following sections.

Conclusion

This evaluation demonstrates the importance of studying the impact of large scale quality improvement programmes to ensure that they are having the desired effect. Based upon the findings of the evaluation we have identified recommendations for policymakers, managers and clinicians which address how the potential positive impact of SBLCB can be developed in future iterations. These include educating frontline staff about the SBLCB and involving them in optimal delivery of

care to improve outcomes and experience of care for mothers and their babies, and to consider how collection of high-quality data is central to providing high-quality care and evaluating changes in practice.



Professor Alexander Heazell
Director, Tommy's Stillbirth Research Centre, University of Manchester
Honorary Consultant Obstetrician, Manchester University Hospitals NHS Foundation Trust

Key Findings

The stillbirth rate improved over the SBLCB period studied however we cannot specifically relate these changes to the SBLCB interventions

A. In participating Trusts, stillbirth rates have declined by 20% over the period during which the Saving Babies' Lives Care Bundle (SBLCB) was implemented, although this improvement cannot be unambiguously attributed to the Care Bundle. The crude stillbirth rate was 4.14/1,000 births before SBLCB and 3.31/1,000 births after SBLCB. Term singleton stillbirths declined by 22% over the same period. There was no demonstrable relationship between stillbirth rates and the overall implementation score for the SBLCB.

B. Significant variation in the stillbirth rate persists across the early adopter Trusts beyond that explicable by care level and aggregated deprivation score. This suggests that there may be variation in practice between Trusts and therefore scope for improvement in some. Associations with deprivation suggest a need for wider scale social and public health policy changes to tackle inequality in addition to the SBLCB if the stillbirth rate is to be further reduced.

C. It was not possible to determine whether implementation of SBLCB or any of its individual components *per se* reduces stillbirth or affects any of the associated clinical and service outcomes. However, due to the nature of the interventions it is highly plausible that SBLCB contributed to the continued improvement in stillbirth rate in the early adopter Trusts.

D. Based on the change in stillbirth rate before and after the launch of the SBLCB, it is estimated that there were potentially 161 fewer stillbirths across the participating Trusts and 1,106 fewer stillbirths across the whole of England between April 2015 and April 2017.

SBLCB elements 1 to 4

E. The proportion of women recorded as smoking at delivery declined from 14.3% before SBLCB to 11.8% after SBLCB. However, there was no evidence for an increase in smoking cessation rates; rather this likely reflects a societal change as fewer women were recorded as smoking at booking. Carbon monoxide (CO) monitoring was almost universal with high acceptance rates yet referral to smoking cessation services was poor, and even when referred many women did not attend their appointment.

F. Antenatal detection of small for gestational age (SGA) babies (defined as an estimated fetal weight (EFW) below the 10th centile at last ultrasound scan in the audit) increased by 58.8% during the SBLCB implementation period from 33.8% before SBLCB to 53.7% after implementation of the SBLCB in participating Trusts. Detection improved due to better fetal surveillance through the use of growth charts and serial ultrasound scanning.

G. Maternal awareness for monitoring fetal movements is good, reflected in the high number of women (36.5%) attending hospital due to perceptions of reduced fetal movement (RFM). Most women attending for RFM received an ultrasound scan (64.9%) and/or had labour induced (54.7%). Most Trusts are using the recommended RFM leaflet although use of the SBLCB checklist was lower.

H. Very few Trusts were able to provide records for staff training in CTG interpretation and auscultation and competency assessment for the five year evaluation period and consequently data was too incomplete to allow reliable interpretation. A buddy/sticker system for intrapartum CTG monitoring is now employed by most Trusts.

Service impact

I. Following implementation of the SBLCB in study sites, the number of ultrasound scans performed increased (by 25.7%) as did interventions at or around the time of birth including induction of labour (by 19.4%) and emergency caesarean section (by 9.5%). Such increases would be an expected consequence of increased detection rates of SGA compromised fetuses. The number of elective caesarean sections also increased over the timeframe of this analysis (by 19.5%) but this may be related in part to other maternity policies given that none of the interventions of the SBLCB recommend an elective caesarean section.

J. Rates of preterm birth, admission to a neonatal unit and the number of babies receiving therapeutic cooling have increased in study sites during the timeframe of the SBLCB evaluation; by 6.5%, 17.1% and 27.7% respectively. As preterm delivery is not recommended in any element of the Care Bundle, and other factors that may influence these rates occurred in the same time frame, it is unclear if these changes are related to implementation of the Care Bundle.

K. Awareness of the SBLCB by staff was modest, with 42% of staff claiming to be unaware of it although staff were implementing all or part of the bundle as part of their daily practice. Awareness was lowest among frontline staff and highest in managers.

L. The methodological quality of clinical practice guidelines in relation to the SBLCB were generally of low quality and highly variable between Trusts.

Implementation costs

M. No additional funding was provided to Trusts to implement the SBLCB and some of the direct resources required are likely to have been obtained through the Maternity Payment Pathway (MPP). In other cases, the Trusts would have been reimbursed for the increased activity e.g. delivery by caesarean section would have been paid through the delivery tariff, and some additional activity will be a marginal additional cost for Trusts. As it was not possible to quantify this, the direct implementation costs reported here should be interpreted as the 'value' of the SBLCB rather than additional funding required.

N. The total estimated implementation and secondary costs associated with the SBLCB between April 2015 and April 2017 in the 19 Trusts was £27m. This cost is based on resource use reported by Trusts. However, the quality of the data reported was variable and as such it was necessary to make a number of assumptions about how Trusts were implementing the SBLCB. This cost should therefore be interpreted as a 'best estimate'.

O. The largest direct costs were for purchasing CO monitors and training in CTG interpretation but this is far outweighed by the secondary costs incurred for ultrasound scans (£9.8m), inductions of labour (£8.4m) and more costly deliveries (£7.8m) which account for 36%, 31% and 29% of the total cost respectively. However, it is not possible to determine how much of these secondary costs are directly attributable to the SBLCB.

P. The projected cost for one year of implementing SBLCB for the whole of England is £94m. The direct costs (£4.8m) are dwarfed by the secondary costs for ultrasound scans (£33.8m), inductions of labour (£28.9m), and more costly deliveries (£26.8m). To put this figure in context, the NHS spends approximately £2-3bn per year on maternity services.

Q. There may also be other costs and costs savings associated with implementing the SBLCB. This includes the impact on staff being required to complete additional tasks within the same amount of time during routine antenatal appointments or owing to the reduction in stillbirths, the costs associated with stillbirths would also be saved.

Recommendations

For managers and policymakers

1. Future iterations of the SBLCB should build upon the successful aspects identified in this evaluation. Consideration should be given to whether unwanted effects are attributable to the Care Bundle, and if so, whether these could be mitigated e.g. increased rate of emergency caesarean sections.
2. Development of a standardised assessment framework for collecting process outcomes (in addition to maternity dashboard for clinical outcomes) should be developed for monitoring SBLCB going forward.
3. Evaluation and data collection tools need to be embedded within future iterations of the SBLCB. Training and support is required for IT staff to enable reliable data extraction from routinely collected maternity data.
4. Training needs to be provided to ensure that professionals providing maternity care are aware of the goals and elements of the SBLCB.
5. Clinical guidelines for use in maternity units need to be updated to include recommended practice in the SBLCB (which is already consistent with NICE and RCOG); guidelines should link to relevant evidence and include audit criteria for process outcomes of the SBLCB.
6. The main outcomes of this evaluation should be disseminated to stakeholders, CCG commissioners, policy makers, and participating units (including frontline staff).
7. Clarity is needed to understand the additional costs of implementing the SBLCB for provider organisations, so that strategies to provide additional resources to manage secondary demands associated with the SBLCB (additional ultrasound scans, inductions of labour etc.) can be developed.
8. Care needs to be "joined up" between different care providers and responsible organisations. From SBLCB perspective this is most relevant for smoking cessation services which are rarely provided within maternity services, preventing easy access for mothers.
9. This evaluation focussed on clinical and service outcomes. Research about mothers' perceptions and priorities for their care should be conducted as the SBLCB is further developed.

For clinicians

1. Clinicians working in maternity units in NHS England need to be aware of the components of the SBLCB and consider how to implement the recommended care into their practice.
2. Clinicians need to consider how consequences such as increased rates of preterm birth and emergency caesarean section relate to implementation of SBLCB (if at all). Practice

recommended by guidelines needs to be individualised within the context of individual mothers and babies.

3. A multidisciplinary approach is required to ensure that health promotion messages are given consistently e.g. smoking cessation, presence of normal fetal activity.
4. Clinicians should be aware of process and outcome measures in their maternity unit.

Key Learning Points for Implementation

Successes

1. Early adopter Trusts demonstrated clear engagement with the SBLCB, as evident by increased implementation of the elements over the timeframe of the evaluation.
2. Carbon monoxide testing and the uptake rate by women.
3. Information provision for RFM and high levels of awareness among women regarding monitoring of baby's movements.
4. Provision of the NHS England RFM leaflet which did not lead to higher hospital attendance rates.
5. Surveillance for fetal growth using growth charts and/or serial ultrasound scans improves identification of SGA babies.

Barriers

1. The lack of awareness of the SBLCB by staff and the need for better training and engagement of staff in implementation of the SBLCB.
2. The inadequate collection of data by Trusts meaning that effective monitoring of birth outcomes and service delivery is not possible.
3. The additional resources needed to manage secondary demands associated with the bundle, in particular for the elements associated with additional ultrasound scans and induction of labour.
4. CO testing is not effective if referrals to smoking cessation services are not made or attended.
5. Continued difficulties in recording competency assessment and ensuring all staff are trained and assessed annually in CTG.
6. Socioeconomic factors remain important contributors to stillbirth and without parallel initiatives to address inequality; healthcare interventions can only have limited impact.

Abbreviations

AGREE II	Appraisal of Guidelines for Research & Evaluation II
AMU	Alongside midwife led unit
BMFMS	British Maternal and Fetal Medicine
CCG	Clinical Commissioning Group
CI	Confidence interval
CO	Carbon monoxide
CQUIN	Commissioning for Quality and Innovation
CTG	Cardiotocograph
EBC	Each Baby Counts
EFW	Estimated fetal weight
EMCS	Emergency caesarean section
EPR	Electronic Patient Record
FGR	Fetal growth restriction
FMU	Free Standing Midwife Led Unit
GAP	Growth Assessment Protocol
HRA	Health Research Authority
IMD	Index of Multiple Deprivation
LNU	Local Neonatal Unit
MBRRACE-UK	Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK
MPP	Maternity Payment Pathway
NICU	Neonatal Intensive Care Unit
NMDS	National Maternity Data Set
OU	Obstetric Unit
PI	Perinatal Institute
RCM	Royal College of Midwives
RCOG	Royal College of Obstetricians and Gynaecologists
RFM	Reduced fetal movements
RR	Risk ratio
SaBiNE	Saving Babies in North England
Sands	Stillbirth and Neonatal Death Charity
SBLCB	Saving Babies' Lives Care Bundle
SCBU	Special care baby unit
SFH	Symphysis fundal height
SGA	Small for gestational age
SPiRE	Saving Babies' Lives Project Impact and Results Evaluation
TAMBA	Twins And Multiple Births Association

Acknowledgements

We are immensely grateful to all NHS Trusts in England who were involved in this collaborative effort to evaluate the implementation of the Saving Babies' Lives Care Bundle (SBLCB). In particular we would like to acknowledge the contribution of the numerous health professionals and organisations for their enthusiasm and commitment to the evaluation, and for contributing their time to gather information for this report. We thank the numerous women and healthcare professionals who took the time to complete the surveys, and to the obstetricians for their contribution and expertise in the clinical guideline assessment. Without the dedication of the maternity services to quality improvement, this report would not have been possible.

We would like to thank the nineteen Trusts who gave up their time to make this evaluation possible: Barnsley Hospital NHS Foundation Trust, Birmingham Women's NHS Foundation Trust, Countess of Chester Hospital NHS Foundation Trust, Doncaster and Bassetlaw Hospitals NHS Foundation Trust, Gateshead Health NHS Foundation Trust, Liverpool Women's NHS Foundation Trust, Manchester Foundation Trust, Norfolk and Norwich University Hospitals NHS Trust, North Cumbria University Hospitals NHS Trust, Oxford University Hospitals NHS Trust, Plymouth Hospital NHS Trust, Royal United Hospitals Bath NHS Foundation Trust, Sherwood Forest Hospitals NHS Foundation Trust, St Helens and Knowsley Teaching Hospitals NHS Trust, Taunton and Somerset NHS Foundation Trust, The Mid Yorkshire Hospitals NHS Trust, The Royal Devon & Exeter NHS Foundation Trust, University Hospitals of Morecambe Bay NHS Foundation Trust and the York Teaching Hospital NHS Foundation Trust.

This report has benefitted greatly from the expertise and contribution from members of professional colleges and charity organisations. We thank the Royal College of Obstetricians and Gynaecologists (RCOG), The Royal College of Midwives (RCM), British Maternal and Fetal Medicine (BMFMS), Twins and Multiple Births Association (Tamba), Tommy's, Mothers and Babies: Reducing Risk through Audits and Confidential enquiries across the UK (MBRRACE-UK), Stillbirth and Neonatal Death Charity (Sands), Mama Academy, Each Baby Counts (EBC) and the Perinatal Institute (PI) for their guidance in producing this report.

Finally, it is with grateful thanks that we acknowledge the support of the Care Bundle team at NHS England for commissioning this study and commitment to improving maternity care, which we hope will be a significant step forward in achieving a substantial reduction in stillbirth in England.

Contents

Tables

Figures

1. Introduction

The death of a baby has significant psychological, social and economic consequences for parents and their families which persist for many years[3]. Stillbirth, the death of a baby before birth, remains a challenge to maternity services in high-income countries such as the UK. In the UK, the majority of stillbirths occur in the antenatal period (~90%) and occur in normally-formed babies[4]. A significant proportion of these deaths are preventable; Confidential Enquiries into normally formed antepartum stillbirths and intrapartum-related deaths identified deficiencies in care that contributed to the outcome for the baby in 60 and 80% of cases respectively[5].

The prevention of stillbirth and other adverse obstetric outcomes remains a challenge to both public health and maternity services. Historically, the stillbirth rate in the UK has lagged behind other high-income countries; in 2015, the UK ranked 24th out of 49 high income countries and the annual rate of reduction of 1.4% is significantly lower than comparable countries (e.g. 6.8% in the Netherlands) with about a 33% variation in rates between regions[4, 6]. In 2016, a series of articles in the Lancet called for efforts to address the disparity in stillbirth rates between, as well as within, individual countries[6]. To address the stillbirth rates in the UK, the Government announced a new ambition to halve the rates of stillbirths by 2030, with a 20% reduction by 2020. Fulfilment of this ambition requires a multifactorial approach which addresses relevant conditions associated with stillbirth.

Some risk factors for stillbirth in high-income countries are well established, these include: fetal growth restriction, maternal medical co-morbidities (e.g. diabetes, hypertension), cigarette smoking and reduced fetal movements[7]. There is also evidence for interventions in these conditions which either improves perinatal outcome or reduces harmful exposure (e.g. smoking cessation therapies)[8]. Furthermore, national programmes to address aspects of maternity care in other countries, such as induction of labour for prolonged pregnancy at 41 weeks in Denmark, have resulted in significant decreases in stillbirth without increases in caesarean section or adverse outcomes for mothers and babies[9]. The Saving Babies' Lives Care Bundle (SBLCB) offers a structured programme of interventions designed by NHS England to improve outcomes in four key elements of maternity care, which best available evidence and good practice show to have the greatest potential in reducing stillbirth and early neonatal death. These include:

- Element 1: Reducing smoking in pregnancy
- Element 2: Risk assessment and surveillance for fetal growth restriction
- Element 3: Raising awareness of reduced fetal movements
- Element 4: Promoting effective fetal monitoring in labour

A detailed review of the evidence underpinning the individual elements is outside the scope of this report, but these were based on the best available national guidance from the National Institute of Health and Care Excellence (NICE) or the Royal College of Obstetricians and Gynaecologists (RCOG).[10-13]

The SBLCB was piloted in early adopter Trusts from April 2015 and subsequent implementation of the care bundle has progressed steadily since entry into practice in March 2016 with over 130 maternity units in England implementing at least one intervention. Since the launch in early adopter Trusts NHS England has asked maternity units to report their implementation of the SBLCB. Responses to this survey demonstrated that, progress towards implementation has been uneven between different maternity care providers and the degree of implementation varied between different interventions of the Care Bundle.

It is imperative that complex interventions to reduce stillbirths such as the SBLCB are based upon the best available evidence. Although the elements were derived from national evidence-based clinical guidelines and widely accepted best practice, more primary data is needed to assess the effectiveness of the SBLCB at reducing stillbirth rates and if possible, to determine which elements are effective in reducing stillbirth rates.

1.1 The Saving Babies' Lives Evaluation

The Saving Babies' Lives evaluation was a focussed evaluation of the SBLCB in 19 Early adopter Trusts in England. The study, entitled *'Saving Babies Lives Project Impact and Results Evaluation'* (SPiRE)[14], was commissioned in May 2016 by NHS England and is led by a team of researchers at the University of Manchester in partnership with professional bodies and stakeholder organisations with expertise in stillbirth audit, research and prevention[1].

The overarching aim of the evaluation was to determine how maternity services in England are implementing the SBLCB into maternity care and whether this translates into improved perinatal outcomes. Crucially, it provides high-quality practice-based evidence about the effect of the SBLCB on the incidence of stillbirth and whether this is related to the extent of implementation.

In particular, the information in this report provides:

- a snapshot of implementation of the SBLCB as reported by the early adopter NHS Trusts and where possible, Trust-level strategies for implementation and subsequent engagement by staff;
- an assessment of the impact of implementing the SBLCB and its four components on stillbirth rates and associated clinical outcomes;
- a detailed assessment of the processes that underpin the four elements of the SBLCB;
- staff perceptions of maternity services and resource use following implementation of the SBLCB;
- a quality appraisal of clinical practice guidelines in relation to the SBLCB and
- an estimated cost of implementing the SBLCB in the 19 Trusts and for the whole of England.

[1] The partnership includes Royal College of Obstetricians and Gynaecologists (RCOG), The Royal College of Midwives (RCM), British Maternal and Fetal Medicine (BMFMS), Twins and Multiple Births Association (Tamba), Tommy's, Mothers and Babies: Reducing Risk through Audits and Confidential enquiries across the UK (MBRRACE-UK), Stillbirth and Neonatal Death Charity (Sands), Mama Academy, Each Baby Counts (EBC) and the Perinatal Institute (PI).

1.2 Things to know about this report

As the evaluation was commissioned after the launch of the SBLCB in early adopter Trusts, the study was by necessity non-randomised and observational in nature. In accordance with the commissioning brief the evaluation relied heavily on the retrospective extraction of routinely collected data from individual NHS organisations, which use varying definitions for a number of outcomes. In addition, as outcomes were not defined prior to the evaluation period some of the outcomes had very high levels of missing or invalid data as Trusts did not collect the requisite information. However, the primary outcome of stillbirth was collected across all Trusts.

Given the retrospective nature of the evaluation and complex nature of the SBLCB, we were not able to obtain accurate longitudinal data on the timing and fidelity of the implementation in each Trust with the detail necessary to drill down to the effects and fidelity of individual elements and interventions. None of the participating organisations moved from no implementation to complete implementation of any of the elements of the SBLCB, so these data do not compare “no intervention” with “complete intervention” of the SBLCB.

The views expressed are those of the authors and not necessarily those of NHS England who commissioned the research and approved the protocol but had no role in the data analysis, data interpretation and writing of the report.

2. Outline Methods and Analysis

2.1 The early adopter Trusts

The evaluation was conducted in 19 NHS Trusts across nine clinical networks in England between May 2016 and December 2017 (Table 1). Trusts varied in terms of the type of maternity unit (secondary/tertiary), their annual birth rate and the level of neonatal services provided.

All Trusts that were deemed early adopters of the SBLCB in 2015 were eligible to take part; these were sites that completed the 2015 NHS England Tracker Survey indicating that they were implementing the SBLCB. Initially, Trusts were selected to take part in the evaluation to compare outcomes in providers reporting full, partial or low implementation stages as reported in the Tracker Survey.

Table 1 Characteristics of the 19 early adopter Trusts (in 2017)

NHS Trust	Hospital or Site	Average Birth Rate	IMD decile [IQR]	Unit Type(s)[§]	Neonatal Unit
Barnsley Hospital NHS Foundation Trust	Barnsley District General Hospital	2900	3 [2-6]	OU+AMU	LNU
Birmingham Women's NHS Foundation Trust	Birmingham Women's Hospital	8265	2 [1-5]	OU+AMU	NICU
Countess of Chester Hospital NHS Foundation Trust	Countess of Chester Hospital	3263	6 [2-9]	OU+AMU	LNU
Doncaster and Bassetlaw Hospitals NHS Foundation Trust	Doncaster Royal Infirmary Bassetlaw Royal Infirmary	5240	3 [2-6]	OU OU	SCBU LNU
Gateshead Health NHS Foundation Trust	Queen Elizabeth Hospital	3205	3 [2-6]	OU	SCBU
Liverpool Women's NHS Foundation Trust	Liverpool Women's Hospital	8550	2 [1-5]	OU+AMU	NICU
Manchester Foundation Trust	Saint Mary's Hospital	8894	2 [1-4]	OU+AMU	NICU
Norfolk and Norwich University Hospitals NHS Trust	Norfolk and Norwich University Hospital	6600	6 [4-7]	OU+AMU	NICU
North Cumbria University Hospitals NHS Trust	Cumberland Infirmary West Cumberland Hospital	5833	NA	OU OU	SCBU
Oxford University Hospitals NHS Trust	John Radcliffe Hospital[†] Cotswold Maternity Unit Horton General Hospital Wallingford Midwife-Led unit Wantage Midwife-led unit	8166	8 [6-9]	OU+AMU FMU FMU FMU FMU	

Plymouth Hospital NHS Trust	Plymouth Hospital	2962	5 [3-7]	OU	NICU
Royal United Hospitals Bath NHS Foundation Trust	Royal United Bath Hospital† Chippenham Birthing Centre Frome Birthing Centre Paulton Birthing Centre	4207	NA	OU FMU FMU FMU	LNU
Sherwood Forest Hospitals NHS Foundation Trust	Sherwood Birthing Unit	1816	4 [2-6]	OU	LNU
St Helens and Knowsley Teaching Hospitals NHS Trust	Whiston Maternity Unit	3808	2 [1-5]	OU	LNU
Taunton and Somerset NHS Foundation Trust	Musgrove Park Hospital† Bracken Birthing Centre Mary Stanley Midwifery led unit†	3436	5 [4-7]	OU+AMU FMU FMU	LNU
The Mid Yorkshire Hospitals NHS Trust	Pinderfields Hospital† Bronte Birth Centre Friarwood Hospital	6309	3 [2-5]	OU+AMU FMU FMU	LNU
The Royal Devon & Exeter NHS Foundation Trust	Wonford Hospital† Honiton Birth Centre Okehampton Birth Centre Tiverton Birth Centre	3970	6 [4-8]	OU+AMU FMU FMU FMU	LNU
University Hospitals of Morecambe Bay NHS Foundation Trust	Royal Lancaster Infirmary† Furness General Hospital† Westmorland General Hospital†	4533	5 [2-7]	OU OU FMU	SCBU LNU
York Teaching Hospital NHS Foundation Trust	Scarborough Hospital† York Hospital	4859	6 [4-9]	OU+AMU OU	SCBU LNU

§ Information taken from the National Maternity and Perinatal Audit - Organisational Report 2017[15]

† Surveys completed at these hospitals

OU - obstetric unit

AMU - alongside midwife led unit

FMU - free standing midwife led unit

LNU - local neonatal unit

SCBU - special care baby unit

NICU - neonatal intensive care unit (level 3)

IMD (Index of Multiple Deprivation) decile estimated from the mother's postcode

2.2 The study design

The evaluation employed a pragmatic before and after study design to determine whether stillbirth rates (and associated intervention outcomes) have improved following implementation of the SBLCB. The start of implementation (the 'intervention launch') was nominally defined as April 2015 for all Trusts; we classified births as 'before SBLCB' or 'after SBLCB' depending on whether they were delivered before or after 1 April 2015 respectively. The national launch of SBLCB took place in March

2016. The study protocol was published in March 2018[14] and approved by the Health Research Authority (HRA) in June 2017 (HRA Reference 17/WM/0197).

2.3 Data reporting

Data was obtained from a number of sources and a pragmatic data collection approach was adopted to minimise burden on participating Trusts as requested by NHS England. Organisational surveys were used to collect information on how the SBLCB was implemented in each Trust between June and December 2017, and to what extent.

Electronic records of all live births (singletons and multiples) were requested from Trusts from April 2012 to October 2017. Individual level information and monthly aggregated data was collected at the Trust level. Stillbirth data was obtained primarily from clinical audit and augmented with electronic submissions where audit was unattainable. Data on a total of 467,661 livebirths and 1,903 stillbirths were obtained retrospectively from hospital databases encompassing the before and after SBLCB period.

Process measures for interventions were assessed using clinical audit alongside surveys of new mothers and health professionals in each Trust between June and December 2017. Seven hundred and twenty term singleton live births and 340 pregnancies with documented RFM were audited from women who gave birth between April 2017 and October 2017. Five hundred and ninety eight SGA pregnancies were audited for women who gave birth before and after the SBLCB. Patient and staff surveys were conducted between June 2017 and December 2017. Two thousand, two hundred and thirty mothers completed the postnatal survey (before discharge). One thousand and sixty four health professionals completed the staff survey. Survey data is descriptive using aggregated data. Table 1 shows which hospitals took part in the survey.

2.4 Assessing implementation levels

A Unit Resource and Leadership survey was sent to organisational leads at each Trust to gather information about the date of when implementation of the SBLCB began, the perceived levels of implementation at the time of the survey, and if any of the interventions were already implemented prior to April 2015. This information was used to calculate a score for current and prior implementation levels for each Trust.

Calculating implementation scores

To assess current implementation levels for SBLCB, Trusts were asked to state on a Likert scale whether each intervention in each element was implemented: a) all of the time, b) most of the time, c) half of the time, d) not much of the time, e) never or f) not relevant – we do not implement this intervention. A score of three was assigned for all of the time, two for most of the time and one for half of the time. Not much, never and not implemented all scored zero (along with no response),

totalling to give a current implementation score for each element and summed over all four elements to give an overall implementation score.

Trusts were also asked to state if any of the elements had been previously implemented, either a) fully, b) partly or c) not at all. A score of two was assigned for fully, one for partly and not at all was scored as zero; scores were summed over the four elements to get a prior implementation score.

Implementation start date

Some Trusts reported very late implementation of some elements or parts of elements of the SBLCB, after the end of the study period in October 2017. In such cases, data from the survey and responses to personal communications with key staff were used to create an implementation score that reflected implementation status in early 2017 (the post-implementation assessment date), during the pregnancies of women who delivered in the post-implementation audit period.

2.5 Analysis of stillbirth rates and outcomes

Pre and Post implementation

Monthly outcomes (women booked, women delivered, term singleton births, preterm singletons, induced deliveries, spontaneous deliveries, number of babies therapeutically cooled, and admissions to the neonatal intensive care unit (NICU)) were fitted using within-Trust longitudinal models. These are visualised by plotting mean values across Trusts with 95% confidence intervals (CI) for each month along with the fitted trend line. The average rates across Trusts at time points 2 years either side of the nominal start date of April 2015 (1 April 2013 and 1 April 2017) were estimated. The relative risk ratio (RR) between these two times is estimated along with its 95% confidence interval and associated significance level (P). Models were considered which allowed for a step change associated with SBLCB implementation, but this approach was unable to demonstrate any significant step changes so only simple linear trends over time are presented in this report. The lack of step-change likely reflects the gradual implementation of elements of the SBLCB over time as opposed to a clear change in practice at a specific timepoint such as would occur in a clinical trial. A full description of the statistical analysis is given in Appendix 1.

For audit or questionnaire data, the rates at the nominal before and after assessment times were computed as simple averages of the available data, and where we have pre and post-implementation data a risk-ratio is estimated.

Note that these comparisons are based on within Trust changes so naturally control for all Trust/population characteristics as there are no known substantive changes in Trust services or their populations over the time period of this evaluation.

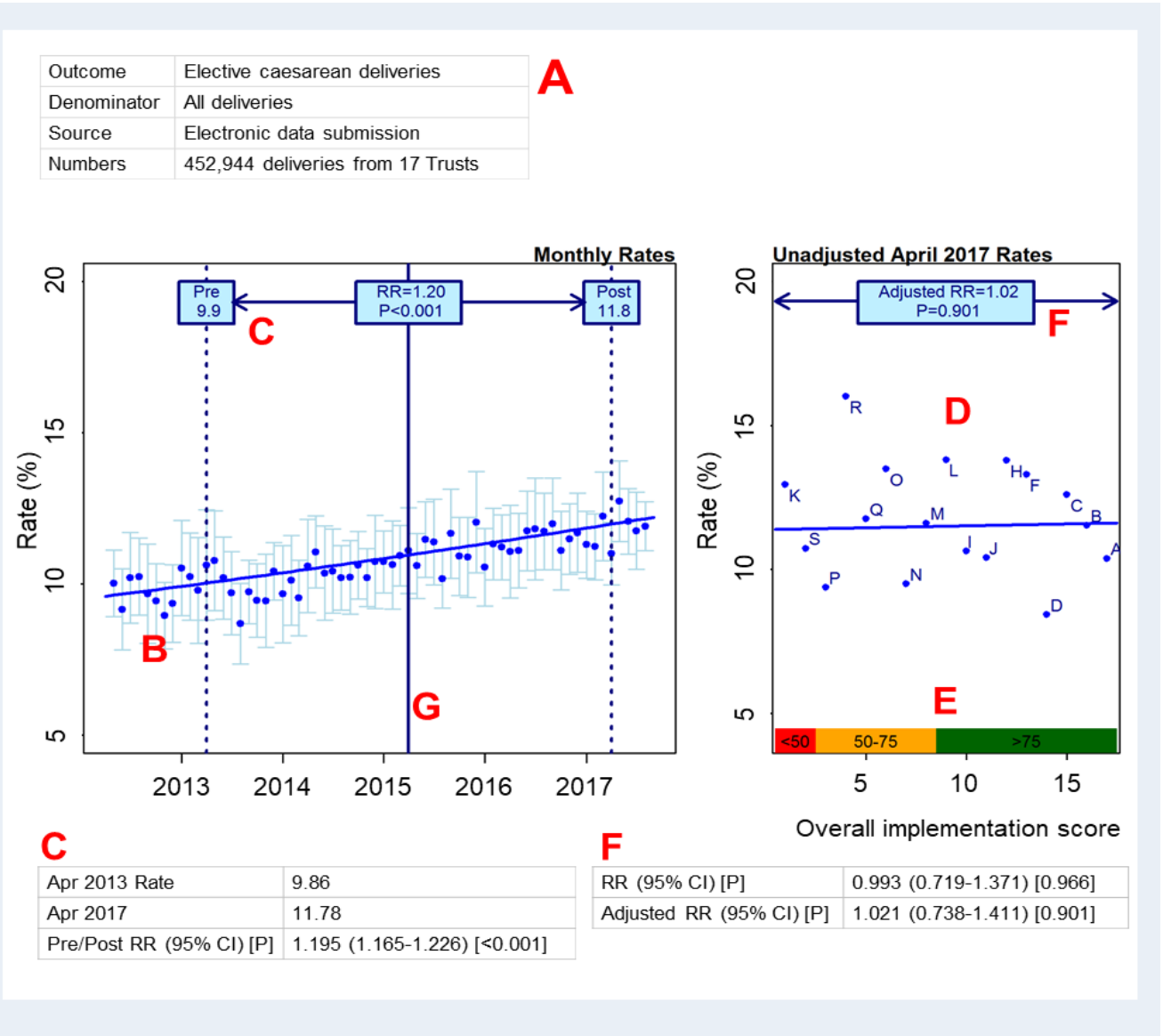
Effect of implementation

Post-implementation outcomes estimated as described above for each Trust were compared with the relevant implementation score (overall or element-specific). A RR and associated significance level for the difference between no and full implementation was computed adjusting for Care Level (Tertiary vs. Secondary) and Index of Multiple Deprivation (IMD) (mean decile of those delivering in each Trust). Note that as two Trusts failed to provide the data required the adjusted estimates were computed excluding these Trusts.

Data visualisation

For anonymization, each Trust has been given a letter and outcome data is shown as aggregated data. Figure 1 describes the components of the data visualisation for a typical outcome.

Figure 1. Example figure for data visualisation



A. Details of the data source and numbers of women included in the analysis.

B. Mean monthly rates with 95%CI and fitted trend line.

C. Derived estimates at nominal pre and post implementation dates as indicated along with risk ratio between the two time points. Table adds 95%CI.

D. Mean, unadjusted, post-implementation rates for each Trust as indicated by code letters ordered by implementation level, along with fitted trend line. Plotted against the rank of the implementation score as indicated.

E. Coloured bar indicates arbitrary low, medium and high implementers with actual scores given.

F. Risk Ratio between no implementation and full implementation, adjusted for deprivation and care level. Table adds 95% CI and shows both unadjusted and adjusted risk ratios.

G. Arbitrary start date of April 2015 for implementation of the SBLCB in early adopter Trusts

2.6 Economic analysis

The costs associated with implementing SBLCB were estimated based on data reported by the Trusts on the resources they used to implement the SBLCB and increases in resources used (e.g. number of ultrasound scans) derived from routinely collected data (as described above). Costs were estimated for the 19 early adopter Trusts and then for the whole of England; per Trust costs are not reported here.

As NHS Trusts were not given any additional funding in order to implement the SBLCB, it is likely that some of the direct resources required to implement the SBLCB have been absorbed as work already accounted for through the Maternity Payment Pathway (MPP). In some cases, Trusts would have been reimbursed for increased activity through the maternity tariff. As it was not possible to quantify this in the evaluation, the direct implementation costs reported here should be interpreted as the 'value' of the SBLCB rather than additional funding required.

The cost of implementation

The implementation cost consists of two parts: the direct cost of putting in place each element and the cost of the secondary effects (e.g. impact on mode of delivery, induction of labour, ultrasound scans). It was not possible to determine which element the secondary effects relate to and so they have been calculated for the SBLCB overall. In the estimate of secondary costs it was assumed that all of the increase in secondary resource use was due to SBLCB, however it was not possible to measure this.

The Unit Resource and Leadership survey was used to gather information about the direct resources used to implement the SBLCB from each Trust. Changes in secondary resource use were estimated as part of the data analysis described in Section 2.5.

Unit costs were derived from published sources (NHS reference cost database 2016; PSSRU Unit Costs of Health and Social Care 2016), NHS partners (NHS supply chain website), and training/software providers (Perinatal Institute; K2). The fees for externally-provided training courses were included in the implementation cost but "in-house" training was assumed to form part of ongoing continuing professional development (CPD) at no additional cost. The cost of staff time to complete either type of training was not included.

Period of implementation

The direct implementation cost was calculated to reflect the timing of implementation of the SBLCB reported by each Trust. The maximum period of implementation for estimating costs was April 2015 to April 2017 (24 months). Direct implementation costs were estimated for each Trust for the proportion of this period that they reported implementing each element. Trusts not implementing a particular element incurred zero direct costs for that element.

Stillbirths

The total annual birth rate for the 19 Trusts was used to estimate a denominator for a nominal two-year period to correspond with the length of the post-launch data collection period (April 2015-April 2017). The time-series-adjusted stillbirth rates from before and after the implementation date were applied to this number of births to estimate the difference in the number of stillbirths before and after implementation of SBLCB. This estimate assumes that the entire reduction in stillbirth rate was associated with SBLCB.

Estimates for the whole of England

Costs were estimated for the whole of England based on the estimated resource use in the early adopter Trusts, under the assumption that all centres in England implemented SBLCB for the time period of interest (one or two years). The number of stillbirths avoided following introduction of SBLCB was estimated based on the annual birth rate for England and the change in stillbirth rate observed in the early adopter Trusts participating in this evaluation.

Assumptions/sensitivity analyses

It was necessary to make a number of assumptions in order to estimate the resources and costs associated with the SBLCB. As such the costs and outcomes reported should be interpreted as 'best estimates'. The impact, on costs and outcomes, of varying some of the assumptions were explored in a series of one-way sensitivity analyses as shown in Appendix 2.

2.7 Guideline analysis

We systematically assessed the methodological quality of relevant maternity unit guidelines that are implemented locally as part of the SBLCB in all 19 participating Trusts. These were broadly categorised into 1) guidelines for smoking cessation in pregnancy, 2) detection and management of

fetal growth restriction, 3) reduced fetal movements and 4) intrapartum fetal monitoring. Staff views towards the use of guidelines in their maternity unit were also assessed using surveys.

Guidelines were assessed by 2 to 5 independent reviewers[2] using the Appraisal of Guidelines for Research and Evaluation (AGREE II)[16] tool which specifically assesses the methodological rigour and transparency with which the guideline was developed and has been employed previously to assess maternity guidelines. For each guideline, 23 appraisal criteria categorised into 6 domains were reviewed: 1) Scope and purpose, 2) Stakeholder involvement, 3) Rigour of development, 4) Clarity of presentation, 5) Applicability and 6) Editorial independence.

A quality score was generated for all six domains between 1 and 7, with 7 being the highest possible quality. An overall score for each guideline was generated independent to the individual domain scores. Both scores are expressed as a percentage.

The recommendations in the unit guidelines were compared against 12 recommendations in the SBLCB; three for element 1, five for element 2, two for element 3 and two for element 4. For each SBLCB recommendation, a score of 2, 1 or 0 was assigned for fully, partially or not included in the unit guideline respectively. For each element, a score was calculated by the sum of the score for each recommendation divided by the maximum possible score for each element, expressed as a percentage.

[2] These included four Consultants and one trainee doctor in Obstetrics and Gynaecology

3. Implementation of the SBLCB

3.1 Implementation scores

Figure 2 provides a snapshot of self-reported implementation levels by Trusts at the time of the survey (current) and post-implementation assessment date (assessment date). Colours indicate low (<50%, red), mid (51-75%, yellow) and high (≥76% green) implementation rates. Eighteen of the 19 Trusts reported to be implementing all four elements of the SBLCB. However, the extent of implementation varied considerably by element between and within Trust.

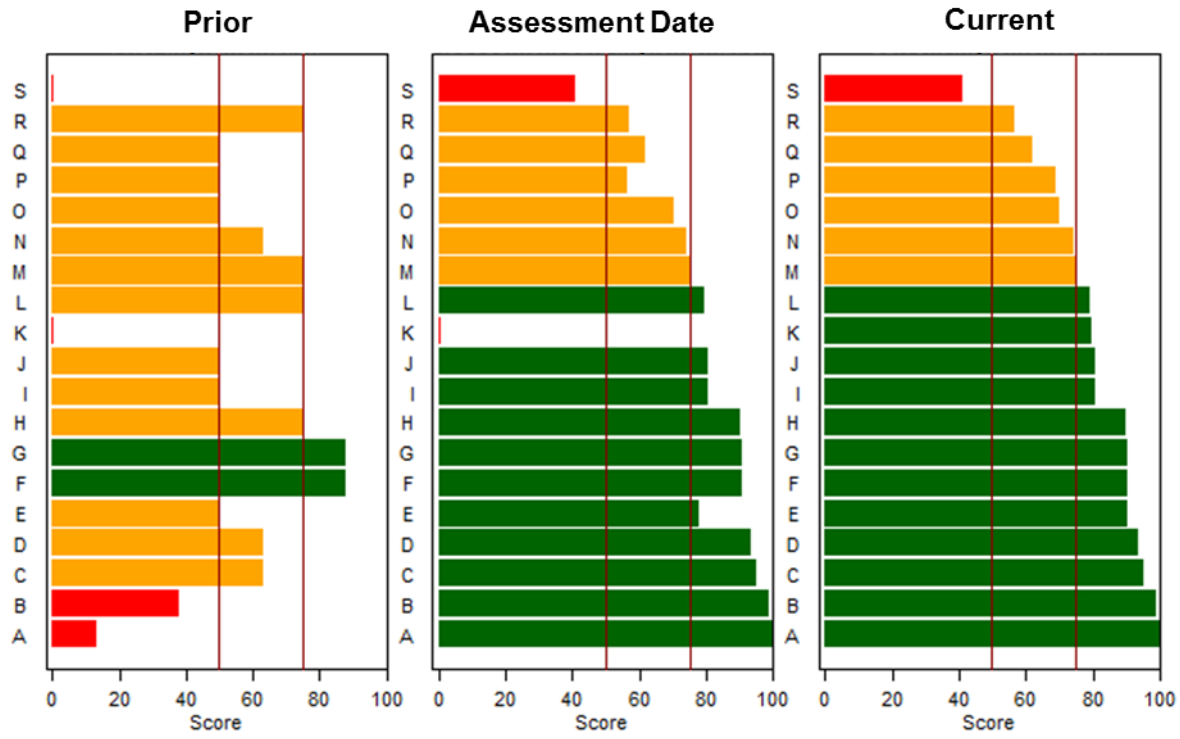


Figure 2. Implementation levels as reported by the early adopter Trusts

Figure 3 shows the implementation scores for each element at the post-implementation assessment date. Implementation of the individual elements was phased with most Trusts reporting implementation dates between April 2015 and December 2017. However, some Trusts reported implementing a particular element before the intervention launch date. Only 4 Trusts reported implementing all four elements at the same time.

In many cases, Trusts have been able to implement 100% of the recommended components for some elements; only one Trust reported full implementation of all four elements. Eleven Trusts reported full implementation for Element 3, 10 Trusts for Element 4, and 5 Trusts for Element 1. Element 2 was the least completely implemented with only one Trust reporting full implementation. A

full description of implementation for the individual elements in relation to intervention outcomes is provided in sections 6 to 9.

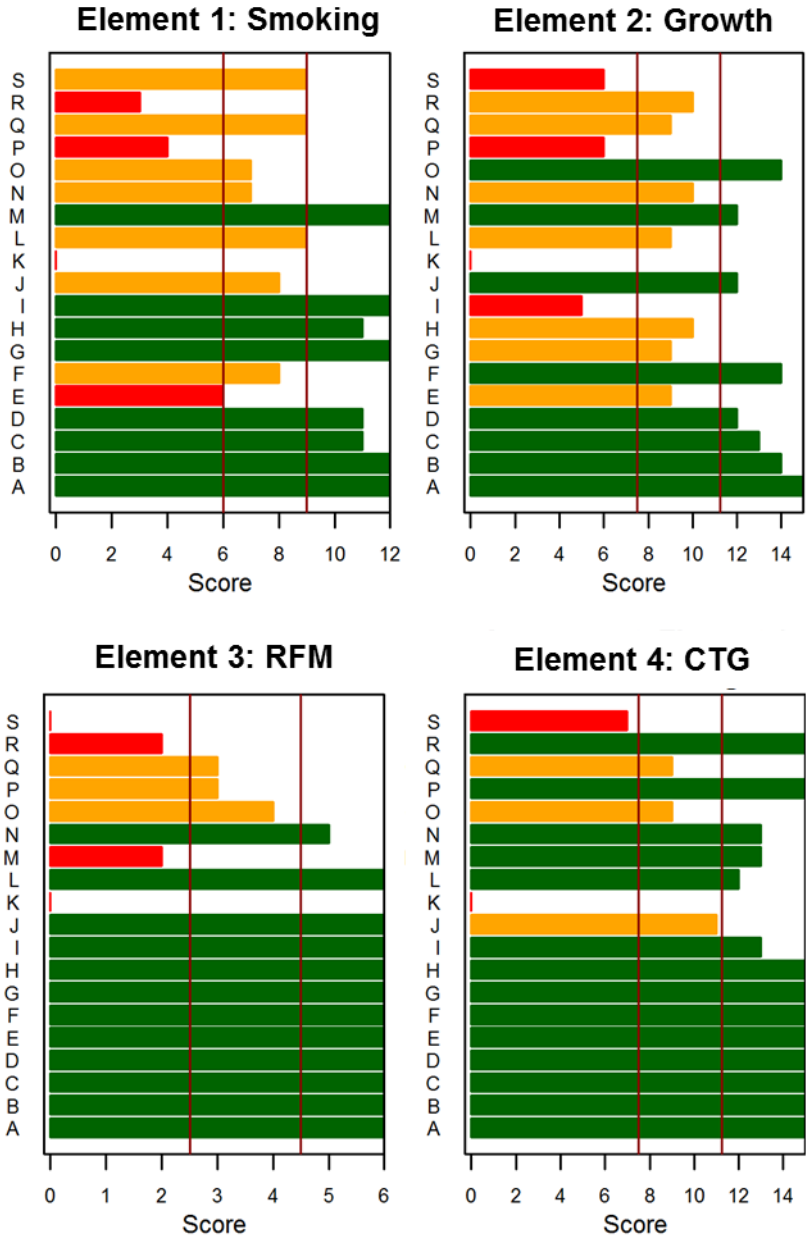


Figure 3. Implementation scores for the individual elements by the early adopter Trusts

3.2 Strategy and engagement

For most Trusts, a range of communication strategies were reported to promote engagement and implementation of the SBLCB by staff, though no formal strategy was reported to the evaluation team by any maternity unit. Peer-to-peer communication was the most common means of providing staff with knowledge of the SBLCB. Staff from 7 Trusts attended the national launch day and 6 Trusts held a local study day for staff.

In 13 Trusts clinical guidelines were reported to have been updated to reflect the guidance provided in the SBLCB. Quality improvement policies that included stillbirth reduction were in place in 2 Trusts. Sixteen Trusts reported having a designated SBLCB "lead" to provide strategic leadership for implementation. These were primarily midwives or consultant obstetricians but in some units these were governance and education staff. However, awareness of the Care Bundle by staff was poor across the Trusts, with only 58% of all respondents reporting awareness of the SBLCB in their unit. However, when asked about daily practices staff were already implementing all or part of the Care Bundle and some respondents were simply unaware that the interventions formed part of 'the 'bundle'. This reflects variations in implementation strategies of the SBLCB at the Trust level. Consultants, managers and midwives reported the highest awareness; ultrasonographers and trainee obstetricians were the least aware though response rates of these groups were low in comparison.

3.3 Clinical governance

In general, maternity risk management strategies were similar across the Trusts and indicated a high-level of engagement with local and national processes. All Trusts reported that a perinatal death review process was in place; a multidisciplinary panel was reported in some but not all cases. All Trusts reported a patient safety review process and virtually all apply the NICE recommendations for safe midwifery staffing for maternity settings.

Seven Trusts had a contract with their Clinical Commissioning Group (CCG) which focussed on stillbirth reduction. One Trust had involvement from NHS Improvement regarding their perinatal mortality figures and two had an inspection from the Care Quality Commission in the 24 months prior to the survey regarding concerns around the number of perinatal deaths.

All Trusts took part in the Perinatal Mortality Surveillance Report from MBRRACE-UK in 2014 and the majority took part in Each Baby Counts.

4. Stillbirth Rates

This chapter presents the information gathered from the 19 Trusts about the rates of stillbirths before and after SBLCB implementation, and the relationship with the implementation score. We also explored service and socio-economic factors associated with stillbirth rates in the post SBLCB implementation period.

4.1 Definition and data sources

Data on the number of stillbirths (defined as a baby delivered at 24+0 weeks gestational age showing no signs of life irrespective or when the death occurred) was obtained from clinical audit or from electronic submissions where audit was not possible. The primary outcome was all stillbirths, with term (≥37w) singleton stillbirths reported as a secondary outcome. We also explored the number of term stillbirths that were SGA, based on a calculated birthweight centile below the 10th customised centile (individual level information from electronic stillbirths submissions) or known SGA as documented in the maternal notes (casenote audit).

It was not possible to reliably determine from the data returned on stillbirth causation the proportion of stillbirths that were normally-formed and data presented in this section includes stillbirths with congenital anomalies. Stillbirths due to terminations of pregnancy were excluded from the analysis.

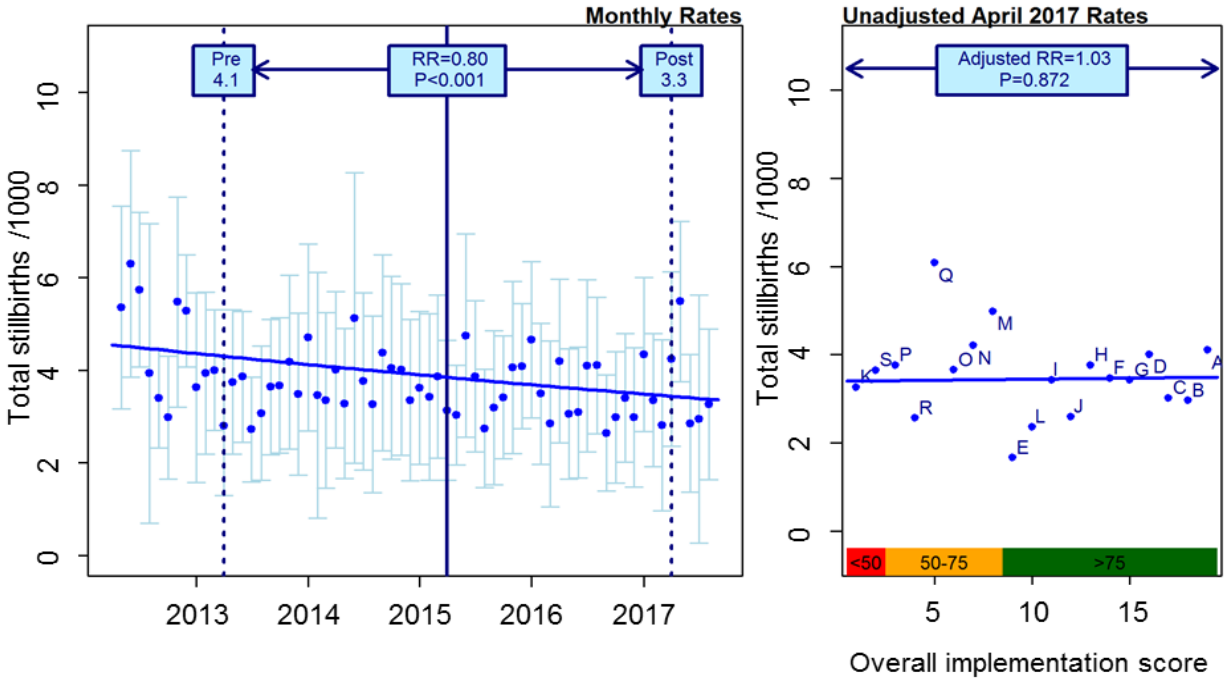
4.2 Stillbirth rates

Figure 4 shows the crude stillbirth rate for all 19 Trusts over the 5 year time period. The total number of stillbirths declined from 4.14/1,000 births before to 3.31/1,000 births after the SBLCB implementation date. This equates to a 20% reduction in the rate of stillbirth in these Trusts. Rates varied considerably between participating Trusts ranging from 1.51/1.21 to 6.18/6.29 per 1,000 births before and after SBLCB respectively.

However, as can be seen from the figure these improvements occurred gradually over time with no step-changes associated with SBLCB implementation and formal statistical analysis failed to find any evidence for step changes associated with implementation dates. Thus we were unable to demonstrate that this reduction was associated with the introduction of SBLCB, or indeed to the reported level of implementation (Figure 4). Rather, these changes reflect an improvement in the stillbirth rate over time and cannot be unambiguously associated with introduction of the SBLCB.

Figure 4. Average total stillbirth rate pre and post SBLCB implementation across the early adopter Trusts

Outcome	All stillbirths
Denominator	All deliveries (per 1000)
Source	Stillbirth audit (electronic or casenote)
Numbers	479,864 deliveries from 19 Trusts



Apr 2013 Rate	4.14
Apr 2017	3.31
Pre/Post RR (95% CI) [P]	0.799 (0.705-0.906) [<0.001]

RR (95% CI) [P]	0.925 (0.512-1.671) [0.797]
Adjusted RR (95% CI) [P]	1.028 (0.735-1.438) [0.872]

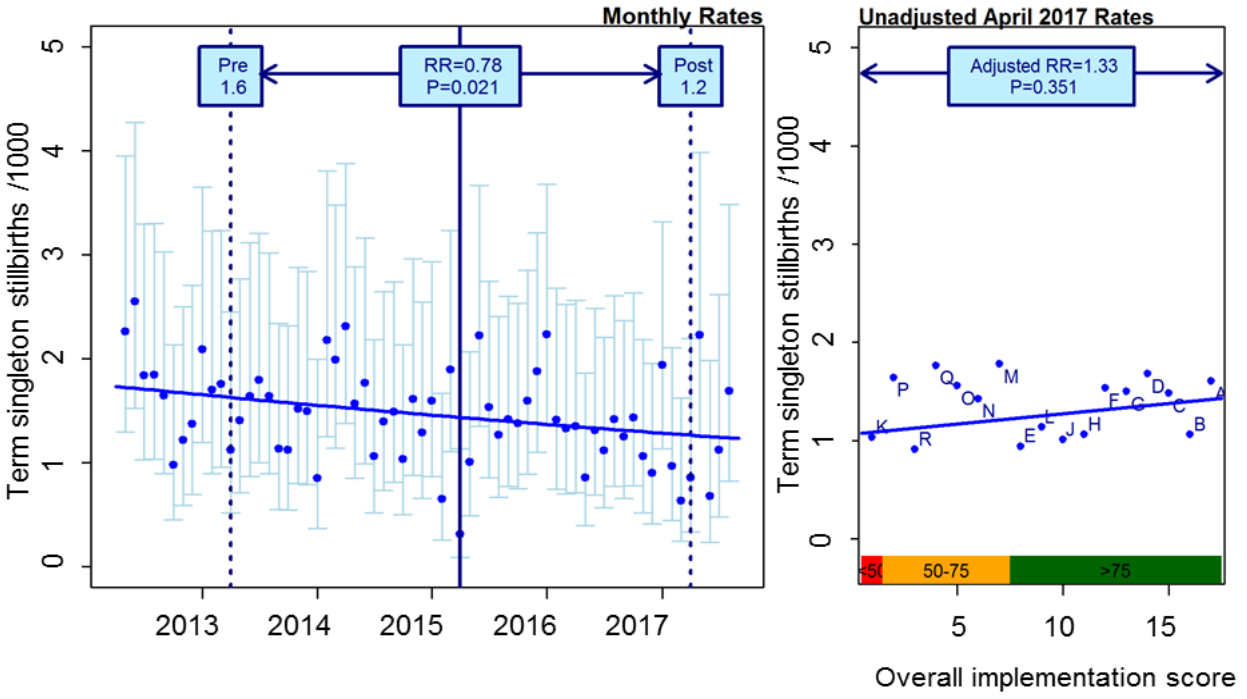
4.3 Term singleton stillbirths

Term singleton stillbirths declined by 22% over the same period from 1.58/1,000 births before to 1.23/1,000 births after the SBLCB implementation date (Figure 5). The proportion of term singleton stillbirths that were born SGA declined by 31% over the same period from 0.54/1,000 births before SBLCB to 0.37/1000, but this was on the border of statistical significance. The rate at the end of the evaluation period was not associated with the level of implementation.

Although data were requested, it was not possible to determine the proportion of normally-formed stillbirths due to poor quality of data from Trusts.

Figure 5. Average rate of term singleton stillbirths pre and post SBLCB implementation across the early adopter Trusts

Outcome	Term singleton stillbirths
Denominator	Term singleton deliveries (per 1000)
Source	Stillbirth audit (electronic or casenote)
Numbers	403,708 deliveries from 17 Trusts



Apr 2013 Rate	1.58
Apr 2017	1.23
Pre/Post RR (95% CI) [P]	0.777 (0.627-0.962) [<0.021]

RR (95% CI) [P]	1.159 (0.570-2.356) [0.683]
Adjusted RR (95% CI) [P]	1.330 (0.729-2.427) [0.351]

4.4 Service and socio-economic factors associated with stillbirth rates

Based on the longitudinal data, we explored service and socio-economic factors associated with stillbirth rates post SBLCB implementation. In particular we explored the roles of care level (secondary vs tertiary centres), deprivation, smoking and reported level of implementation of the SBLCB, and some process variables. It is important to note that only the mean IMD decile of women attending per Trust could be used in this analysis (due to confidentiality and data structure), which is likely to under-estimate the effects of deprivation.

Table 2 shows the unadjusted stillbirth risk ratios for each factor and those adjusted for care level and IMD. Care level is strongly associated with stillbirth, and deprivation is associated with higher stillbirth rates, approximately 7% increase per decile. Having adjusted for these by implementation levels across all Trusts, we were not able to demonstrate that implementation of SBLCB *per se* reduces stillbirths. As expected, cigarette smoking was strongly associated with stillbirth. In relative terms, each 1% increase in smoking rates increases stillbirth by 1.7%.

Table 2. Service and socio-economic factors associated with stillbirth

Factor	Unadjusted RR (95% CI)	P value	Adjusted RR (95% CI)	Adjusted p value
Care Level	1.37 (1.07-1.77)	0.022	1.28 (1.10-1.49)	<0.001
IMD (per decile)	0.94 (0.90-0.99)	1.000	0.94 (0.87-0.99)	0.029
Overall Implementation†	0.93 (0.51-1.67)	0.797	1.03 (0.74-1.44)	0.872
Element 1 Implementation†	1.21 (0.73-1.99)	0.463	1.09 (0.79-1.52)	0.598
Element 2 Implementation†	1.05 (0.60-1.84)	0.874	1.18 (0.84-1.67)	0.349
Element 3 Implementation†	0.81 (0.56-1.19)	0.291	0.98 (0.79-1.21)	0.827
Element 4 Implementation†	0.86 (0.51-1.53)	0.666	0.93 (0.68-1.29)	0.678
Smoking Rate (per 10%)	0.94 (0.74-1.19)	0.612	1.17 (1.03-1.33)	0.031

† RR for 100% versus 0% implementation

4.5 Stillbirth rates in the UK from routine sources

To compare the stillbirth rates observed in this analysis with those derived from routinely collected sources, we collaborated with MBRRACE-UK to obtain perinatal mortality data for the 19 early adopter Trusts by year from 2013 to 2016 inclusive. To provide context for the findings, and to demonstrate the representativeness of the 19 Trusts, we also show perinatal mortally data from MBRRACE-UK for Trusts not involved in the evaluation. The total number of stillbirths (Table 3), stillbirths by cause of death (Tables 4 and 5), and stillbirths by gestational age (Table 6) from MBRRACE-UK are provided. Small numbers are suppressed to avoid disclosure in accordance with guidance from ONS and the Governmental Statistical Service (GSS). The data is purely descriptive and no formal analysis was conducted.

Overall, the stillbirth rates derived from the evaluation were comparable to the perinatal mortality collected via MBRRACE-UK data. The stillbirth rates declined from 4.20 to 3.87 stillbirths per 1,000 total births between 2013 to 2015. However, the stillbirth rate for the UK in 2016 remained fairly static at 3.93 per 1,000 total births.

Table 3. Total stillbirths by Trust by year of birth for the 19 Trusts in England which participated in the Stillbirth Care Bundle evaluation and for the English Trusts which did not participate in the evaluation*

Trust	Year of Birth				
	2013	2014	2015	2016	Total
York Teaching Hospital	24	23	12	14	73
The Mid Yorkshire Hospitals	28	34	23	27	112
Royal Devon and Exeter	16	5	10	10	41
Barnsley Hospital	10	5	14	12	41
St Helens and Knowsley	11	13	12	14	50
Liverpool Women's	31	49	42	35	157
Norfolk and Norwich	21	17	26	20	84
North Cumbria	12	6	8	7	33
Taunton and Somerset	5	17	7	11	40
Countess of Chester	7	7	11	*	≥25
Plymouth Hospitals	15	31	13	21	80
Sherwood Forest Hospitals	6	9	16	16	47

Royal United Hospitals	19	12	20	18	69
Gateshead	6	9	*	7	≥22
University Hospitals of Morecambe	9	11	11	9	40
Oxford University	35	33	31	35	134
Manchester University	71	62	67	58	258
Birmingham Women's	50	47	45	44	186
Doncaster and Bassetlaw	18	21	21	17	77
All the rest of English Trusts which did not participate	2398	2374	2229	2237	9238

*Small number suppression will be applied for cell counts of <5 and also for totals from which small cell counts could be derived

Table 4. Total stillbirths by cause of death by year for the 19 Trusts in England which participated in the Stillbirth Care Bundle evaluation*

Cause of death – CODAC code – level 1	Year of Birth				
	2013	2014	2015	2016	Total
Infection	6	14	22	14	56
Neonatal	*	*	*	8	16
Intrapartum	30	24	11	6	71
Congenital anomaly	17	31	35	32	115
Fetal	10	29	10	22	71
Cord	16	22	18	19	75
Placenta	105	143	143	140	531
Maternal	15	12	17	17	61
Unknown	179	128	131	111	549
Termination	13	5	*	8	≥26
Total	≥391	≥408	390	377	1572

*Small number suppression will be applied for cell counts of <5 and also for totals from which small cell counts could be derived

Table 5. Total stillbirths by cause of death by year for the Trusts in England which did not participate in the Stillbirth Care Bundle evaluation*

Cause of death – CODAC code – level 1	Year of Birth				
	2013	2014	2015	2016	Total
Infection	58	56	80	71	265
Neonatal	27	39	38	32	136
Intrapartum	228	148	61	53	490
Congenital anomaly	133	128	184	196	641
Fetal	84	106	123	112	425
Cord	84	87	94	88	353
Placenta	364	413	547	576	1900
Maternal	84	85	97	89	355
Unknown	1255	1238	947	902	4342
Termination	81	74	58	118	331
Total	2398	2374	2229	2237	9238

Table 6. Total stillbirths by gestational age at birth by year for the 19 Trusts in England which participated in the Stillbirth Care Bundle evaluation*

Gestational age at birth (completed weeks)	Year of Birth				
	2013	2014	2015	2016	Total
24-27	103	98	93	90	384
28-31	64	62	77	63	266
32-36	76	112	90	99	377
37-41	149	133	126	123	531
42+	*	5	*	*	13
Total	≥392	410	≥386	≥375	1571

*Small number suppression will be applied for cell counts of <5 and also for totals from which small cell counts could be derived

4.6 Summary

The stillbirth rate declined significantly and consistently over the period during which SBLCB has been implemented in the 19 participating Trusts, continuing the long-term downward trend from 2013. However, given the phased implementation in most Trusts and the lack of detailed implementation data, we could not unambiguously demonstrate that all or any of this decrease was due to SBLCB, nor could we demonstrate any relationship between implementation level and the stillbirth rate at the end of the evaluation period. Thus, we cannot conclusively demonstrate casual attribution of the SBLCB to the reduction in stillbirths. However, it is likely to be one the important components that have contributed to the steady decline in the stillbirth rate in these Trusts, which exceeds the national rate of decline, which slowed in 2016.

As expected, we demonstrated associations with social deprivation, emphasising the potential impact that public policies have on stillbirth and that wider approaches (beyond maternity care) are needed to reduce and mitigate the effects of deprivation on stillbirth and need to be considered in future policy decisions. Future studies should include individual-level measures of deprivation.

5. Clinical and service outcomes

An important aim of the evaluation was to determine the impact of implementing the SBLCB on relevant clinical and service outcomes in the early adopter Trusts. Figures 6-11 show the average rates of preterm birth, inductions of labour, caesarean, instrumental and spontaneous deliveries, obstetric ultrasound scans and neonatal admissions to NICU before and after implementation of the SBLCB across the early adopter Trusts.

5.1 Definitions and data sources

Clinical and service outcomes were obtained from electronic records of deliveries from each Trust encompassing the five year evaluation period. A total of 467,661 deliveries were returned for the total study period; an average of 95,000 per year. Preterm birth was defined as a birth before 37 completed weeks of gestation.

5.2 Preterm birth

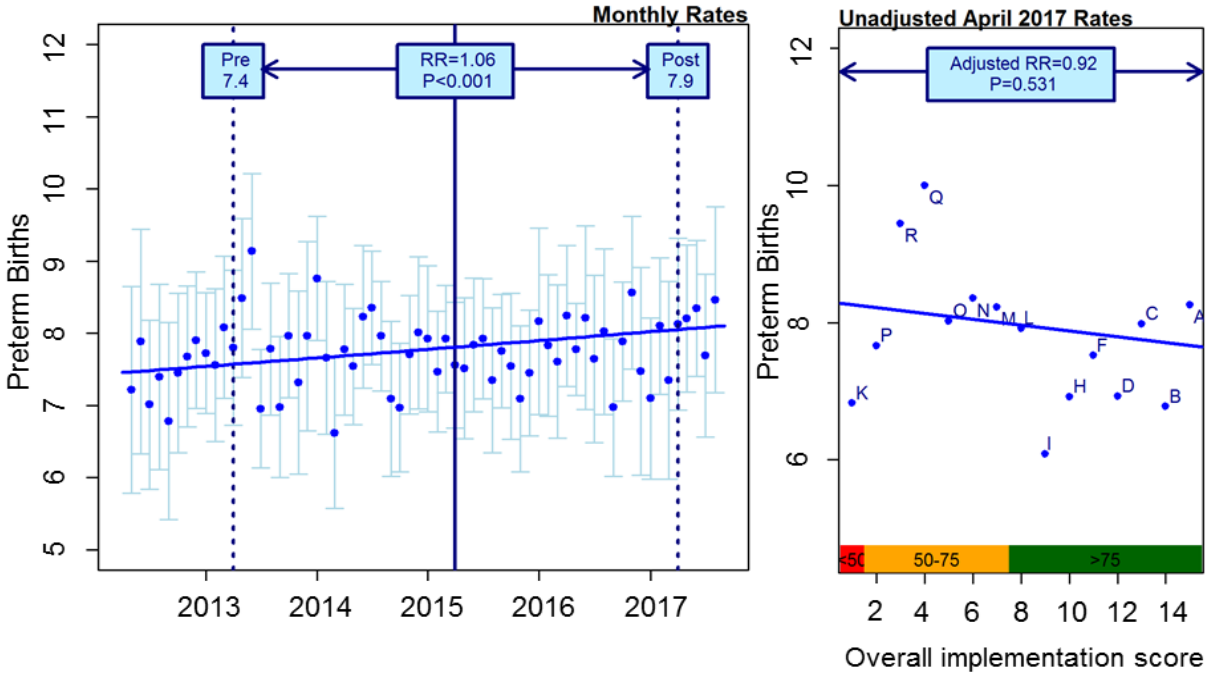
The number of preterm births increased steadily over the five year time period from 7.4/100 births before SBLCB to 7.9/100 births after the SBLCB implementation date; a proportional increase of 6.5% (Figure 6). A similar increase was also observed in the proportion of preterm singleton births which increased by 4.8% in the post SBLCB implementation period. There was no relationship between the rate of preterm birth and the overall implementation score for the SBLCB.

5.3 Mode of delivery

There was an increase in the number of induced labours over the five year period with significantly more (19.4%) women having induction of labour after SBLCB implementation (31.4%) compared to before (26.3%) (Figure 7). There was a similar sized increase in the proportion of elective caesarean sections (19.5%) over the same time course, increasing from 9.86% before to 11.78% after the SBLCB (Figure 8). There were 9.6% more emergency caesarean sections carried out after the implementation of SBLCB (Figure 9). Consequently, the rate of spontaneous deliveries declined post SBLCB (Figure 10). There were no changes in the rate of instrumental deliveries (Figure 11). There was no correlation between the overall implementations score for the SBLCB and either of these outcomes.

Figure 6. Average rate of preterm births pre and post SBLCB implementation in the early adopter Trusts

Outcome	Preterm births
Denominator	All deliveries
Source	Electronic Data Submission
Numbers	446,378 deliveries from 17 Trusts

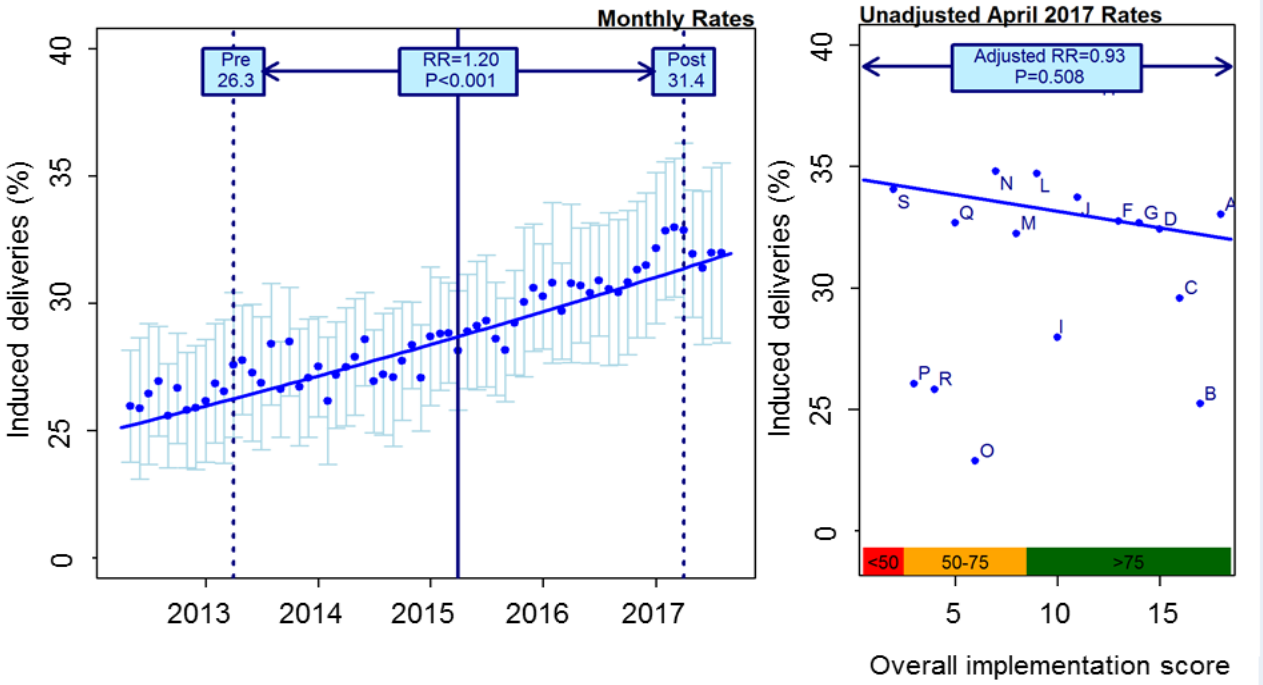


Apr 2013 Rate	7.42
Apr 2017	7.90
Pre/Post RR (95% CI) [P]	1.064 (1.032-1.096) [<0.001]

RR (95% CI) [P]	0.852 (0.542-1.132) [0.274]
Adjusted RR (95% CI) [P]	0.924 (0.721-1.184) [0.531]

Figure 7. Average rate of induced deliveries pre and post SBLCB implementation in the early adopter Trusts

Outcome	Induced deliveries
Denominator	All deliveries
Source	Electronic data submission
Numbers	473,889 deliveries from 18 Trusts



Apr 2013 Rate	26.27
Apr 2017	31.40
Pre/Post RR (95% CI) [P]	1.195 (1.178-1.212) [<0.001]

RR (95% CI) [P]	0.870 (0.670-1.131) [0.305]
Adjusted RR (95% CI) [P]	0.928 (0.746-1.155) [0.508]

Figure 8. Average rate of elective caesarean sections rate pre and post SBLCB implementation in the early adopter Trusts

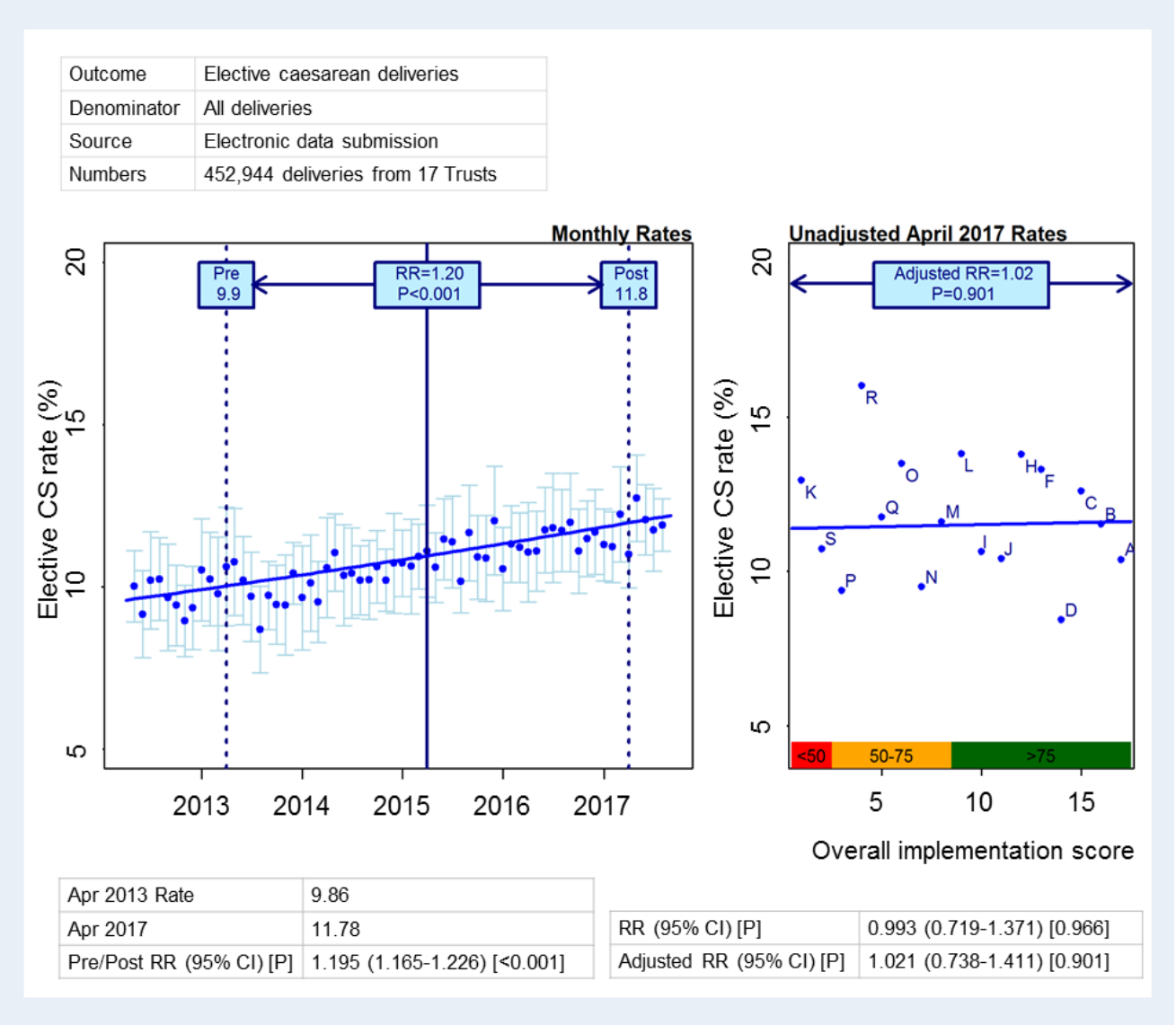
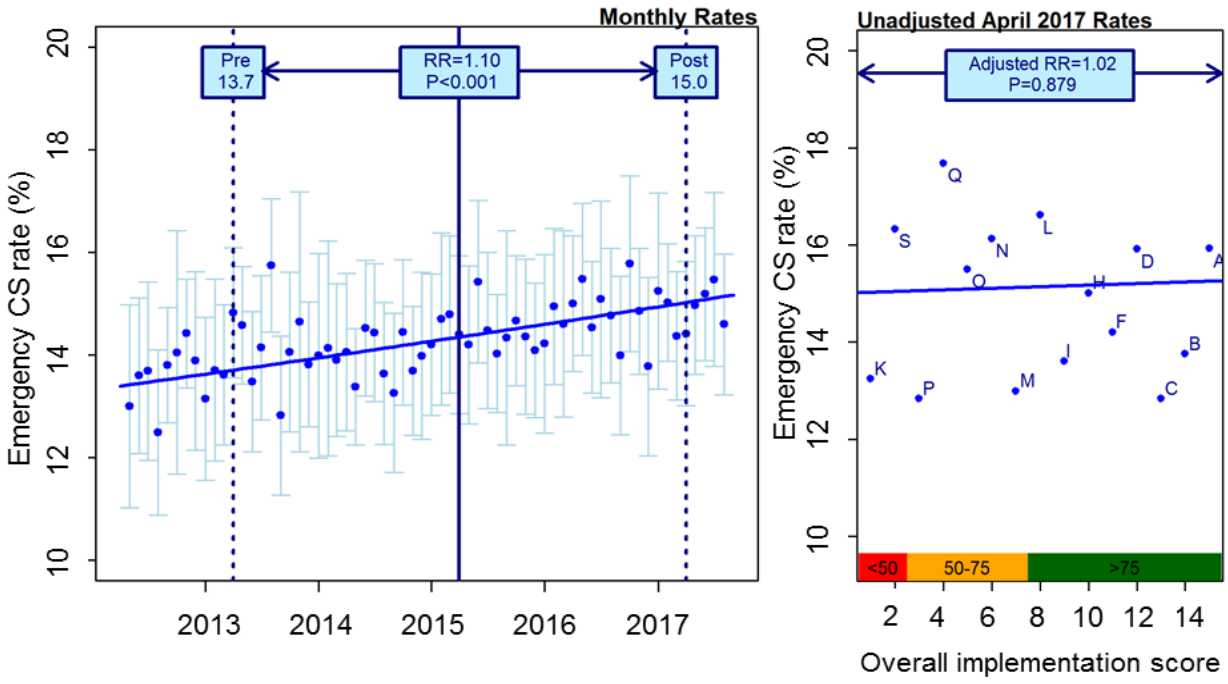


Figure 9. Emergency caesarean section rate pre and post SBLCB implementation in the early adopter Trusts

Outcome	Emergency CS
Denominator	All deliveries
Source	Electronic Data Submission
Numbers	386,817 deliveries from 15 Trusts

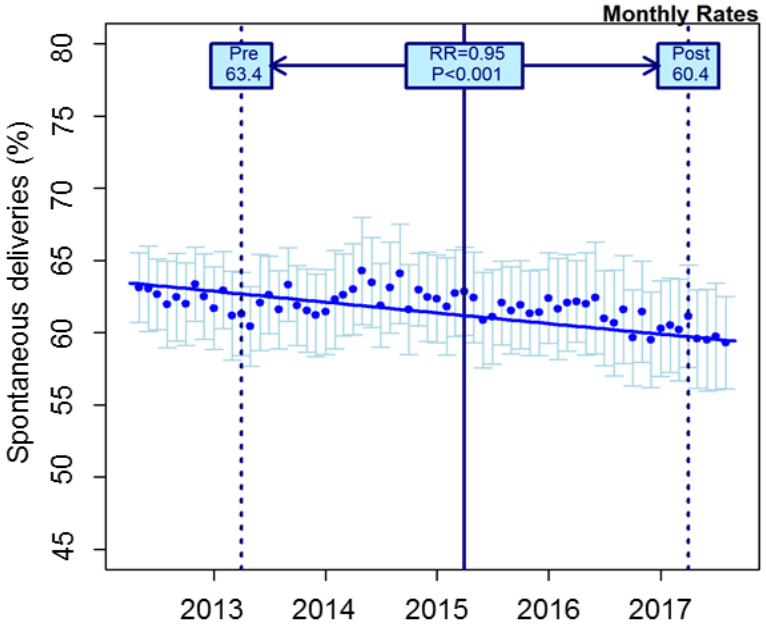


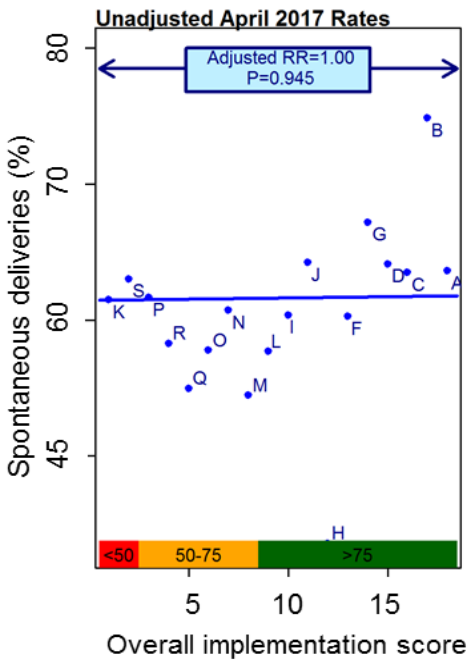
Apr 2013 Rate	13.69
Apr 2017	15.01
Pre/Post RR (95% CI) [P]	1.096 (1.071-1.122) [<0.001]

RR (95% CI) [P]	0.962 (0.767-1.206) [0.738]
Adjusted RR (95% CI) [P]	1.016 (0.825-1.252) [0.879]

Figure 10. Spontaneous delivery rate pre and post SBLCB implementation in the early adopter Trusts

Outcome	Spontaneous Deliveries
Denominator	All deliveries
Source	Electronic Data Submission
Numbers	473, 889 deliveries from 18 Trusts



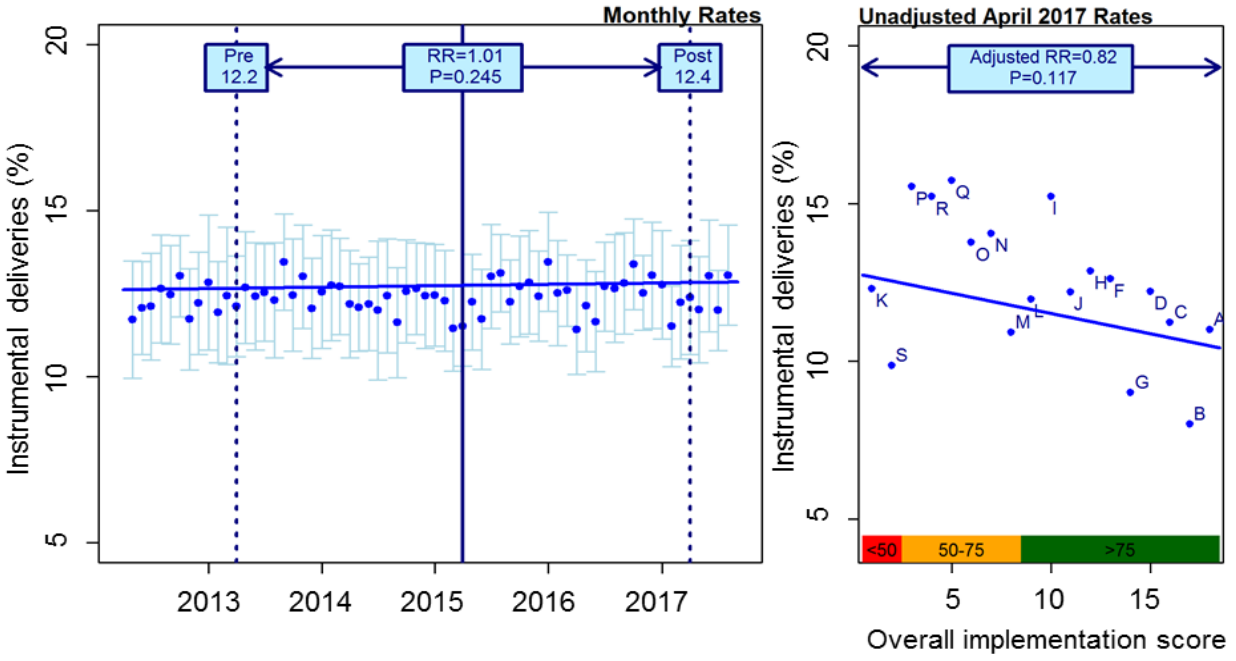


Apr 2013 Rate	63.42
Apr 2017	60.42
Pre/Post RR (95% CI) [P]	0.953 (0.946-0.960) [<0.001]

RR (95% CI) [P]	1.109 (0.878-1.183) [0.803]
Adjusted RR (95% CI) [P]	1.005 (0.874-1.155) [0.945]

Figure 11. Instrumental delivery rate pre and post SBLCB implementation in the early adopter Trusts

Outcome	Instrumental Deliveries
Denominator	All deliveries
Source	Electronic Data Submission
Numbers	473, 889 deliveries from 18 Trusts



Apr 2013 Rate	12.25
Apr 2017	12.41
Pre/Post RR (95% CI) [P]	1.014 (0.991-1.037) [0.245]

RR (95% CI) [P]	0.803 (0.568-1.137) [0.226]
Adjusted RR (95% CI) [P]	0.819 (0.643-1.042) [0.117]

5.4 NICU admissions

Trusts were asked to provide information on the number of term babies admitted to their neonatal intensive care unit (five of the early adopter Trusts are tertiary NICU centres) or transfers to tertiary centres with appropriate neonatal services from secondary units. However, the data returned was highly variable with some Trusts reporting over 20% of NICU admissions and conversely others with very low admission rates (<1%). It was therefore apparent that the definition of a 'NICU' admission was highly variable between Trusts, and that Trusts had erroneously included admissions to their special care baby unit and local neonatal unit. For these reasons, the data was usable for only 14 out of the 19 Trusts which likely include admissions to all types of neonatal care.

Figure 12 shows the proportion of term babies admitted to a neonatal unit before and after SBLCB implementation in the 14 Trusts. There was a 17.1% increase in the proportion of term singleton babies reported as being admitted to neonatal units post implementation of SBLCB. The reported proportion of admissions rose from 3.5/100 births before SBLCB to 4.1/100 births after SBLCB.

5.5 Obstetric ultrasound scanning

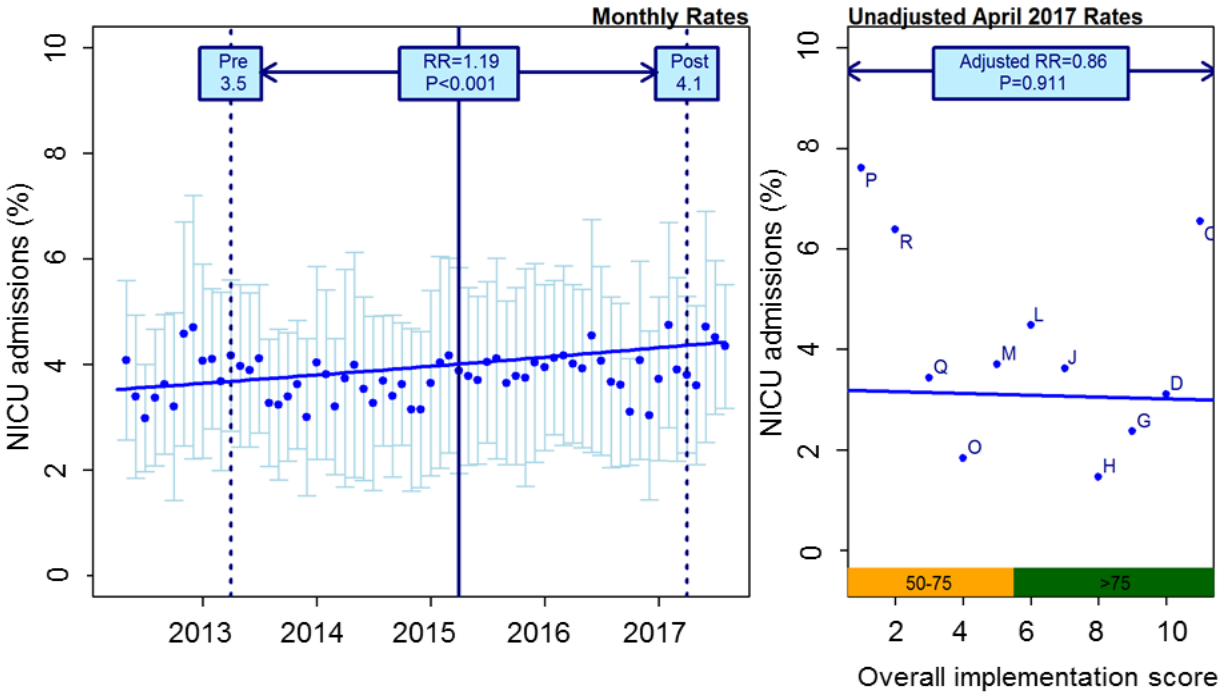
The total number of obstetric ultrasound scans carried out increased progressively over the 5 year period (Figure 13), with 23.9% more ultrasound scans carried out following the SBLCB implementation, increasing from an average of 3.5 scans per pregnancy before SBLCB to 4.4 scans per pregnancy afterwards. It is likely that a proportion of women (e.g. those deemed to be at increased risk of an SGA baby) received a number of additional scans rather than each woman receiving an additional scan.

The provision of additional ultrasound scanning has had a clear impact on maternity services, with eight Trusts increasing staff hours to meet the increased demand. Five Trusts are training midwife sonographers for third trimester growth scanning and some Trusts have increased capacity through additional evening and weekend clinics.

It should be noted that data was limited to 14 Trusts due to poor data quality. Furthermore, it was not possible to determine the proportion of third trimester growth scans during this time period due to variations in scan classification and coding between Trusts and incompleteness of the data provided on gestational age at scan.

Figure 12. Average rate of NICU admissions from term singleton deliveries pre and post SBLCB implementation in the early adopter Trusts

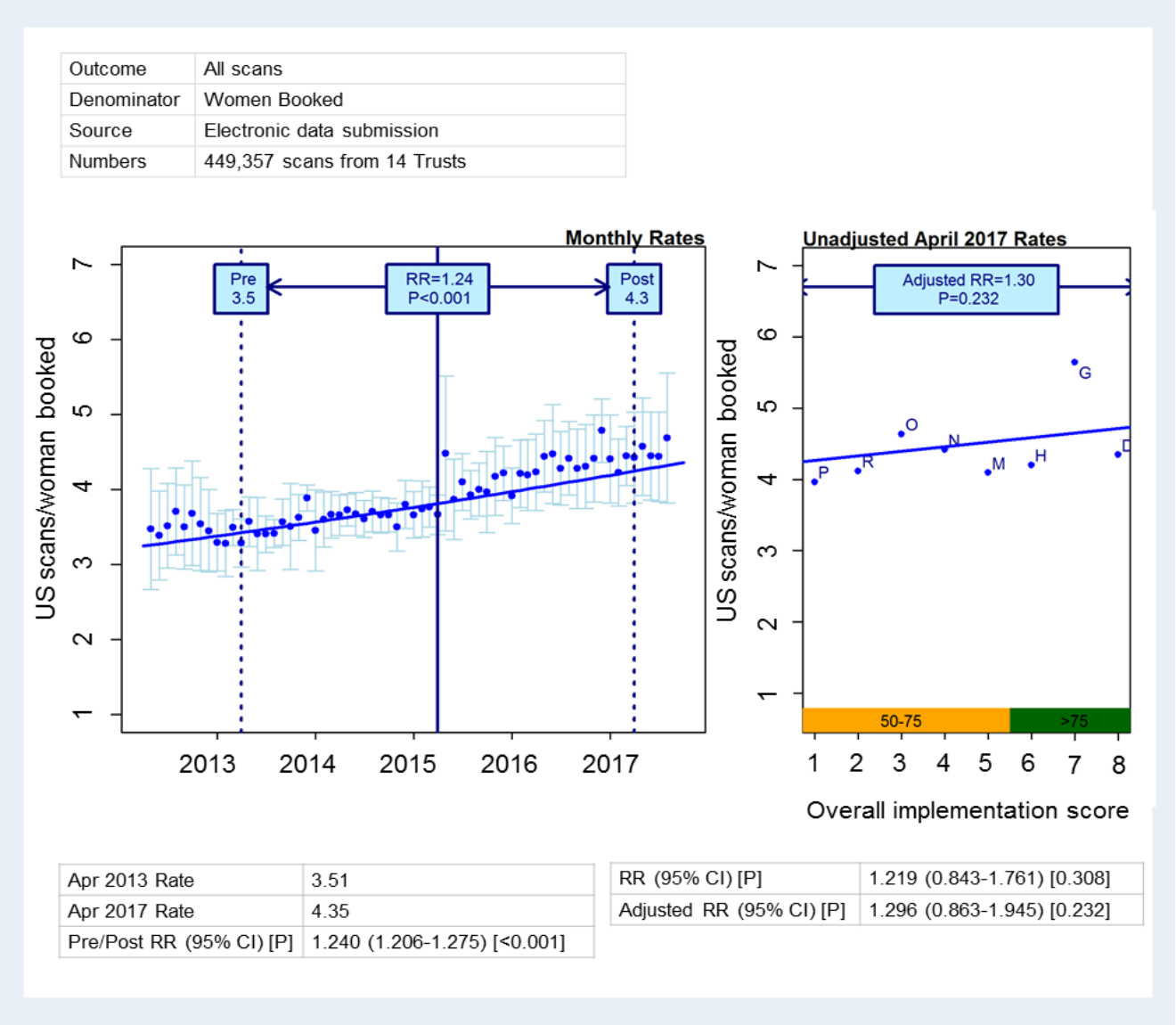
Outcome	NICU admissions (term singleton deliveries)
Denominator	Term singleton deliveries
Source	Electronic data submission
Numbers	384,584 deliveries from 14 Trusts



Apr 2013 Rate	3.46
Apr 2017	4.11
Pre/Post RR (95% CI) [P]	1.186 (1.113-1.263) [<0.001]

RR (95% CI) [P]	0.354 (0.039-3.206) [0.362]
Adjusted RR (95% CI) [P]	0.861 (0.061-12.048) [0.911]

Figure 13. Average number of obstetric ultrasound scans performed per woman pre and post SBLCB implementation in the early adopter Trusts



5.6 Outcomes not reported

Although requested from participating sites, we were unable to obtain data on the number of reported clinical incidents in each Trust and the number of admissions to antenatal triage. For most Trusts, triage admissions are not recorded in electronic systems and paper audit was not feasible within the timeframe of this study.

Data about birthweight, gestation, sex, maternal height and weight for all term singleton births were requested to allow the computation of customised birthweight centiles for estimation of SGA incidence. However, for most Trusts the submitted data were unreliable and the resultant centiles were not credible. However, there was evidence that recording improved markedly over the evaluation period, and the more recent data returned by Trusts appeared to be more reliable. As we

had no information on which to select Trusts to reliably utilise this data, we cannot report this outcome.

5.7 Summary

In the early adopter Trusts, rates of preterm birth, inductions of labour, emergency and elective caesarean sections, obstetric ultrasound scans, and term admissions to neonatal units have increased progressively over the past five years. From the analysis we found no evidence to suggest that these changes are specific consequences of the SBLCB, nor were they related to the reported levels of implementation. However, given the nature of some interventions within the Care Bundle it is plausible that some increases are associated with implementation of the SBLCB. For example, one of the most striking change in services is the dramatic increase in the number of ultrasound scans carried out over the SBLCB period. Given the recommendations to perform ultrasound scans contained within element 2 (growth) and 3 (reduced fetal movements) it is conceivable that this increase reflects these interventions. This increase is also perceived at the ground-level with 97% of staff believing that the demand for scanning has significantly increased.

The proportion of induced labours has also increased significantly over the implementation period. Again the nature of the interventions in elements 2 (growth) and 3 (reduced fetal movements) suggests that this change could be attributable to SBLCB. However, rates of induced of labour also differed markedly between Trusts with similar implementation levels, so this may not prove to be an inevitable consequence of the SBLCB.

There was also a large increase in the proportion of elective caesarean sections over the timeframe of this evaluation. As there is little in the SBLCB that could account for this (although NICE guidance has changed to support maternal request for elective caesarean during the timeframe of this analysis), this is unlikely to be related to the SBLCB. Consequently the proportion of vaginal births has reduced over the period. It is unclear whether the increase in induced labours has contributed to the increase in emergency caesarean section.

Preterm births and term admissions to the neonatal unit all appeared to increase during the SBLCB implementation period. However, there is no evidence to suggest these are specific consequences of the Care Bundle and other national maternity and neonatal initiatives provide plausible mechanisms as well as differences in the recording of neonatal admissions for differing indications.

6. Element 1- Smoking monitoring and cessation

This chapter reports on the implementation of Element 1 – smoking monitoring and cessation in the 19 early adopter Trusts. Table 8 summarises the information obtained about the process variables as well as maternal smoking and cessation rates. In an effort to ensure complete data collection, and to ensure good practice when evaluating new interventions, some information was obtained from surveys with new mothers to gather information regarding carbon monoxide monitoring and attendance at smoking cessation services following referral.

6.1 Element description and interventions

There is strong evidence that reducing smoking in pregnancy reduces the likelihood of stillbirth[17] and reducing smoking also impacts positively on other elements of the Care Bundle by reducing incidence of fetal growth restriction and intrapartum complications. Element 1 provides a practical approach to reducing smoking in pregnancy by following NICE guidelines which requires electronic testing of all pregnant women for exposure to carbon monoxide (CO) and referral of those with a positive reading to smoking cessation services[18]. The recommended interventions include:

1. CO testing of all pregnant women at booking appointment
2. Referral of all women identified as smokers to smoking cessation services on an opt out basis

6.2 Definitions and data sources

Data on CO monitoring and referrals were obtained from surveys with postnatal women at all 19 Trusts. Data reflects antenatal care received between September 2016 and December 2017. Data about maternal smoking status during pregnancy was obtained from electronic records where these were available (term singleton deliveries) encompassing the before and after SBLCB period. Smoking cessation was defined as any woman recorded as smoking at booking but recorded as a non-smoker at delivery.

6.3 Implementation

Table 7 shows the implementation scores and duration of implementation for each Trust. Eighteen out of 19 Trusts reported to be implementing CO monitoring and 15 Trusts said they offered women referral services for smoking cessation. Nine Trusts reported implementing both interventions at 100% compliance. Nine Trusts were implementing activities prior to implementation ranging from 3 months to 5 years before SBLCB.

Cost of implementation

The estimated total direct cost of implementing element 1 across the 19 Trusts between April 2015 and April 2017 was £183,063. This cost included the purchase of CO monitors and the cost of consumables required to conduct the CO tests such as mouthpieces that attach to the monitors.

Table 7. Implementation of Element 1- smoking monitoring and cessation in the 19 early adopter sites

Trust	Imp.Score (%)†	Reported Start Date	CO monitoring	Referral to cessation services
H	92	*prior*	Most of the time	Not much of the time
F	67	*prior*	All of the time	Not much of the time
G	100	*prior*	All of the time	All of the time
D	92	*prior*	All of the time	All of the time
P	33	*prior*	Most of the time	Most of the time
O	58	*prior*	All of the time	All of the time
B	100	*prior*	All of the time	All of the time
J	67	*prior*	Most of the time	Not much of the time
L	75	*prior*	All of the time	All of the time
A	100	Apr-15	All of the time	Most of the time
C	92	Apr-15	All of the time	All of the time
M	100	Jul-15	Most of the time	Most of the time
N	58	Feb-16	Most of the time	Never
I	100	Apr-16	All of the time	All of the time
S	75	Jun-16	All of the time	Never
E	50	Nov-16	All of the time	All of the time
Q	75	Nov-16	Never	Never
K	0	Apr-17	All of the time	All of the time
R	25	Jan-18	All of the time	Never

† Implementation score for element 2

Prior; implemented before the nominal start date

6.4 Maternal smoking and cessation rates

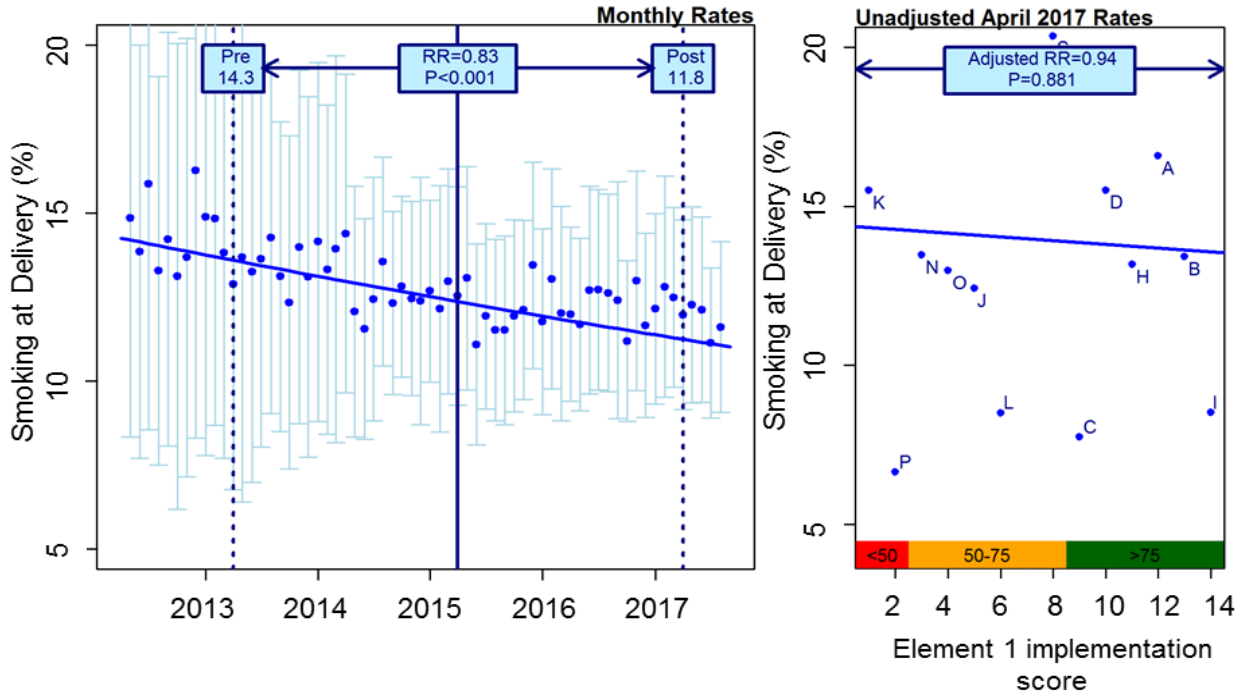
There was considerable variation in the quality of data returned by Trusts about women's smoking status with high rates of missing data (in particular for the pre SBLCB period), and there were inconsistencies in smoking documentation between Trusts. We were therefore unable to generate a complete dataset for maternal smoking across all Trusts and the data presented below is limited to 11 or 14 Trusts.

Smoking at the time of delivery

As shown in Figure 14, the number of women smoking at the time of delivery (SATOD for term deliveries) declined progressively over the five year time period. Fourteen percent of women smoked at the time of delivery before SBLCB compared to 12% after SBLCB; this equates to a proportional reduction of 17% between the two time points.

Figure 14. Maternal smoking rates at the time of delivery (term deliveries) pre and post SBLCB implementation in the early adopter Trusts

Outcome	Smoking at delivery
Denominator	All term deliveries
Source	Electronic data submission
Numbers	268,736 deliveries from 14 Trusts



Apr 2013 Rate	14.28
Apr 2017 Rate	11.81
Pre/Post RR (95% CI) [P]	0.827 (0.800-0.855) [<0.001]

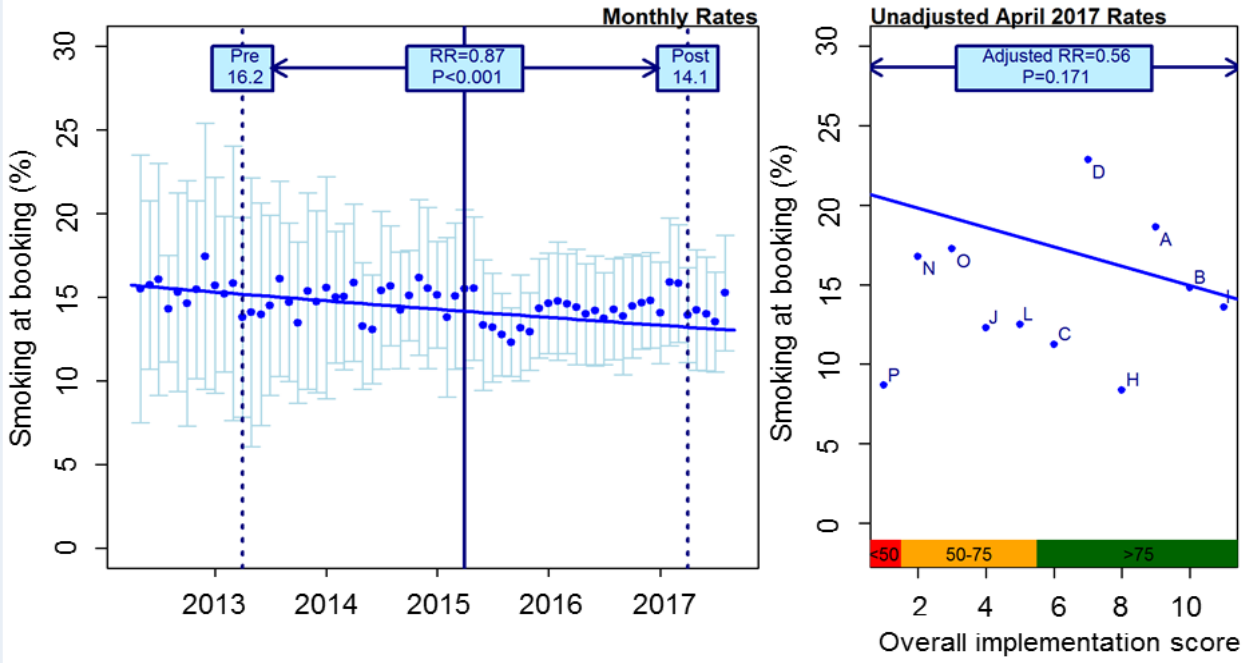
RR (95% CI) [P]	1.151 (0.498-2.661) [0.742]
Adjusted RR (95% CI) [P]	0.943 (0.438-2.030) [0.881]

Smoking at booking

Similar to the SATOD rates, the proportion of women recorded as smoking at booking also declined over the five year period from 16.2% before implementation of the SBLCB to 14.1% after (Figure 15). This is slightly lower than the 16% of women surveyed who said they smoked at the time of booking in their pregnancy.

Figure 15. Maternal smoking rates at booking (term deliveries) pre and post SBLCB implementation in the early adopter Trusts

Outcome	Smoking at Booking
Denominator	Smoking at Booking (term singletons)
Source	Electronic Data Submission
Numbers	203,635 pregnancies rom 11 Trusts



Apr 2013 Rate	16.16
Apr 2017	14.06
Pre/Post RR (95% CI) [P]	0.870 (0.841-0.900) [<0.001]

RR (95% CI) [P]	1.259 (0.578-2.742) [0.566]
Adjusted RR (95% CI) [P]	0.558 (0.250-1.243) [0.171]

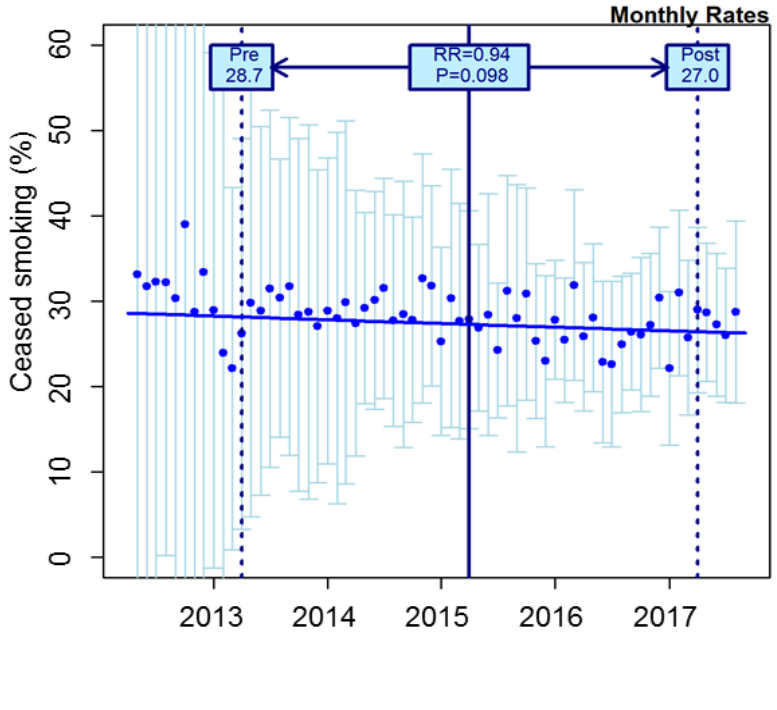
Smoking cessation rates

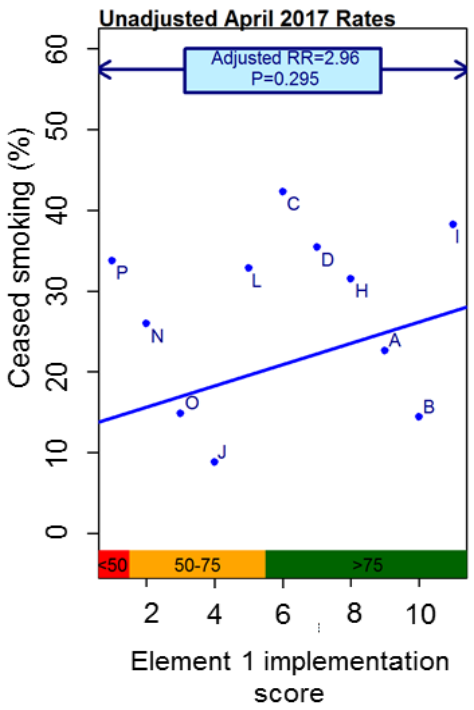
Figure 16 shows the proportion of women who ceased smoking during pregnancy in 11 early adopter Trusts. Overall, there is no evidence of an improvement in the rates of smoking cessation; 28.7% of women ceased smoking before SBLCB and 27% ceased smoking after SBLCB. However, smoking cessation rates varied considerably by Trust with some achieving a 40% rate cessation rate whilst others only 10%. Furthermore, the cessation rates derived from Trust data are somewhat lower than the patient reported rates in the survey (41%). There was no association between smoking rates or cessation rates and the implementation score for Element 1.

This data should be considered in the light of the overall reducing smoking rate at booking and the evidence that access to smoking cessation services have been reduced (some Trusts noted termination of their CQUIN for smoking cessation during the timeframe of this evaluation).

Figure 16. Proportion of women (term deliveries) who ceased smoking pre and post SBLCB implementation in early adopter Trusts

Outcome	Women recorded as smoking at booking but not delivery
Denominator	Smoking at booking (term singletons)
Source	Electronic data submission
Numbers	27,550 pregnancies from 11 Trusts





Apr 2013 Rate	28.74
Apr 2017 Rate	26.98
Pre/Post RR (95% CI) [P]	0.939 (0.871-1.1012) [0.098]

RR (95% CI) [P]	1.430 (0.375-5.454) [0.602]
Adjusted RR (95% CI) [P]	2.964 (0.407-21.507) [0.295]

6.5 CO monitoring and referral to smoking cessation services

Although requested, data about CO monitoring and referral to cessation services was poorly recorded by Trusts and could not be obtained from electronic records. Table 8 presents the findings from the patient survey in relation to CO monitoring and referral to smoking cessation services.

Seventy percent of women surveyed said they were asked to perform a CO breath test during pregnancy and virtually all those offered accepted the breath test; a 99.1% self-reported uptake rate. Sixty percent of smokers said they were referred to smoking cessation services (implying a positive CO reading); although a large proportion of these women said they did not attend their appointment (39%).

More women were offered the CO test in Trusts with higher implementation scores for element 1, indicating fidelity in implementation of this intervention (adjusted RR 8.79, 95% CI 5.52-13.99, p<0.001).

Table 8 CO monitoring and referral to cessation services in the early adopter Trusts

Outcome	Number/Number of responses	Percentage
Patient reported		
Smoking at delivery	210/2085	10.1
Smoking in pregnancy	338/2154	15.7
Ceased smoking	135/330	40.9
Referred to smoking cessation	187/311	60.2
Attended smoking cessation	58/187	31.0
Offered CO test	1310/1870	70.1

6.6 Summary

Although maternal smoking rates at delivery have decreased significantly during the SBLCB implementation period this likely reflects a wider change as fewer women are smoking at booking, and a significant trend in the number of women who ceased smoking in pregnancy could not be identified. However, there is wide variation in the proportion of smokers who cease during pregnancy between Trusts, suggesting that the provision of appropriate services and support can increase the number giving up.

In most sites where it is implemented, high rates of CO testing can be achieved with very few women refusing. In comparison, referral of women who smoked or had a positive CO test to smoking cessation services was modest (60%) with no evidence that SBLCB interventions improve this proportion. Importantly, a large proportion of women referred for smoking cessation report not attending their referral appointment. The provision and type of smoking cessation service offered to women was variable across the Trusts. In many areas smoking cessation services are not provided within maternity services and require referral to another location or care provider, these included referrals to external services, GPs and pharmacies. This need for additional referral may act as a practical barrier or a disincentive for women to attend these appointments. In addition, three Trusts did not offer referral due to withdrawal of funding for smoking cessation (e.g. CQUINS). Thus, there is a need for better access to smoking cessation services, a greater ability/willingness to refer women to these services, and motivation for women to attend their appointments.

The routine collection of data on smoking status, and referral by Trusts is presently incomplete preventing robust analysis, meaning that effective monitoring of service delivery and process outcomes is not possible. Better recording and monitoring of smoking and CO levels at booking is essential if this element is to be successfully delivered and evaluated. There is some evidence that recording of smoking status at least is improving is some Trusts, suggesting this can be achieved.

7. Element 2 - Monitoring fetal growth

This chapter presents findings for Element 2 - risk assessment and surveillance for fetal growth restriction of the SBLCB. Table 10 shows data about the various process variables for Element 2 and antenatal detection rates of SGA babies pre and post SBLCB in the early adopter Trusts. Evaluation of this complex element relied on the audit of SGA pregnancies performed for this analysis as the majority of Trusts do not perform local audits of SGA detection rates and missed cases even though this is one component of Element 2. Forty SGA cases per Trust were audited for the evaluation project.

7.1 Element description and interventions

Element 2 ensures that the risk for FGR has been assessed for all pregnancies through appropriate risk assessment and surveillance for high and low risk pregnancies. A key recommendation in this element is that Trusts should publish their antenatal detection rates of SGA babies and audit SGA cases not detected antenatally, thereby encouraging benchmarking and improvement in performance. There are five recommended interventions in this element including:

1. Use of SBLCB algorithm (or RCOG algorithm) for risk classification
2. For high-risk women (as per RCOG Green Top Guideline)[13], fetal growth assessed using serial ultrasound and estimated fetal weight plotted on chart
3. For low-risk women (as per RCOG Green Top Guideline), fetal growth assessed using symphysis fundal height
4. Ongoing audit of SGA birth rates, antenatal detection rates on local dashboard or similar
5. Ongoing case-note audit of 'missed' SGA cases

7.2 Definitions and data sources

Term singleton live births were audited for use of growth charts after the implementation of the SBLCB. SGA pregnancies were audited in 17 Trusts before and after SBLCB. In these pregnancies, antenatal detection of SGA was defined as an estimated fetal weight below the 10th centile at last ultrasound scan. A correctly plotted estimated fetal weight was defined as having the correct gestation and weight based on the scan. Use of the algorithm and training for growth chart plotting was derived from responses to staff surveys. For comparison, SGA incidence and antenatal detection rates were obtained from Trusts using the GROW app for SGA reporting from those enrolled in the Growth Assessment Programme (GAP) programme from the Perinatal Institute[19].

7.3 Implementation

Table 9 shows the implementation scores and duration of implementation for Element 2 as reported by Trusts. Overall, implementation was good with all 19 Trusts reporting using the growth charts; only

1 Trust reported complete implementation of all components in Element 2. Most Trusts said they plotted estimated fetal weight on the charts either most or all of the time; three Trusts reported that they did not plot estimated fetal weight on the charts. Virtually all Trusts said they plotted symphysis fundal height. Fifteen Trusts are enrolled in the GAP programme (although only 13 Trusts reported their participation) and 13 are using the GROW-App for SGA reporting. Ten Trusts currently use GAP SCORE for missed case audit. The duration of implementation varied, ranging from 5 to 55 months. One Trust reporting a start date of April 2017 was scored as zero for implementation as this was after the nominal SBLCB launch date.

Table 9. Implementation of Element 2 – monitoring of fetal growth in the early adopter sites

Trust	Imp. Score (%)†	Reported Start Date	Growth Charts used	GROW-App used	GROW Audit Tool used
F	93	*prior*	All of the time	Most of the time	All of the time
M	80	*prior*	All of the time	Most of the time	Half of the time
E	60	*prior*	All of the time	Never	Never
B	93	*prior*	All of the time	Most of the time	All of the time
H	67	*prior*	Most of the time	Most of the time	Most of the time
J	80	*prior*	All of the time	Most of the time	-
L	60	*prior*	All of the time	Never	Never
G	60	*prior*	All of the time	Not much of the time	Never
A	100	Apr-15	All of the time	All of the time	All of the time
C	87	Apr-15	All of the time	Most of the time	All of the time
D	80	Jun-15	All of the time	Most of the time	Half of the time
O	93	Jun-15	All of the time	All of the time	All of the time
R	67	Jun-15	All of the time	Most of the time	Never
N	67	Feb-16	All of the time	All of the time	Most of the time
I	33	Apr-16	All of the time	Never	Never
S	40	Jun-16	All of the time	Never	Never
P	40	Aug-16	All of the time	Never	Never
Q	60	Nov-16	All of the time	Never	Never
K	0	Apr-17	All of the time	Most of the time	Not much of the time

† Implementation score for element 2

Prior; implemented before the nominal start date

Cost of implementation

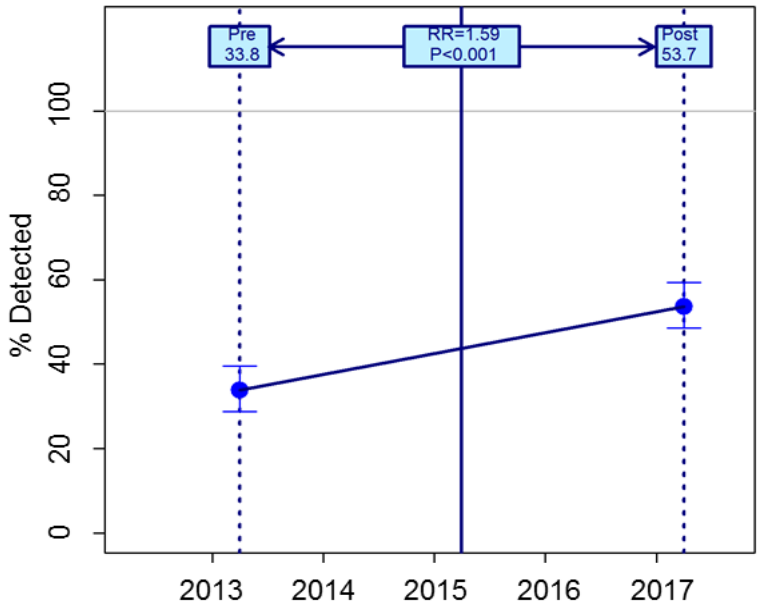
The estimated total direct cost of implementing element 2 across the 19 Trusts between April 2015 and April 2017 was £74,250. This included the cost of using GAP software to produce customised growth charts in the Trusts which reported doing so.

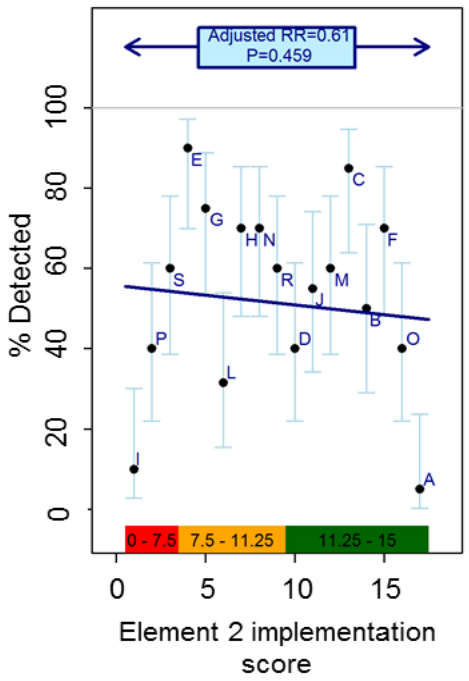
7.4 Antenatal SGA detection rates

Antenatal detection rates of SGA babies increased significantly from 33.8% before SBLCB to 53.7% afterwards (Figure 17). This equates to a 59% proportionate increase in the detection of SGA antenatally in the SBLCB implementation period.

Figure 17. Proportion of singleton babies identified as SGA before birth pre and post SBLCB in the early adopter Trusts

Outcome	Last EFW recorded < 10th centile
Denominator	Audited SGA pregnancies
Source	Pre/post casenote audit
Numbers	636 scans from 17 Trusts





Apr 2013 Rate	33.78
Apr 2017 Rate	53.71
Pre/Post RR (95% CI) [P]	1.59 (1.32-1.92) [<0.001]

RR (95% CI) [P]	1.21 (0.37-1.76) [0.730]
Adjusted RR (95% CI) [P]	1.61 (0.14-2.72) [0.469]

Notably, detection rates varied extensively between Trusts from <10% to >90% and there was no association between antenatal SGA detection rates and the implementation score for element 2,

suggesting that there may be other local initiatives which play a role in improving detection rates e.g. local feedback for ultrasonographers regarding estimated fetal weight measurements, local training in symphysis-fundal height measurement.

7.5 Algorithm and growth chart compliance

We asked staff about the use of the SBLCB algorithm for risk classification for FGR. Use of the supplied algorithm was relatively low with only 36% of staff reporting its use. Nineteen percent of staff used a different algorithm (type not identified) and 20% were unsure of whether they used it or not. Twenty six percent did not use an algorithm for risk assessment for SGA.

Implementation of the SBLCB had a significant impact on the use of growth charts, ultrasound scanning and plotting of results on growth charts. All term singleton pregnancies had a growth chart in the maternal case notes and nearly all of these were customised growth charts.

Serial growth scans were carried out in the majority of SGA pregnancies (increasing from 62% before to 81% after the intervention launch) (Table 10). Estimated fetal weight was plotted on significantly more growth charts post SBLCB (80% compared to 20% before SBLCB). Fundal height was plotted on growth charts in under half of SGA pregnancies post SBLCB, an increase of 34.7% compared to before SBLCB. When asked, 83% of staff felt adequately trained in measuring fundal height and 89% felt competent plotting measurements on growth charts.

The proportion of growth charts with EFW and SFH measurements plotted was positively correlated with the implementation score for element 2, indicating fidelity in implementation of these interventions (adjusted RR 7.35, 95% CI 15.9-335.9, p=0.017; adjusted RR13.72, 95% CI 2.75-68.3, P<0.001 respectively).

Table 10. Growth chart compliance pre and post implementation of SBLCB in the early adopter Trusts

Outcome	n	Number Deliveries audited	Pre rate	Post rate	Relative Risk (95% CI)	P value
Term singleton births with growth chart in notes	18	720	-	97.78	-	-
SGA pregnancies with growth chart in notes	17	636	86.62	96.44	1.11 (1.06-1.17)	<0.001
EFW plotted after every scan	17	636	24.75	75.67	3.06 (2.48-3.76)	<0.001
SFH plotted	17	636	35.45	47.77	1.35 (1.11-1.63)	0.002
Serial US scans (for suspected SGA)	16	591	61.73	80.89	1.31 (1.18-1.46)	<0.001

n; number of Trusts providing data

7.6 The GAP programme and SGA detection rates

For comparison, the annual referral and SGA detection rate for 2015/16 to 2017/18 for the 15 Trusts enrolled in GAP is shown in Table 11. The proportion of babies referred for suspected SGA/FGR and those detected as SGA antenatally increased progressively over the SBLCB implementation period. The proportion of stillbirths that were SGA at birth declined over the last 3 (post-SBLCB) years from 40% to 32%. It should be noted that SGA detection rates from the data submitted to GAP are somewhat lower than the rates estimated in this report. This is likely due to differences in the definition and fewer number of cases analysed in the evaluation project.

Table 11. SGA detection rates from Trusts enrolled in GAP

Indicator	2015/16		2016/17		2017/18	
	n	%	N	%	n	%
Annual births	20,544	85.8	58,124	88.2	52,255	88.0
SGA incidence (at birth)†	5061	13.2	7405	12.2	5881	11.9
Pregnancies referred for suspected SGA/FGR	2435	48.1	3868	52.2	3172	53.9
SGA babies detected antenatally	1895	37.4	3158	42.6	2588	44.0
SGA babies detected antenatally >37 wks	1484	33.8	2413	38.4	1978	39.7
Number of false positive SGA babies	1736	5.2	3510	6.6	2876	6.6
Stillbirths identified as SGA at birth	65	40.6	69	34.3	57.0	32.0
Stillbirths identified as SGA antenatally	17	26.2	23	33.3	17.0	29.8

† Percentage calculated from the number of babies with a calculated birthweight centile

7.7 Summary

Antenatal detection of SGA babies has increased significantly over the SBLCB implementation period. Growth charts are now universally used by Trusts though some care providers fail to plot estimated fetal weight and/or fundal height measurements for detection of an SGA fetus. Use of the SBLCB algorithm for risk classification was poor.

Although there is no direct evidence to suggest that implementation of SBLCB interventions increase detection rates, better monitoring of fetal growth through (accurate) implementation of growth charts and serial scanning (i.e. GAP programme) can lead to improved identification of SGA babies before birth.

8. Element 3 - Reduced fetal movements

This chapter presents the information gathered about implementation of Element 3 – raising awareness of reduced fetal movements (RFM) in the early adopter Trusts. Data about information provision for RFM, women's experience of RFM and management of RFM by Trusts is summarised in Table 13. We explored the fidelity of implementation of the various interventions to determine if Trusts were implementing what they reported. It is important to note that data presented here is cross-sectional and limited to the post SBLCB implementation period (Apr 2017).

8.1 Element description and interventions

Epidemiological studies have consistently described a relationship between episodes of RFM and stillbirth[20]. Critically, findings from the 8th Report of the Confidential Enquiry into Stillbirths and Deaths in Infancy[21] and the 2015 MBRRACE-UK Confidential Enquiry into Antepartum Stillbirth[5] found that unrecognised or inappropriately managed episodes of RFM are contributory factors to avoidable stillbirths. Element 3 focusses on raising awareness amongst pregnant women of the importance of detecting and reporting RFM and ensuring that providers have protocols in place, based on best available evidence, to manage the care of women who report perceptions of RFM. There are three recommended interventions which are aligned with RCOG Green Top guideline[12]:

1. Information and advice leaflet on RFM to be provided to all women by 24 weeks pregnancy
2. Reduced fetal movements discussed at every antenatal appointment
3. Use of the provided checklist to manage care of women who report RFM

8.2 Definitions and data sources

Data regarding the provision of the RFM leaflet to women was obtained from surveys of postnatal women in 19 Trusts. Data on the management of RFM and use of the provided checklist (by health professionals) was obtained from clinical audit of pregnancies with documented RFM from 17 Trusts along with staff surveys.

8.3 Implementation

Table 12 shows the implementation scores and duration of implementation as reported by Trusts. Ten Trusts reported 100% implementation for all interventions in element 3. Only 2 Trusts said they didn't use the leaflet for mothers and 14 Trusts reported using the checklist. Auditing for RFM was reported by 10 Trusts. The duration of implementation varied (from 5 to 73 months) with 7 Trusts reporting implementation prior to the SBLCB launch.

Table 12. Reported implementation of element 3- raising awareness of reduced fetal movements in the early adopter Trusts

Trust	Imp. Score (%)	Reported Start Date	Leaflet given	Leaflet < 24w	Managed with Checklist	RFM audits
F	100	*prior*	All of the time	All of the time	All of the time	No
O	67	*prior*	Most of the time	Most of the time	Most of the time	Yes
E	100	*prior*	All of the time	Never	All of the time	Yes
M	33	*prior*	Most of the time	Not much of the time	Never	Yes
H	100	*prior*	All of the time	All of the time	All of the time	No
J	100	*prior*	All of the time	All of the time	All of the time	No
L	100	*prior*	All of the time	All of the time	All of the time	No
G	100	Apr-15	All of the time	All of the time	All of the time	Yes
I	100	Apr-15	All of the time	Never	All of the time	No
D	100	Jun-15	All of the time	All of the time	All of the time	Yes
A	100	Sep-15	All of the time	All of the time	All of the time	No
B	100	Jan-16	All of the time	All of the time	All of the time	No
R	33	Jan-16	Most of the time	Most of the time	Never	Yes
N	83	Feb-16	Most of the time	Most of the time	All of the time	Yes
S	0	Jun-16	Never	Never	Never	No
C	100	Sep-16	All of the time	All of the time	All of the time	Yes
P	50	Nov-16	All of the time	All of the time	All of the time	Yes
Q	50	Nov-16	Never	Never	All of the time	Yes
K	0	Apr-17	All of the time	Never	Most of the time	No

† Implementation score for element 2

Prior; implemented before the nominal start date

Cost of implementation

The estimated total direct cost of implementing Element 3 across the 19 Trusts between April 2015 and April 2017 was £13,187. This included the cost of producing the RFM leaflets.

8.4 Use of the RFM leaflet

The majority of women (74%) said they received and read the information and advice leaflet on RFM (Table 13); 18% of women said they did not remember if they were given the leaflet on RFM. The percentage of women receiving the leaflet was positively correlated to the implementation score indicating fidelity in implementation (RR 2.36, 95% CI 1.6-3.4, p<0.001).

When asked about the amount of information provided, 91% of women said they felt they received the right amount of information about monitoring baby's movements. Most were aware of the 'Kicks Count' Campaign.

8.5 Women's experience of monitoring baby's movements

Virtually all women (96%) said they monitored their baby's movements during their current pregnancy (Table 13). Most said this was based on verbal advice given by their midwife or doctor and one third said the leaflet motivated them to monitor their baby's movements. Only 7% used an online App and even fewer (4%) used a Kick Chart to monitor movements.

When asked about their feelings toward monitoring baby's movements, 65% of women reported that it made them feel calm; 30% said it made them feel anxious during pregnancy.

8.6 Attendances for RFM and actions taken

Forty nine percent of women said they were concerned that their baby's movements had slowed or stopped in their current pregnancy when explicitly asked. Nearly all women experiencing RFM contacted their midwife immediately and 37% of women surveyed attended their maternity unit on at least one occasion due to concerns about fetal movements. Interestingly, women who received the RFM leaflet were less likely to visit their maternity unit than those who did not (36% versus 40%) although this difference was not statistically significant.

When staff were asked about the use of the checklist, 70% said they used a checklist to manage women reporting RFM; 40% using the checklist provided in the SBLCB. The use of the checklist did not correlate with implementation score (indicating a lack of fidelity for this part of element 3).

A checklist for management of RFM was present in 52% of patient notes from RFM pregnancies. A high proportion of women perceiving RFM attended their maternity unit (77.3%). Of those women attending their maternity unit with RFM, 74% received fetal heart monitoring, 65% of women received an ultrasound scan; 20% at every visit. Half were scanned within 24 hours and 20% of women were scanned within 2 to 3 days. Fifty five percent of women reporting RFM had induction of labour.

The implementation score for element 3 was negatively correlated with the proportion of women who received an ultrasound scan at every attendance for perceived RFM (adjusted RR 0.18, 95% CI 0.07-0.45, $p<0.001$). This suggests that implementation of this element does not necessarily lead to increased scanning.

Table 13. Information provision and management of RFM post implementation of the SBLCB in the early adopter Trusts

Outcome	Number/ Responses	% of women
Patient reported (n=19)		
RFM leaflet received	1290/1735	74.4
Overall attendances for perceived RFM	793/2171	36.5
Women with RFM who attended	793/1053	75.3
Women scanned for RFM	233/793	29.4
Heart trace for RFM	583/793	73.5
Audit of RFM pregnancies (n=17)		
RFM checklist used	177/339	52.2
Scanned at every RFM visit	68/322	21.1
Scanned at any RFM visit	209/322	64.9
Fetal heart rate monitoring at every RFM visit	330/339	97.4
Women induced due to RFM	188/344	54.7

8.7 Summary

Provision of the NHS advice leaflet on RFM was good across the Trusts and three quarters of women said they received *and* read the leaflet, suggesting that the leaflet is accessible and appropriate for women's needs. However, the leaflet was not the main motivation for monitoring their baby's movements and most women said they acted on verbal advice given by their healthcare professional.

Receiving information made most women feel calm, though one third of women said they experienced some anxiety over monitoring their baby's movements. Distributing information was not associated with an increase in anxiety or in frequency of presentation for RFM. Of particular note was the high proportion of women who reported experiencing RFM when explicitly asked, with most attending their maternity unit for RFM on at least one occasion. The higher than expected proportion (prior studies suggest 5-14% of women present with RFM during pregnancy)[22, 23] suggests that the messages regarding RFM may need to be refined further.

Although the reported use of the checklist by Trusts and staff was high, only half of the RFM pregnancies contained the checklist in the patient notes. This may be due to the use of alternative checklists e.g. Cheshire and Mersey SCN Checklist. Furthermore, a significant proportion of women who attended with RFM did not receive the recommended investigations, specifically fetal heart monitoring or an ultrasound scan. This represents an area for improvement in future implementation.

9. Element 4 - Effective fetal monitoring in labour

This chapter presents the information gathered about the implementation of Element 4 – effective fetal monitoring in labour in the early adopter Trusts. The information returned for annual training and competency assessment in cardiotocography (CTG) interpretation and auscultation was highly variable across the Trusts, with most unable to provide up to date records for the five year evaluation period, highlighting the need for improved documentation by Trusts. For these reasons, we are unable to report metrics on CTG training. Table 15 summarises the findings about the use of a buddy and sticker system for review of CTG interpretation across the early adopter Trusts. Figure 18 shows the average number of babies therapeutically cooled across the early adopter Trusts.

9.1 Element description and interventions

CTG monitoring is a well-established method of confirming fetal wellbeing and screening for fetal hypoxia and it is currently the recommended method to monitor a fetus during a high risk labour. However, there are significant variations in judgment in CTG interpretation between clinicians and by the same clinician over time[24], which can lead to deviations in care planning and consequent impact on perinatal outcomes[13]. The 2015 MBRRACE Confidential Enquiry into Intrapartum-related Perinatal Deaths [5] found deficiencies in care related to fetal monitoring in the majority of cases. This element specifies that Trusts must be able to demonstrate that all qualified staff who care for women in labour are competent to interpret intrapartum CTGs, use the buddy system at all times and escalate accordingly when concerns are raised. The specific interventions are:

1. All staff who care for women in labour to undertake annual training and competency assessment on CTG interpretation and auscultation. No member of staff should care for a woman in a birth setting without evidence of training and competence within the last year.
2. Buddy system in place for review of CTG interpretation with protocol for escalation if concerns are raised. All staff to be trained in the review system and escalation protocol.

9.2 Definitions and data sources

Data for a buddy/sticker system and escalation protocol were obtained from clinical audit of 720 singleton term live births that were delivered post SBLCB implementation. Information on the number of babies therapeutically cooled (pre and post SBLCB) was obtained from Trusts electronic records.

9.3 Implementation

Table 14 shows the implementation scores and duration of implementation for Element 4 as reported by Trusts. Ten Trusts reported 100% implementation for all interventions. One Trust reported not carrying out annual training for CTG for staff that care for women in labour. A buddy/sticker system

was used in 17 Trusts and escalation protocols were in place in all Trusts. Twelve out of the 19 Trusts reported implementation of element 4 before the SBLCB implementation date.

Table 14. Implementation of Element 4 - effective fetal monitoring in labour in the early adopter sites

Trust	Imp. Score (%)†	Reported Start Date	CTG Training (labour)	Buddy System used	Stickers used	Escalation Protocol used
C	100	*Prior*	All of the time	All of the time	All of the time	All of the time
D	100	*Prior*	All of the time	All of the time	All of the time	All of the time
H	100	*Prior*	All of the time	All of the time	All of the time	All of the time
M	87	*Prior*	All of the time	All of the time	Most of the time	Most of the time
R	100	*Prior*	All of the time	All of the time	All of the time	All of the time
G	100	*Prior*	All of the time	All of the time	All of the time	All of the time
P	100	*Prior*	All of the time	All of the time	All of the time	All of the time
O	60	*Prior*	Most of the time	Most of the time	Never	All of the time
E	100	*Prior*	All of the time	All of the time	All of the time	All of the time
B	100	*Prior*	All of the time	All of the time	All of the time	All of the time
J	73	*Prior*	All of the time	Most of the time	Most of the time	Most of the time
L	80	*Prior*	All of the time	Never	All of the time	All of the time
A	100	Apr-15	Most of the time	All of the time	All of the time	All of the time
F	100	Jun-15	All of the time	All of the time	All of the time	All of the time
N	87	Feb-16	All of the time	Most of the time	Most of the time	All of the time
I	87	Apr-16	All of the time	Most of the time	Never	All of the time
S	47	Jun-16	NA	Never	Most of the time	All of the time
Q	60	Feb-17	All of the time	Most of the time	Never	Most of the time
K	0	Apr-17	Never	Never	Never	Never

† Implementation score for element 4

Cost of implementation

The estimated total direct cost of implementing Element 4 across the 19 Trusts between April 2015 and April 2017 was £755,117. This included the fee for midwives, consultants, and junior doctors to complete an externally-facilitated CTG training course annually.

9.4 Annual training for CTG interpretation and auscultation

Trusts were asked to provide training records on the number of staff who completed annual training for CTG auscultation and interpretation. Very few Trusts were able to provide electronic records for the whole 5 year period and consequently data was too incomplete to allow reliable interpretation. In the unit survey, 11 out of the 19 Trusts reported to be undertaking annual training using the maternity EPR system, K2MS Athena. Eighteen Trusts reported to be training most or all staff annually in CTG interpretation and auscultation. Thus, rather than failing to deliver or complete CTG training for staff, this may be a failure to keep/access records which highlights the need for improved documentation processes, and local protocols should be in place in all Trusts for audit and monitoring for CTG training.

9.5 Buddy and sticker system for CTG interpretation

Overall, 73% of the term singleton livebirths audited had evidence for CTG monitoring during labour. A buddy for CTG interpretation, either recorded in the patient notes or computer system, was evidenced in 63.5% of the audited pregnancies (Table 15). A sticker was visible in 58.7% of pregnancies that were monitored for CTG and 50% had evidence of both a buddy and sticker system in the notes. Only 3 out of 514 cases (0.6%) reviewed had no evidence of escalation (excluding cases with no CTG monitoring or where no concerns were raised).

The percentage of pregnancies with evidence of a buddy system was positively correlated with the implementation score for element 4 indicating fidelity in implementation of this element (adjusted RR 41.4, 95% CI 11.7-147.1, p<0.001).

Table 15. Buddy system for CTG interpretation

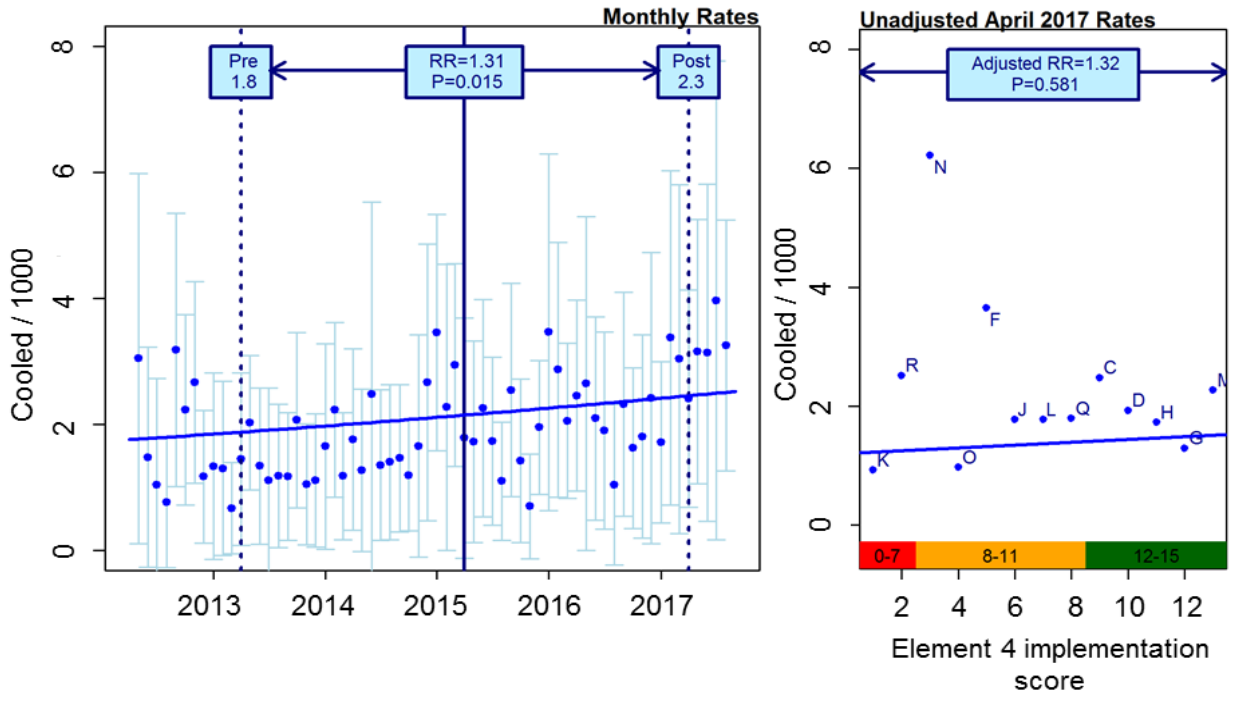
Outcome	Number/number of cases audited	%
Buddy recorded and signed in notes or computer system	334/526	63.5
Sticker visible in patient notes	309/526	58.7
Buddy and sticker system used and evidenced in notes or computer system	265/526	50.3
Concerns were raised regarding CTG interpretation and escalated to local protocol	511/514	99.4

9.6 Therapeutic cooling

Figure 18 shows the number of babies therapeutically cooled over the five year evaluation period from 13 early adopter Trusts who provided data. The number of babies therapeutically cooled increased steadily over the 5 year time period, although was highly variable between Trusts. The proportion increased from 1.8 per 1,000 births before SBLCB to 2.3 per 1,000 births after implementation of the SBLCB. This represents a 28% proportional increase.

Figure 18. Proportion of babies therapeutically cooled pre and post SBLCB in the early adopter Trusts

Outcome	Babies therapeutically cooled
Denominator	Per 1000 babies
Source	Electronic Data Submission
Numbers	312,582 Babies from 13 Trusts



Apr 2013 Rate	1.79
Apr 2017 Rate	2.34
Pre/Post RR (95% CI) [P]	1.31 (1.05-1.62) [0.015]

RR (95% CI) [P]	0.81 (0.22-2.91) [0.746]
Adjusted RR (95% CI) [P]	1.32 (0.49-3.57) [0.581]

9.7 Summary

Documentation of staff CTG training is poor across Trusts which led to inadequate data for analysis. Anecdotally, some Trusts reported that compliance with training is not monitored at the Trust level and it therefore depends on the individual to ensure they are adequately trained. Trusts need to develop reliable systems to ensure that all relevant staff receiving training and their competency is assessed.

The buddy/sticker systems (or electronic equivalents) achieve moderately high levels of utilisation when this element is implemented, although even in the best-performing Trusts 10-20% of deliveries are non-compliant with this component of the SBLCB. Escalation protocols were well utilised across all Trusts.

Rates of therapeutic cooling have increased over the implementation period. However, this is a relatively new technology with high-quality randomised evidence in its favour being relatively recent[25]. Thus, the observed increase may to reflect the increased uptake and acceptance of technology (from nationally reported rates of 0.8/1,000 in 2015 compared to 2.3/1,000 in 2017 reported here) rather than the SBLCB interventions leading to increased rates of adverse outcome.

10. Economic analysis

The quality of data collected from the 19 Trusts was highly variable (with three sites not reporting any data on resource use as part of the Unit Resource and Leadership survey) and comprising largely subjective qualitative responses rather than quantitative measures of resources used. As such it was not possible to calculate a definitive cost per Trust. Instead, the total cost across all 19 Trusts between April 2015 and April 2017 is reported alongside estimates for the whole of England.

10.1 The cost of implementation

The cost of implementing the SBLCB is reported in Table 16. The total cost (direct and secondary costs) between April 2015 and April 2017 is estimated to be **£27m**. The key direct implementation costs are purchasing CO monitors and training in CTG interpretation. However, the direct implementation cost represents just 4% of the overall cost and is outweighed by the cost of secondary resource use associated with the SBLCB.

Under the assumption that all of the increase in secondary resource use is attributable to SBLCB, the most significant component of the total estimated cost is due to the increase in the number of ultrasound scans conducted (£9.8m (36% of the overall cost)). This cannot be attributed to any specific element but likely to be largely driven by Element 2 and somewhat by Element 3.

Also of note is the increased delivery cost (£7.8m (29% of the overall cost)) which is due to greater spending on emergency caesarean sections and more inductions of labour (costing £8.4m (31% of the overall cost)) after the SBLCB launch compared to before.

There may also be a secondary effect on the number of neonatal unit admissions however data were not available for a number of Trusts, and there was uncertainty about level of care, therefore this was not included in this economic analysis.

10.2 Stillbirths

The stillbirth rate across the Trusts for the two years before SBLCB was 4.14/1,000 births and for the two years after it was 3.31/1,000, or a reduction of 0.83/1,000 births. Applying this difference to the number of births across the 19 early adopter Trusts over two years (n=193,632), an estimated 161 stillbirths may have been avoided. This estimate assumes that the entire reduction in stillbirth rate observed was due to SBLCB.

For term-singleton babies the stillbirth rate for the two years before the intervention launch was 1.58/1,000 births and for the two years after it was 1.23/1,000, or a reduction of 0.35/1,000 births. Assuming that 90% of births were term singletons (n=174,269) this equates to 275 stillbirths 'without' the SBLCB and 214 'with' the SBLCB, or 61 stillbirths potentially avoided.

Of the total 161 stillbirths potentially avoided, an estimated 38% of those would have been term-singleton babies[4], suggesting that the majority of stillbirths avoided were from the smaller group of premature and/or multiple births.

Table 16. Estimated costs associated with the SBLCB (total costs across the early adopter sites)

A. Direct implementation cost			
Element	**Resources included**	**Resources excluded**	**Cost (£)**
Element 1	i. CO monitors (£165 each) ii. D-pieces for monitors, to be replace monthly (£3 each) iii. Mouthpieces for monitors, one per each woman booked (£0.25 each)	i. 10 minutes of midwife time to speak to smokers (9-24% of women in study) about smoking cessation and/or do referral ii. Two centres reported monitors not being purchased by the Trust iii. Calibration of monitors	£183,063
Element 2	i. GAP software set-up (£500/Trust) ii. GAP annual software cost (£1500-5000 depending on size of Trust)	i. Staff time (midwives and sonographers) to attend training course in GAP software run for free by Perinatal Institute ii. Administrator time to generate customised growth charts iii. Some units may use GAP *plus* iv. Two centres do not use GAP	£74,250
Element 3	i. Trusts instructed to add logos to leaflet and then photocopy from a master copy, two sides of A4 (£0.10 each)	i. Midwife time to discuss leaflet ii. Midwife time to discuss RFM at subsequent visits iii. One Trust reported not distributing leaflets iv. Attendances with perceived RFM	£13,187
Element 4	i. Online training course in CTG interpretation (£100) completed annually by midwives, consultants, and junior doctors ii. One site sent staff on an additional annual one-day CTG masterclass (£120)	i. Staff time (two-days) to complete training course	£755,117
Direct Cost	**£1,025,617**		

B. Secondary implementation costs					
Inductions	Induction rate increased from 26.27 to 31.40 per 100 births, costing £847.15 per induction.				£8,415,013
Deliveries		**Before**	**After**	**Cost**	
	Normal	63.42	61.94[b]	-£4,884,677	£7,778,032
	EMCS	13.69	15.01	£11,638,254	
	Instrumental	12.25	12.41	£1,024,456	
Scans	Number of scans per woman booked increased from 3.51 to 4.35 (24% increase), costing £52.94 per scan.				£9,774,329
Secondary costs	**£25,967,375**				
TOTAL	**£26,992,992**				

[a] Deliveries includes normal, instrumental, and emergency C-sections
[b] Assuming that additional elective sections would have been normal deliveries so that same number of deliveries are included in the before and after cost
For all elements staff time to complete in-house training is excluded

10.3 Costs and stillbirths for the whole of England

There were 666,025 births in England in 2015/16. The primary estimated cost of implementing the care bundle for the first year in England is **£94,315,343**. A breakdown of the costs is shown in Figure 19. The year one implementation cost (excluding secondary costs) is £4,849,049 (5%) of the total cost. The cost per subsequent year is only £1m lower as most of the costs are recurring; start-up costs are limited to the purchase of CO monitors and fees for the initial setup of GAP software. The estimated cost of implementing SBLCB over two years across the whole of England is £187,575,599.

From a national perspective, in 2014/15 approximately £2.5bn was spent in the NHS on maternity services (with 664,399 births)[26, 27], and in 2016/17 obstetric claims handled by the NHS Litigation Authority accounted for £4,370m of new claims reported, or 50% of all claims[28]. Based on figures for 2014/15, the maternity tariff per birth was approximately £3760, to which the direct and secondary costs associated with SBLCB are estimated to add £142 (i.e. £94.3m divided by 666k births).

In the 19 early adopter Trusts, the stillbirth rate was 0.83/1,000 births lower in the two year period after SBLCB was implemented than the previous two years. Based on the number of births in England, an estimated 553 stillbirths per year may have been avoided (1106 over two years i.e. the SBLCB evaluation period).

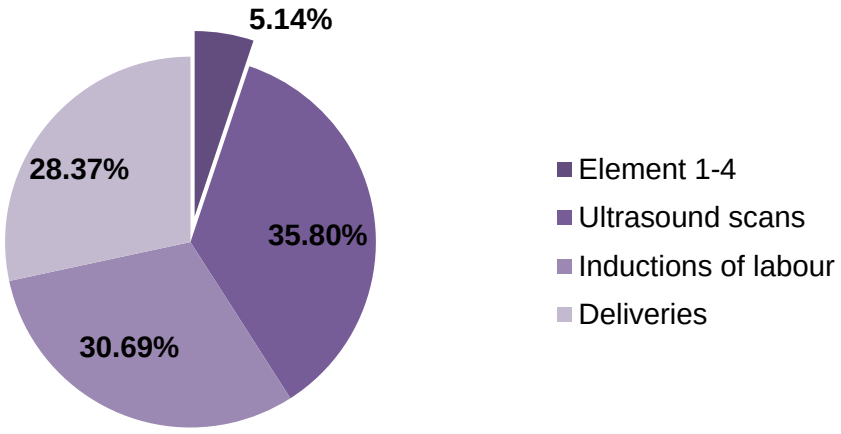


Figure 19. Breakdown of costs for implementing the SBLCB across the whole of England

10.4 Sensitivity analyses

The primary estimates have been made under a number of assumptions regarding both costs and stillbirths. A series of one-way sensitivity analyses exploring the impact of these assumptions were conducted (Table 17) (see Appendix 2 for all alternative assumptions). Selected assumptions are shown in Table 17 below. The assumptions for the different cost components were combined to produce a lowest and highest estimate; the total cost associated with implementing SBLCB for one year across the whole of England was between £69,589,179 and £165,175,700.

Table 17. Alternative assumptions for costs associated with the SBLCB (total costs across the whole of England)

Alternative assumptions	Change in cost versus base case†	Total cost
10% increase in induction rate (versus ~20% observed)	£14,123,076 lower	£80,192,267
No direct implementation costs	£4,849,049 lower	£89,466,293
50% of maternity units use GAP software (versus 100%)	£195,500 lower	£94,119,843
Include cost for 5% of births to attend antenatal clinic with perceived RFM (£75.15/visit) (versus no visit)	£2,502,691 higher	£96,818,034
Include cost of increased elective section rate (versus assume would have been normal delivery)	£26,711,019 higher	£121,026,362

† The total cost in the base case estimate was £94,315,343

10.5 Summary

The direct cost of implementing the SBLCB is a small proportion of the total cost, which includes the cost of secondary resources associated with SBLCB. However, it is not possible to determine to what extent or how existing resources have been reconfigured to release the resources required to implement SBLCB. Furthermore, it is not possible to determine how much of the increase in use of secondary resources or the reduction in number of stillbirths observed are directly attributable to SBLCB; these results assume the whole increase is due to SBLCB and so may be an overestimation.

The most significant driver of cost is related to additional demand for ultrasound scans. Scanning has had a clear impact on maternity services, with eight Trusts increasing staff hours to meet the increased demand. Five Trusts reported training midwife sonographers for third trimester growth scanning and some Trusts have increased their capacity through additional evening and weekend clinics.

Assuming that a full time sonographer conducts 4,000 ultrasound scans/year [29], the equivalent of an additional 159 full-time sonographers would be needed across England to conduct the 635,000+ additional scans associated with SBLCB in one year. In light of the significant cost and workforce

implications of additional ultrasound scans conducted, more work is needed to determine if the increased number of ultrasound scans is cost-effective and defining what other benefits there are from detecting SGA babies.

The direct implementation cost included use of GAP software for monitoring fetal growth and use of the K2 training programme for CTG interpretation as these were reported by the majority of the participating Trusts. However, these were not mandated as part of SBLCB but rather how the individual Trusts opted to implement their interpretation of the recommendations contained with the SBLCB.

In order to properly implement the SBLCB, midwives are required to fit a number of additional tasks into routine antenatal appointments and are presumably not able to schedule longer or more frequent appointments. While in theory this minimises the cost of implementing the bundle there are likely to be intangible costs of increasing the burden on midwives such as burn out and stress. Another potential cost may be a detrimental impact on the quality of care that midwives are able to provide under these conditions, for example having less time to hear and respond to the concerns of mothers. On the other hand it is also possible that by reducing the number of stillbirths there is a potential saving of the associated direct costs (e.g. post-mortem examinations and tests) estimated to be £1,804 in 2010 prices [30] and the intangible costs (e.g. litigation, adverse psychological outcome, social isolation, unemployment) which are likely to be significant [31].

11. Staff opinions of services

Surveys were carried out with 1,064 health professionals to explore the views and experiences of staff who deliver the SBLCB as part of maternity care, and the potential impact this may have on service delivery.

11.1 Survey respondents

Table 18 summarises the respondents of the staff survey. The response rate was highly variable across the 19 early adopter Trusts and by role of respondent. As completion of the questionnaire was not compulsory, responses cannot be assumed to be a fully representative sample. The information presented below offers a snap shot of current opinion regarding service delivery in a self-selected group of responders (mainly midwives) in Trusts who are likely to be more engaged in the SBLCB implementation.

Table 18. Staff respondents by professional role across the early adopter Trusts

	Trusts responding	Number of staff responding	Estimated Response Rate	Response rate range between Trusts
Consultant	16	65	23%	8-60%
Manager	3	3	NA	
Midwife	19	830	22%	8-55%
Nurse/Sister	3	9	NA	
Trainee Doctor	5	15	5%	6-43%
Ultrasonographer	11	34	NA	
Not Stated	19	98	NA	
Other	8	10	NA	
All	**19**	**1064**		

NA reliable denominators not available

11.2 Staff opinions of services

Only 58% of all respondents were aware of the SBLCB (Table 19). Forty two percent of midwives stated they were unaware of the SBLCB and even higher rates of lack of awareness were seen in junior doctors (53%) and ultrasonographers (68%).

It was almost universally perceived by staff that the demand for ultrasound scans has increased over the past 5 years (97% of respondents perceiving an increase), along with the increased frequency of inductions (98%) and caesarean sections (80%) and increased demand for neonatal unit admissions

(62%) (Table 20). Overall, there is a perception amongst staff of a decreasing stillbirth rate, although individual perceptions differ and do not seem to be associated with position or Trust.

Table 19. Staff awareness of the SBLCB across the early adopter Trusts

	Yes	No	No Response
Consultant	55 (89%)	7 (11%)	3
Manager	3 (100%)	0 (0%)	0
Midwife	475(58%)	344 (42%)	11
Nurse/Sister	2 (22%)	7 (78%)	1
Trainee Doctor	7 (47%)	8 (53%)	0
Ultrasonographer	11 (32%)	23 (68%)	0
Not Stated	24 (73%)	9 (27%)	66
Other	7 (70%)	3 (30%)	0
All	584 (59%)	401 (41%)	81

Table 20. Staff opinions of services across the early adopter Trusts

Q. Over the last 5 years	Greatly increased	Slightly increased	Not changed	Slightly decreased	Greatly decreased	Don't know
The demand on ultrasound scanning has…	839 (87%)	98 (10%)	15 (2%)	2 (0%)	11 (1%)	99
The number of stillbirths has…	10 (1%)	126 (16%)	323 (41%)	260 (33%)	65 (8%)	280
The number of babies admitted to a NICU has…	108 (15%)	330 (47%)	214 (30%)	47 (7%)	5 (1%)	360
The number of inductions…	713 (79%)	171 (19%)	17 (2%)	4 (0%)	1 (0%)	158
The number of caesarean sections has…	270 (31%)	425 (49%)	161 (18%)	13 (1%)	2 (0%)	193

11.3 Staff opinions on resources and safety

When asked to consider their own work area, most staff (68%) perceived that mother and baby outcomes are improving (Table 21). However, there were strong perceptions of being understaffed (75%) and under-equipped (53%) to ensure the best outcomes for mothers and their babies. Twenty three percent of respondents believe that safety is being sacrificed and 23% believe staff workloads are compromising outcomes. Thirty seven percent of staff believe that their senior management do not take safety seriously enough.

Table 21. Staff opinions about resources and safety

In my work area:	Completely agree	Agree	Neutral	Disagree	Completely disagree	Don't know
We have enough staff to ensure the best possible outcomes for the mother and baby:	15 (2%)	83 (8%)	142 (14%)	417 (42%)	327 (33%)	80
We have enough equipment to ensure the best possible outcomes for the mother and baby:	27 (3%)	228 (24%)	201 (21%)	360 (37%)	150 (16%)	98
We are actively doing things to improve the safety of mothers and babies:	267 (27%)	540 (55%)	130 (13%)	35 (4%)	11 (1%)	81
The safety of the mother and baby are sacrificed to get more work done:	43 (4%)	182 (19%)	204 (21%)	368 (38%)	165 (17%)	102
Management only seem interested in safety after an adverse event happens:	104 (11%)	248 (26%)	192 (20%)	321 (33%)	102 (11%)	97
Staff work longer hours than is best for the mother and baby:	206 (21%)	360 (37%)	191 (20%)	181 (19%)	25 (3%)	101

11.4 Staff opinions about the use of clinical guidelines

Overall, there is a strong belief that clinical guidelines offer women high-quality care, and 93% of respondents believe that the use of guidelines ensures all women receive the same level of basic care (Table 22). Almost all staff (97%) believe that their managers and colleagues encourage the use of guidelines. However, 34% of respondents state they don't have the time to use guidelines and 24% state they are not able to implement guideline recommendations. In general, staff feel that their clinical guidelines are readable, though 17% of staff reported they cannot easily access their guidelines (this appears to be mostly Trust dependent).

Table 22. Staff opinions about the use of clinical guidelines across the early adopter sites

Do you agree that:	Completely agree	Agree	Neutral	Disagree	Completely disagree	Don't know
Guidelines offer women higher-quality care:	286 (29%)	571 (58%)	111 (11%)	19 (2%)	0	77
Guidelines ensure that all women receive the same level of basic care:	376 (38%)	540 (55%)	44 (4%)	21 (2%)	5 (1%)	78
A lack of time greatly impedes the use of guidelines in my unit:	87 (9%)	239 (25%)	169 (18%)	366 (38%)	93 (10%)	110
Poor readability of guidelines of greatly impedes the use of guidelines in my unit:	44 (5%)	188 (20%)	186 (19%)	427 (44%)	117 (12%)	102
I am not able to carry out all recommendations in the guidelines:	33 (3%)	206 (21%)	197 (20%)	438 (46%)	87 (9%)	103
It is easy for me to access the relevant guideline when I need it:	241 (25%)	467 (48%)	109 (11%)	133 (14%)	31 (3%)	83

11.5 Summary

The staff who responded to the survey accurately perceived changes in maternity outcomes over the preceding two years. The majority noted the increases in inductions of labour, caesarean section and neonatal admission and decrease in stillbirths. Staff also reported a significant increase in their workload and voiced concerns that this increased pressure compromised safety. This may compound a lack of confidence in the safety culture in their Trusts.

Staff value clinical guidelines, but may not be able to access them, or have sufficient time to do so. They may not be able to implement the guidelines, which may reflect that 53% of respondents said they did not have sufficient equipment to ensure the best possible outcomes for mother and baby.

In future iterations of the SBLCB and other maternity improvement projects it will be important to engage with frontline workers (particularly midwives and doctors in training) who currently report the lowest levels of awareness of the SBLCB, but may experience changes to their workload. It is also important that members of these professional groups have accurate and accessible clinical guidance relating to the elements of the SBLCB.

12. Guideline appraisal

A total of 74 clinical practice guidelines from 19 Trusts were assessed using the AGREE II tool. Virtually all Trusts were able to provide guidelines relevant to each element of the SBLCB. In particular, 8 Trusts had guidelines specifically for “smoking cessation in pregnancy” in addition to their antenatal care guidelines; one Trust had a guideline specifically for “carbon monoxide testing in pregnancy”.

12.1 Overall guideline scores

Overall, the highest scoring unit guideline in terms of methodological quality was smoking cessation (58%; range 25-92%) (Table 23). This was followed by guidelines for the detection and management of FGR (54%; range 33-83%) and intrapartum fetal monitoring (53%; range 17-92%). Guidelines for RFM had the lowest score (50%; range 13-92%).

Only 4 (5%) guidelines were recommended for use in clinical practice without modifications and 54 (72%) were recommended for use subject to modifications. Twelve (16%) guidelines were not recommended for use (6 were for RFM) for reasons such as exceeding the review date and guidance falling below national standards.

12.2 Individual domain scores

In terms of the individual domains, some scored much higher than others for all categories of guidelines (Table 23). Domain 1 (Scope and Purpose) and Domain 4 (Clarity of Presentation) received the highest scores for each guideline category. Both domains had a median score of 85% or more.

Rigour of development (Domain 3) of unit guidelines was poor across all four guideline categories, with most having a score of 50% or less. Very few guidelines identified how the evidence was generated and references were frequently omitted making it difficult to identify the underpinning evidence, the SBLCB was rarely cited in clinical guidelines. The greatest source of variance was in the processes in place for audit and monitoring the impact of the guideline, and the procedure for updating the guidelines which was frequently omitted (Domain 3). A minority of guidelines were out of date.

Stakeholder involvement (Domain 2) also scored low. Applicability (Domain 5) had the lowest score with units failing to identify barriers to implementation and resources required to implement the guideline recommendation(s). Editorial independence (Domain 6) was excluded from the analysis as it was not relevant to NHS maternity guidelines.

Table 23. Guideline scores using AGREE II

AGREE II Domain	Smoking cessation guidelines	Fetal growth restriction guidelines	Reduced fetal movement guidelines	Intrapartum fetal monitoring guidelines	Median Domain Score
1 - Scope and Purpose	89	87	83	86	**87**
2 - Stakeholder Involvement	50	52	47	46	**48**
3 - Rigour of Development	42	45	38	49	**44**
4 - Clarity of Presentation	88	88	82	89	**88**
5 - Applicability	44	38	33	43	**40**
Overall score	**58**	**54**	**50**	**53**	**53**

Scores are median scores computed by AGREE II across the 19 early adopter Trusts

12.3 Unit guideline recommendations and agreement to SBLCB

The 12 recommendations from the SBLCB are shown in Table 24 alongside the percentage of guidelines that included each recommendation. The majority of guidelines contained all 3 the SBLCB recommendations for element 1. Carbon monoxide testing of all pregnant women at antenatal booking was included in 68% of antenatal and or smoking cessation guidelines. Referral to smoking cessation services and follow up was included in 58% of guidelines.

Most of the unit guidelines contained the SBLCB recommendations for assessment of fetal growth using serial ultrasound scanning (95%), estimated fetal weight derived from ultrasound measurements and measurement of symphysis fundal height. 53% of guidelines included the algorithm for risk classification and surveillance of pregnancies. Most contained partial recommendation for serial ultrasound scanning for women at high risk of fetal growth restriction, estimated fetal weight measurements and fetal growth assessed using symphysis fundal height. Of particular concern was that none of the guidelines contained the SBLCB recommendation for ongoing audit and reporting for small for gestational age (SGA) babies.

Only 32% of the unit guidelines recommended giving women the information and advice leaflet on RFM, although 89% recommended using the checklist for management of RFM by health professionals. Training for CTG interpretation and auscultation was omitted from 74% of unit guidelines. The buddy system was fully recommended in 68% of guidelines.

Table 24. Unit guideline recommendations and agreement to the SBLCB

SBLCB recommendation			Full	Partial	Omitted
Element 1	1	Carbon monoxide (CO) testing of all pregnant women at antenatal booking appointment	68%	0%	32%
	2	Referral, as appropriate, to a stop smoking service/ specialist, based on an opt out system	58%	0%	42%
	3	Referral pathway to stop-smoking service includes feedback and follow up processes	58%	0%	42%
Element 2	4	Use supplied algorithm to aid decision making on classification of risk, and corresponding surveillance of all pregnancies (Some providers may wish instead to use the RCOG algorithm)	53%	37%	11%
	5	For women at high risk of fetal growth restriction, fetal growth to be assessed using serial ultrasound scans as per algorithm	0%	95%	5%
	6	Estimated fetal weight derived from ultrasound measurements recorded on a chart	0%	89%	11%
	7	For low risk women, fetal growth to be assessed using antenatal symphysis fundal height charts by clinicians trained in their use. All staff must be competent in measuring fundal height with a tape measure, plotting measurements on charts, interpreting appropriately and referring when indicated	0%	84%	16%
	8	Ongoing audit, reporting and publishing (on local dashboard or similar) of Small for Gestational Age (SGA) birth rate, antenatal detection rate, false positive rate and false negative rate.	0%	0%	100%
Element 3	9	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.	32%	0%	68%
	10	Use provided checklist to manage care of pregnant women who report reduced fetal movement, in line with RCOG Green-top Guideline 57	89%	0%	11%
Element 4	11	All staff who care for women in labour to undertake and pass an annual training and competency assessment on cardiotocograph (CTG) interpretation and use of auscultation. No member of staff should care for women in a birth setting without evidence of competence within the last year.	0%	26%	74%
	12	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.	68%	32%	0%

The percentage represents the number of Trusts

12.4 Summary

The methodological quality of maternity unit guidelines for smoking cessation in pregnancy, detection and management of FGR, RFM and intrapartum fetal monitoring varied considerably by Trust and were generally of low quality. Improvements in the development and implementation strategies of local guidelines are needed to ensure units can effectively deliver the SBLCB to maximise the benefit in reducing stillbirth through standardised high quality care. In particular, Trusts should ensure their guidelines are audited and make clear how they are approved for clinical use and by whom. No guideline should be out of date and efforts should be made to specify audit standards and the frequency of audit within each guideline.

13. Discussion and Conclusions

Historically, the stillbirth rate in the UK has been higher than comparable countries and has shown a slower rate of reduction[3, 32]. Confidential Enquiries into both antepartum and intrapartum-related deaths conducted over a 20 year timespan have shown persistent evidence of deficiencies in care, which if resolved, may have prevented this adverse outcome[5, 33, 34]. The SBLCB was introduced by NHS England to implement recommendations from established national guidance to address specific risk factors for stillbirth (cigarette smoking, FGR, RFM and intrapartum hypoxia).

Strengths and limitations of this evaluation

The overarching aim of this evaluation was to determine the degree to which early adopter Trusts in England implemented the SBLCB in maternity care, whether this translates into improved perinatal outcomes, what resources are required and what were the barriers and facilitators for implementation. This evaluation represents one of the largest such projects. The study included more than 95,000 deliveries a year in England which included 19 secondary and tertiary units across 9 local authorities. In the completion of this project, 1,658 case notes were audited, 2,230 women responded to a questionnaire and 1,064 health professionals completed a survey. The evaluation has combined contemporaneous analysis of maternity outcome data with analysis of staff and service user's views and analysis of unit guidelines to give as complete a view as possible of the impact of the SBLCB. This evaluation would not have been possible without the engagement and commitment of participating sites, and the authors would like to thank those involved.

Critically, in terms of the data available to the researchers it is difficult to ascribe causal relationships between clinical and service impacts and the SBLCB and its elements due to the complex and poorly described implementation patterns, the quality of the longitudinal data and parallel maternity initiatives (e.g. National Maternal and Neonatal Health Safety Collaborative) and studies such as the AFFIRM study, which was a stepped-wedge cluster randomised controlled trial of the management of RFM[35]. In particular, data were not available for many of the process outcomes that would be informative e.g. number of attendances with RFM, proportion of smokers at time of delivery, proportion of staff trained in CTG interpretation. Thus, the fidelity of implementation could not be accurately quantified, meaning that only the unit reported level of implementation could be correlated with a reduction in stillbirth, which did not show a relationship.

The overall quality of the electronically provided data was poor, with inconsistent recording and an inability to provide all the agreed outcomes. The protocol stipulated a two-phase data extraction with a period of several months allocated to reviewing the initial (pre-intervention) extraction, allowing the resolution of inconsistencies, refinement of definitional ambiguities and correction of extraction errors. Despite having formally agreed to a clear written protocol, with precise descriptions of the data required, no Trust was able to provide the full data specified. Additionally, no Trust was able to provide the initial data extraction, mainly due to delays in the approval processes, and the vast

majority of Trusts also failed by several months to meet the commitments to provide final complete data. Thus, there was no opportunity to review and revise the data collection and no time to request any more than minimal correction and clarification within the agreed timescale of this project.

Given the incompleteness of the electronic data the evaluation relied rather more heavily than anticipated on data collected from patient surveys. We were successful in getting data from a large number of patients across all settings. Whilst the response rate (25% of deliveries) was good given the logistics and setting, this may not be a fully representative sample, although where there is overlapping data on smoking rates these are similar. We also note that the aim was to administer the surveys electronically, but the lack of IT infrastructure (WiFi and internet access) made this impractical and we had to fall back on a traditional paper format, with additional resourcing for data entry. Staff surveys had a similar low response rate, with considerable variation between Trusts suggesting that with appropriate commitment higher rates could be achieved. Audits of clinical records were performed well in most Trusts, although the resourcing of even such a small audit was an issue. This method of data acquisition is labour-intensive and only very limited sample sizes are possible.

Main findings

We evaluated the implementation of a complex multi-component intervention across different NHS organisations and showed improvements in the stillbirth rate significantly above the previously reported national annual rate of 1.4% per year from 2000-2015[1, 6]. Although national data showed an accelerated annual rate of reduction of 2.4% from 2010-2016, there was no change in the stillbirth rate from 2015-2016. Data from these early adopter Trusts suggest that there has been a greater reduction in stillbirth than seen nationally (20% vs 14%) which has continued. National data for 2017, the final year included in this analysis, will be available in June 2019 which will allow further analysis. Importantly, if sustained, the average annual rate of reduction seen in the early adopter units is on target to achieve the national ambition to halve stillbirth by 2025.

The areas of focus for the SBLCB (smoking cessation, detection and management of SGA fetuses, management of RFM and monitoring in labour) have been emphasised in recent Confidential Enquiries into Antepartum and Intrapartum Stillbirth[36, 37] and a case-control study conducted in 41 maternity units in England[20, 38]. The latter study reported a population attributable risk for smoking of 14.0% and 45.3% for the SGA fetus. Thus, given these risk factors for stillbirth it is plausible that an effective intervention to reduce cigarette smoking and improve the detection of an SGA fetus would reduce stillbirth rates. Furthermore, the findings of this evaluation are in agreement with analysis of the Saving Babies Lives in the North of England (SaBiNE) which found an increased detection of SGA fetuses and a reduction in stillbirth in 40 Trusts[39]. The data from this evaluation also highlights the need for a multifactorial approach to address stillbirth rates in the UK. This and other studies have demonstrated a relationship between maternal education, deprivation, particularly child poverty, and stillbirth[40] indicating that initiatives beyond the scope of maternity healthcare are also required to reduce stillbirth and neonatal mortality.

The uptake of SBLCB in the early adopter Trusts was varied, with only one Trust stating 100% implementation of all four elements, emphasising the challenge of implementing all the elements. In particular, the variation in the processes between Trusts may partly be explained by difference in the fidelity of implementation of the interventions. As the SBLCB is rolled out and developed it is anticipated that more Trusts will be able to move towards fuller implementation as there is a trend towards this over the timeframe of the evaluation. Nevertheless, barriers to adoption, particularly those involving human and financial resource need to be addressed.

Critically, implementation of some aspects of the SBLCB appeared to significantly improve performance in some key areas. CO screening was acceptable and the leaflet providing information about fetal movements was seen and read by the majority of women. In addition, the use of growth charts increased as did the detection of SGA. However, the actions taken after women tested positive on CO screening or presented to hospital then varied, with 40% of women not referred for smoking cessation and 26.5% not having assessment of the fetal heart rate after referral with RFM. This may result from poor quality of or insufficient access to guidelines or inadequate resources to implement the SBLCB, all of which were raised by staff. It is essential that the positive effects of the SBLCB in more effectively screening for established risk factors are not lost due to inadequate or inappropriate action when they are identified. This requires improved clinical guidance and appropriate resources to ensure that the elements of the SBLCB can be effectively delivered, for example provision of accessible smoking cessation services and financial incentives for appropriate referral (e.g. CQUINs). Furthermore, implementation requires relevant organisations which may be in different sectors and funded via different routes work together e.g. maternity services and smoking cessation services (which are now under local authority control).

Clinical practice guidelines play a crucial role in ensuring clinicians provide evidence-based practice and are valued by professionals on the frontline of the clinical service. Yet this and previous studies demonstrate that guidelines are often of low and variable quality, meaning that the opportunity to deliver high-quality, standardised care is lost[41, 42]. National guidelines are developed using rigorous methodology, clearly identifying the processes involved in formulating recommendations to ensure high quality standards are achieved for all women. However, this was not translated to the guidelines in units implementing SBLCB, which frequently omitted evidence-based guidance from NICE, RCOG and the SBLCB. The role of unit guidelines when developing an implementation strategy for the SBLCB needs to be considered. Unit guidelines may be improved by having a template guideline within the SBLCB which can be formatted according to local needs, whilst retaining the essential information.

Resource use and costs

Over the timeframe of implementation of the SBLCB there has been an increase in pregnancy interventions and resource use, most notably in the number of ultrasound scans and induction of labour. The increase in both of these interventions could be perceived as evidence that the SBLCB is effective, as an increase in the detection of SGA and compromised babies with RFM would be

expected to lead to a greater number of inductions of labour. However, these data also sound a note of caution that other adverse consequences do not result from the SBLCB such as increased rates of preterm birth and emergency caesarean section which have their own consequences for maternal and fetal health. These interventions also impact upon the rate of normal unassisted birth and potentially upon women's experience of birth. Future iterations of the SBLCB may need to address recommendations to minimise the risk of adverse consequences in both resource use and mothers experience of pregnancy as well as to maximise potential benefits. More research is required to elicit mothers' perspectives of the SBLCB and its impact on pregnancy care.

The NHS currently spends approximately £3.3 billion per year on maternity services, so the estimated cost of implementing the SBLCB nationally would equate to 2.8% of the overall maternity budget. However, despite additional activity and consequent resource use Trusts were not given any additional funding directly to implement SBLCB and the resources required for the delivery of the SBLCB have been absorbed through the MPP or the provider would have been reimbursed for the increased rates of operative deliveries by the delivery tariff. In addition, there have been some initiatives to support activities relating to the SBLCB, for example, in December 2016, NHS England granted £75k (£1.95m total) of additional funding to each of 26 CCGs with the highest rates of smoking at time of delivery to help CCGs implement CO monitoring at booking, and opt-out referrals to stop smoking services. Nevertheless, some additional activity will be a marginal additional cost for Trusts. Due to this complexity, the direct implementation costs reported here represent the 'value' of the Care Bundle rather than the cost of additional resources required to implement it. Further analysis is required to determine the optimal funding mechanisms which facilitate implementation of the SBLCB.

Steps need to be taken to maximise data quality used to evaluate changes in care. It is clear that reliance on routine data held in Trusts requires more by way of Trust commitment and study resource, and it is likely that an insistence on proven validated data collection instruments in each Trust prior to the commencement of any future evaluation is essential to complete, accurate and timely evaluation. Such validation requires resource in both the evaluation team and the Trust, along with sufficient lead-in time. Moving forward it is hoped that initiatives such as the National Maternity Data Set (NMDS) will improve the quality of unit-level data which is essential to ongoing evaluation of national initiatives. Furthermore, consideration should be given to inclusion of the process measures and outcomes described here in the NMDS to facilitate case identification required for detailed analysis. For example, there is currently no SNOMED code for antenatal presentation with RFM and birthweight centile is not routinely recorded, meaning that cases of RFM or SGA can only be identified by specific audits, rather than in routine data.

To increase their integrity, future implementation studies of similar interventions and quality improvement should consider how they will be evaluated prior to the start of implementation, and build an independent evaluation plan into the implementation. Ideally interventions should be rolled out in a structured and phased approach (such as a stepped-wedge type design) that allows the

prospective collection of implementation data using validated tools, prior to full implementation of the intervention(s).

Conclusion

Evaluation of the implementation of SBLCB in early adopter Trusts has demonstrated significant changes in outcomes for women and their babies over the study timeframe; the reduction in stillbirth in these sites is in line with that required to achieve the national maternity ambition. The adoption of the SBLCB has increased since its launch in early adopter Trusts in 2015 and service-user feedback indicates that the interventions are acceptable to the majority of respondents. Information from evaluation in practice such as this are critical to refining and developing future iterations of the SBLCB and learning can be generalised to other developments in maternity care.

Appendices

A1. Detailed Statistical Methods

All primary, secondary and exploratory outcomes were pre-specified in the study protocol. Analyses were performed in R version 3.4.

Monthly data

Electronic data was provided as, or converted to, monthly counts of outcomes and appropriate denominators (women to whom the event could have happened). These are described alongside each analysis. Raw data are plotted showing the between Trust mean and 95% CI without any weighting for the Trust size.

The majority of outcomes were binary (the outcome occurred or did not occur) and the data were assumed to be binomially distributed and fitted using quasi-binomial models to allow for the possibility of overdispersion. Scan rates, were fitted assuming quasi-poison models. Generalised linear models with logarithmic link functions were used to estimate a linear trend over time, adjusting for Trust. Thus time trends are estimated within Trusts. Models additionally containing a step change at the nominal or reported implementation dates were also considered, but proved to be uninformative and step-changes could not be detected, which we ascribe to the fact that implementation was phased and poorly reported. From this model we also derived estimates of the outcome rates at dates 2 years either side of the nominal SBLCB date of April 2015 and estimate the risk- (or rate) ratio between these two time points as a measure of the change over the implementation period.

In order to investigate the relationship with reported implementation status we fitted the data using generalised linear mixed models with Trust as a random intercept and implementation level and month as fixed effects. From this model we derived and plotted the fitted mean post-implementation (2 years after the nominal start date) rates per Trust against the rank of the relevant implementation score; a linear regression line is added to aid visualisation. A further model additionally adjusting for Care Level (Tertiary vs. Secondary) and Index of Multiple Deprivation (IMD) (mean decile of those delivering in each Trust) was used to derive an adjusted risk ratio and associated significance level for the difference between no and full implementation. Note that as two Trusts failed to provide the data required the adjusted estimates are computed excluding these Trusts.

Pre-post audit data

Where there were data from just 2 time points (from audit data) mean rates are plotted with exact Binomial 95%CI. Risk ratios between the two time points are derived from binomial regression models with logarithmic link functions.

Associations with implementation are visualised by plotting post-implementation score against implementation rank. And risk-ratios for no versus full implementation derived from general linear models of the post-implementation rates against implementation with and without adjustment for care level and deprivation as above.

Factors associated with stillbirth

The aim here was to explore factors associated with stillbirth rates. The data are fitted using binomial generalised linear mixed models with Trust as a random intercept and model the stillbirth rate at the 2 year post-SBLCB date using the entire monthly dataset as a function of the variables of interest with and without adjustment for care level and IMD as defined above.

A2. Economic assumptions

Table 25. Key assumptions and sensitivity analyses

Element /outcome	Assumption	Sensitivity Analysis
Element 1	An average of 9 CO monitors per 1000 births was reported across the study sites.	The range of CO monitors per 1000 births reported was 1 to 17 - costs were calculated assuming that the i) lowest and ii) highest number of CO monitors were purchased for all maternity units in England.
Element 2	The setup cost of for GAP is £500. All sites were assumed to use GAP software unless stated otherwise	50% or 75% of units use GAP software
Element 3	i. The RFM leaflet was given out once per delivery (i.e. two for twins) ii. Distributing the RFM leaflet did not increase the number of women presenting with RFM	i. The leaflet was given out twice per delivery ii. 5% of deliveries had one unplanned antenatal visit due to perceived RFM
Element 4	i. Midwives, consultants, and junior doctor's complete training in CTG interpretation which costs £100pp/year. ii. The mean number of obstetric consultants reported by the Trusts was 3 per 1000 births; the same was true for the number of junior doctors. Based on this it was estimated that there were 1998 obstetric consultants in England. RCOG figures estimate 2686 obstetric (or gynaecology) consultants in England so this estimate appears plausible.	i. The cost of training is free. ii. Only midwives complete training.
Deliveries	The increase in elective C-sections was unrelated to the care bundle and would have been normal deliveries otherwise	The increase in elective C-sections was attributable to the bundle and so the increased cost was a secondary care of the bundle.
Scans	The cost per scan is £52.94 (NHS reference costs 2015/16 - ultrasound scan <20 minutes)	Alternative scan costs £43 (NHS tariff costs 2016/17 - ultrasound scan <20 minutes); £103.84 (NHS reference costs 2015/16 - antenatal ultrasound scan)
Inductions	An approximate 20% increase in the number of inductions was observed in the study sites	10% and 25% increase
Stillbirths	All of the stillbirths avoided following the introduction of the care bundle were as a result of the bundle	25%, 50%, and 75% of the stillbirths avoided were attributable to the bundle

Table 26. Sensitivity analysis and alternative costs

Element 1	Element 2	Element 3	Element 4	Scans	Inductions	Deliveries
Base case						
£1,394,713	**£391,000**	**£66,605**	**£2,996,731**	**£33,765,735**	**£28,945,817**	**£26,754,741**
9 monitors/1000 births	100% of units use GAP software (132)	Leaflet given out once, no additional visits costed	Training costs £100pp; midwives, junior doctors, consultants training	Cost per scan is £52.94 (NHS reference costs 2015/16 - ultrasound scan <20 minutes)	Observed ~20% increase from 26.27 per 100 births to 31.40 per 100 births	Assume that additional elective sections would have been normal deliveries
Sensitivity 1						
£2,465,725	**£195,500**	**£133,210**	**£0**	**£27,425,890**	**£14,822,741**	**£53,465,760**
highest number of monitors/1000 births (17)	50% of units use GAP software (66)	Leaflet given out twice	Training is free of charge	Scan cost £43 (NHS tariff costs - ultrasound scan <20 minutes)	10% increase in inductions	Including increase in elective sections
Sensitivity 2						
£323,701	**£293,250**	**£2,569,296**	**£2,597,200**	**£66,230,335**	**£37,056,853**	**£26,754,741**
Lowest number of monitor/1000 births (1)	75% of units use GAP software (99)	5% of births attend once re: RFM (£75.15/visit);one leaflet	Only midwives are trained	Scan cost £103.84 (NHS reference costs - antenatal ultrasound scan)	25% increase in inductions	As base case

References

1. NHS England. *Saving Babies Lives: a care bundle for reducing stillbirth*. March 2016. https://www.england.nhs.uk/wp-content/uploads/2016/03/saving-babies-lives-car-bundl.pdf.
2. Department of Health. The Government's mandate to NHS England for 2016-17. DoH. 2015. https://www.england.nhs.uk/wp-content/uploads/2015/12/05.PB_.17.12.15-Annex-A-Mandate-to-NHS-England.pdf.
3. Heazell AE, Siassakos D, Blencowe H, et al. Stillbirths: economic and psychosocial consequences. *Lancet.* Feb 6 2016;387(10018):604-616.
4. Manktelow BN SL, Seaton SE, Hyman-Taylor P, Kurinczuk JJ, Field DJ, Smith PW, Draper ES on behalf of the MBRRACE-UK Collaboration. MBRRACE-UK Perinatal Mortality Surveillance Report, UK Perinatal Deaths from January to December 2014. *Leicester: The Infant Mortality and Morbidy Studies, Deaprtment of Health Sciences, University of Leicester.* 2016.
5. McParland P LC, Latham J on belhaf of MBRRACE-UK. Diagnosis of the stillbirth and intrapartum care. In Draper ES, Kurinczuk JJ, Kenyon S (Eds.) on behalf of MBRRACE-UK. *MBRRACE-UK Perinatal Confidential Enquiry: Term, singleton, normally formed, antepartum stillbirth* 2015;Leicester: The Infant Mortality and Morbidity Studies, Department of Health Sciences, University of Leicester:36-42.
6. Flenady V, Wojcieszek AM, Middleton P, et al. Stillbirths: recall to action in high-income countries. *Lancet.* Feb 13 2016;387(10019):691-702.
7. Flenady V, Koopmans L, Middleton P, et al. Major risk factors for stillbirth in high-income countries: a systematic review and meta-analysis. *Lancet.* Apr 16 2011;377(9774):1331-1340.
8. Page JM, Silver RM. Interventions to prevent stillbirth. *Semin Fetal Neonatal Med.* Jun 2017;22(3):135-145.
9. Zizzo AR, Kirkegaard I, Pinborg A, Ulbjerg N. Decline in stillbirths and perinatal mortality after implementation of a more aggressive induction policy in post-date pregnancies: a nationwide register study. *Acta Obstet Gynecol Scand.* Jul 2017;96(7):862-867.
10. National Instititute for Health and Care Excellence. *Antenatal care for uncomplicated pregnancies*. NICE. London. 2008.
11. National Institute for Health and Care Excellence. *Intrapartum care for healthy women and babies.* NICE. London. 2014.
12. Royal Collage of Obstetricians and Gynaecologists (RCOG) Green Top Guideline 57. *Reduced Fetal Movements*. London. 2011. *London.*
13. Royal College of Obstetricians and Gynaecologists (RCOG) Green Top Guideline 31. *Small-for-Gestational-Age Fetus, Investigation and Management.* London. 2002.
14. Widdows K, Reid HE, Roberts SA, Camacho EM, Heazell AEP. Saving babies' lives project impact and results evaluation (SPiRE): a mixed methodology study. *BMC pregnancy and childbirth.* Jan 30 2018;18(1):43.

15. NMPA project team. *National Maternity and Perinatal Audit: organisational report 2017*. RCOG 2017. .

16. Brouwers M KM, Browman GP, Cluzeau F, Feder G, Fervers B, Hanna S, Makarski J on behalf of the AGREE Nest Steps Consortium. AGREE II: Advancing guideline development, reporting and evaluation in healthcare. *Can Med Assoc J.* Dec 2010;182:E839-842.

17. Marufu TC, Ahankari A, Coleman T, Lewis S. Maternal smoking and the risk of still birth: systematic review and meta-analysis. *BMC Public Health.* Mar 13 2015;15:239.

18. National Institute for Clinical Excellence (NICE). *Smoking cessation in routine antenatal care. NICE guideline (PH26)*. London. 2011.

19. Gardosi J FA. Customised Antenatal Growth Chart - GROW version 6.1.Gestation Network. 2016. www.gestation.net.

20. Heazell AEP, Budd J, Li M, et al. Alterations in maternally perceived fetal movement and their association with late stillbirth: findings from the Midland and North of England stillbirth case-control study. *BMJ Open.* Jul 6 2018;8(7):e020031.

21. Maternal and Child Health Research Consortium. 8th Annual Report. Confidential Enquiry into Stillbirths and Deaths in Infancy. London: Maternal and Child Health Research Consortium.

22. Sergent F, Lefevre A, Verspyck E, Marpeau L. [Decreased fetal movements in the third trimester: what to do?]. *Gynecol Obstet Fertil.* Nov 2005;33(11):861-869.

23. McCarthy CM, Meaney S, O'Donoghue K. Perinatal outcomes of reduced fetal movements: a cohort study. *BMC Pregnancy Childbirth.* Jul 19 2016;16(1):169.

24. Alfirevic Z, Devane D, Gyte GM. Continuous cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour. *Cochrane Database Syst Rev.* May 31 2013(5):CD006066.

25. Azzopardi DV, Strohm B, Edwards AD, et al. Moderate hypothermia to treat perinatal asphyxial encephalopathy. *N Engl J Med.* Oct 1 2009;361(14):1349-1358.

26. Office for National Statistics. 2016 Birth Summary Tables, England and Wales. https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/livebirths/datasets/birthsummarytables. ONS: 2016.

27. NHS England. 2013-14 Programme Budgeting. NHS 2015. https://www.england.nhs.uk/resources/resources-for-ccgs/prog-budgeting/

28. NHS England. 2016-17 Annual reports and accounts. NHS England. London. 2017. https://resolution.nhs.uk/wp-content/uploads/2017/07/NHS-Resolution-Annual-report-and-accounts-2016_17.pdf.

29. Williams JGaM. Serial ultrasound scanning in pregnancies at risk of intrauterine growth restriction.Cost Benefit Analysis 2014.

30. Mistry H, Heazell AE, Vincent O, Roberts T. A structured review and exploration of the healthcare costs associated with stillbirth and a subsequent pregnancy in England and Wales. *BMC Pregnancy Childbirth.* Dec 17 2013;13:236.

31. Ogwulu CB, Jackson LJ, Heazell AE, Roberts TE. Exploring the intangible economic costs of stillbirth. *BMC Pregnancy Childbirth.* Sep 1 2015;15:188.

32. Flenady V, Middleton P, Smith GC, et al. Stillbirths: the way forward in high-income countries. *Lancet.* May 14 2011;377(9778):1703-1717.

33. Confidential Enquiry into Stillbirths and Deaths in Infancy. Confidential Enquiry into Stillbirths and Deaths in Infancy: Intrapartum deaths. CESDI: London.

34. Confidential Enquiry into Stillbirths and Deaths in Infancy SR, Maternal and Child Health Research Consortium. Confidential Enquiry into Stillbirths and Deaths in Infancy: 8th annual report., CESDI National Advisory Body.

35. Heazell AEP, Weir CJ, Stock SJE, et al. Can promoting awareness of fetal movements and focusing interventions reduce fetal mortality? A stepped-wedge cluster randomised trial (AFFIRM). *BMJ Open.* Aug 11 2017;7(8):e014813.

36. Draper ES KJ, Kenyon S (Eds.) on behalf of MBRRACE-UK. . MBRRACE-UK 2017 Perinatal Confidential Enquiry: Term, singleton, intrapartum stillbirth and intrapartum-related neonatal death. *The Infant Mortality and Morbidity Studies, Department of Health Sciences, University of Leicester: Leicester, 2017.* 2017.

37. Draper ES KJ, Kenyon S (Eds) on behalf of MBRRACE-UK. MBRRACE-UK Perinatal Confidential Enquiry: Term, singleton, normally formed, antepartum stillbirth. *Leicester: The Infant Mortality and Morbidity Studies, Department of Health Sciences, Univesity of Leicester 2015.*

38. Heazell A, Li M, Budd J, et al. Association between maternal sleep practices and late stillbirth – findings from a stillbirth case-control study. *BJOG: An International Journal of Obstetrics & Gynaecology.* 2018;125(2):254-262.

39. Perinatal Institute. Saving Babies in the North England. 2016. https://www.perinatal.org.uk/SaBiNE_final_report_2016.pdf.

40. Heazell AEP, Li M, Budd J, et al. Association between maternal sleep practices and late stillbirth - findings from a stillbirth case-control study. *Bjog-Int J Obstet Gy.* Jan 2018;125(2):254-262.

41. Jokhan S, Whitworth MK, Jones F, Saunders A, Heazell AEP. Evaluation of the quality of guidelines for the management of reduced fetal movements in UK maternity units. *Bmc Pregnancy Childb.* Mar 5 2015;15.

42. Bazzano AN, Green E, Madison A, Barton A, Gillispie V, Bazzano LA. Assessment of the quality and content of national and international guidelines on hypertensive disorders of pregnancy using the AGREE II instrument. *BMJ Open.* Jan 18 2016;6(1):e009189.

The University of Manchester
Oxford Road
Manchester
M13 9WL
United Kingdom

www.manchester.ac.uk

Royal Charter RC000797