



Evaluating the Saving Babies Lives Care Bundle – SPiRE and eVOLVE

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Tommy's



MAMA
Academy
positive about pregnancy



Royal College of
Obstetricians &
Gynaecologists

Tamba
THE UK & IRELAND MULTIPLE BIRTH ASSOCIATION

each baby
COUNTS.



Stillbirth in High Income Countries:

Large Variation in Stillbirth Rate

Lancet Ending Preventable Stillbirth Series, Lawn et al 2016

Variation in absolute rates (≥ 28 wks) across 49 HICs

- Lowest rate: Iceland = 1.3 per 1,000
- Highest rate: Ukraine = 8.8 per 1,000
- Range = 6-fold variation
- UK = 24th out of 49 High Income Countries
- US = 20th – **2nd lowest annual rate of reduction (0.4%)**
- If all countries achieved a rate of 2 per 1,000 or less (equals top 6 performing countries) ~20,000 stillbirths could have been avoided in 2015

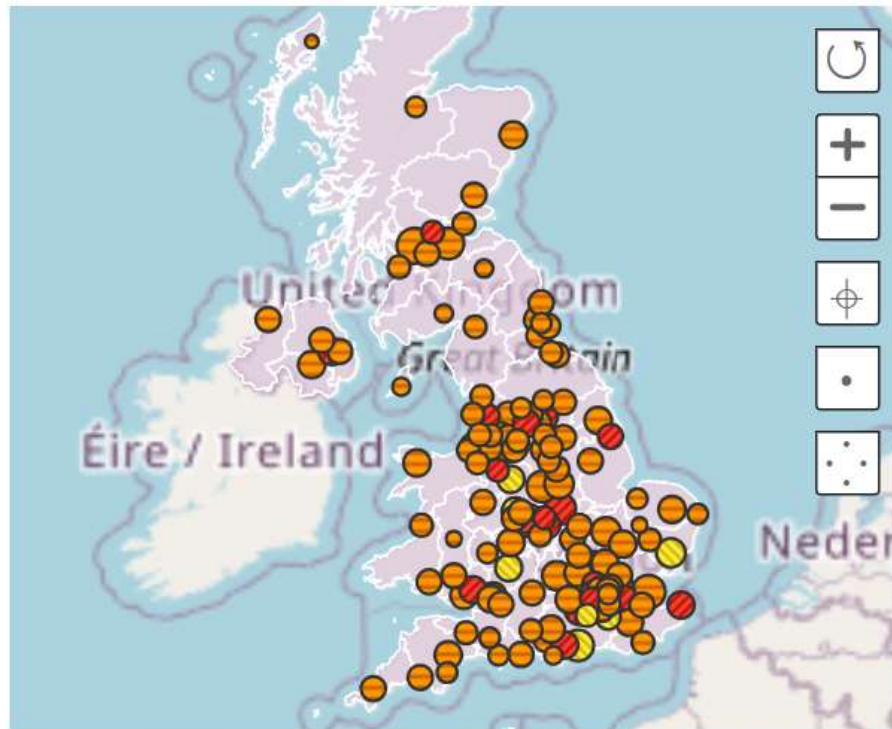


Stillbirth in HICs:

Large Variation in Stillbirth Rate

Mortality rates excluding congenital anomalies, births, 2021

Stabilised & adjusted stillbirth rate per 1,000 total births excluding congenital anomalies. Bubbles are proportional to the total number of births



Highcharts.com Map data ©2023 OpenStreetMap

- Variation within countries reflects:
 - Deprivation
 - Ethnicity
 - Population factors
 - Access to care

UK National Maternity Ambition

“The ambition is to reduce the number of stillbirths, neonatal deaths, maternal deaths and brain injuries that occur during or soon after birth by 50% by 2030 and to keep on track we want to see these reduced by 20% by 2020”

*Jeremy Hunt, Secretary of State
November 2015*



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Suboptimal Care in Stillbirth

- 85 cases of antepartum stillbirth in 2013
- 78 cases of intrapartum related perinatal deaths in 2013



Poor growth of the baby in the womb: in nearly two thirds of cases reviewed national guidance for screening and monitoring the growth of the baby was not followed.

Missed Opportunity: Monitoring Growth

- Woman's abdomen not measured to check how her baby was growing
- Measurements not plotted on a graph
- Woman not referred for closer monitoring when the baby's growth didn't follow a normal pattern

Fetal Growth



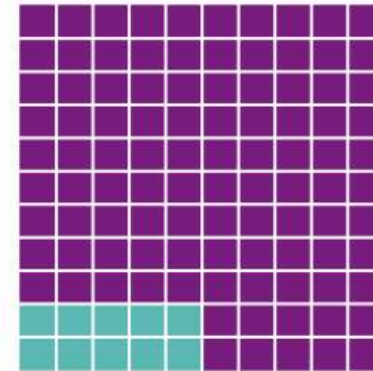
Baby's movements: almost half the women had contacted their maternity units concerned that their baby's movements had slowed, changed or stopped. In half of these there were missed opportunities to potentially save the baby.

Missed Opportunity: Identifying Reduced Fetal Movements

- Not investigating when a woman presents with concerns about her baby's movements
- Misinterpreting the fetal heart trace
- Not responding appropriately to additional risk factors, including the woman returning with further concerns about her baby's movements

Reduced Fetal Movements

In 80% of cases different care might have prevented the baby's death



In 1 in 4 deaths there were problems with adequate staffing and resources



Guidelines weren't followed when monitoring the baby's heart rate during labour, leading to delays when babies needed to be delivered urgently

The Saving Babies' Lives Care Bundle – V1

Launched by NHSE in March 2016 to reduce stillbirth rates –

Pilot sites started intervention from March 2015

Brings together four key elements of care that are recognised as evidence-based and/or practice:

- 1. Reducing smoking in pregnancy**
- 2. Risk assessment and surveillance for fetal growth restriction**
- 3. Raising awareness of reduced fetal movements**
- 4. Effective fetal monitoring during labour**



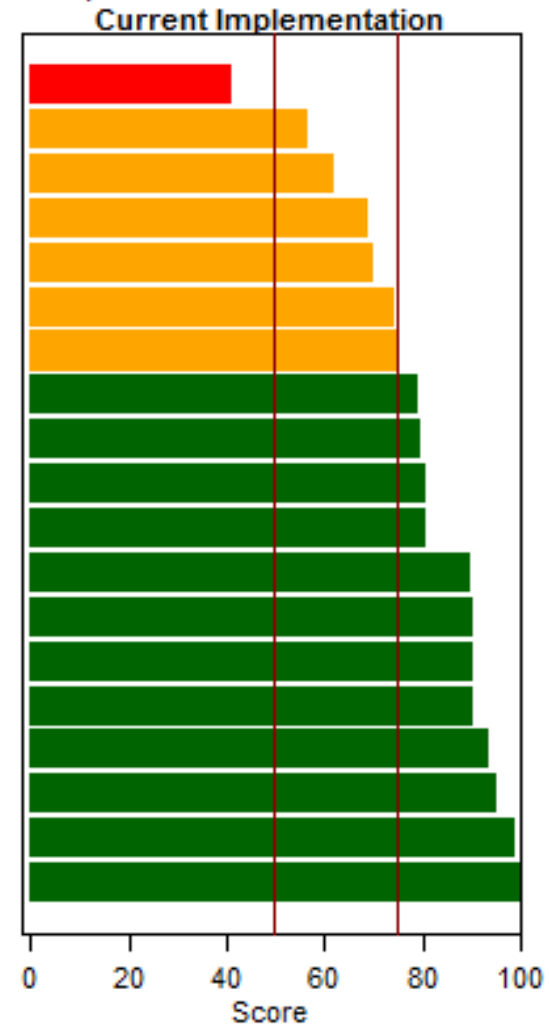
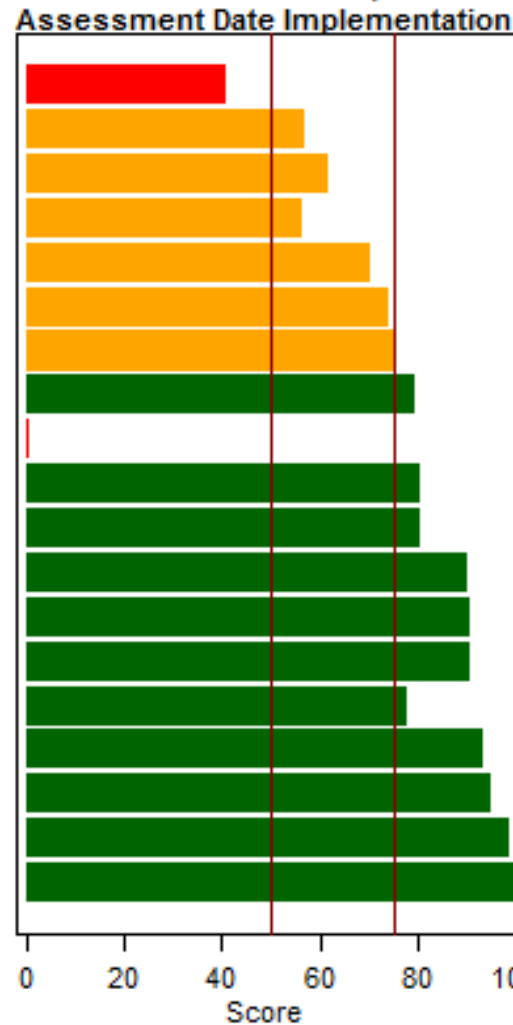
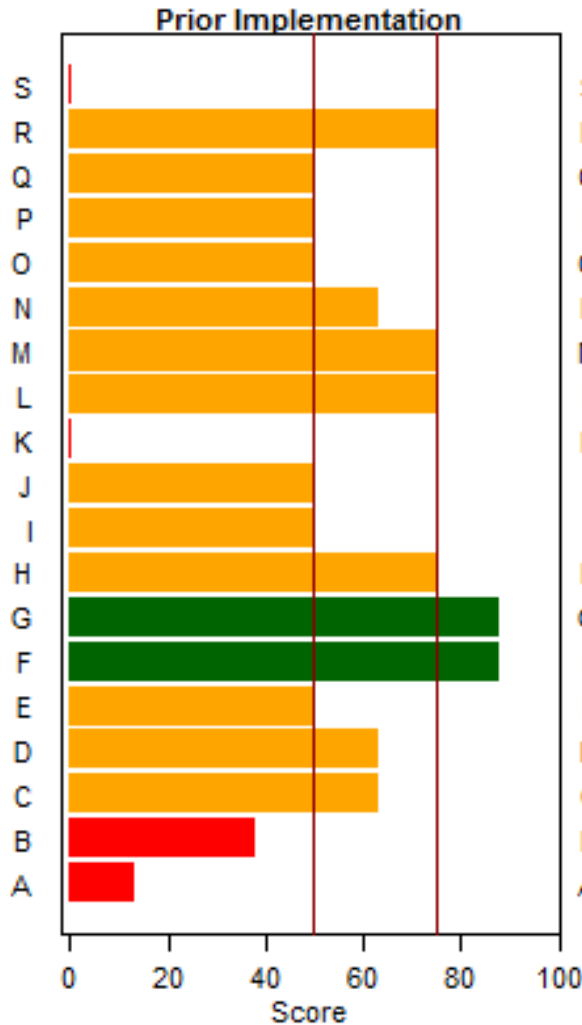
SPIRE Evaluation - Overview

- 19 sites (evaluation period 2013-2017)
- *Electronic data* on 467,661 livebirths and 1,903 stillbirths in whole time period
- *Clinical audit* of 720 term live singleton births and 340 pregnancies with reduced fetal movements
- 598 Small for gestational age births (before/after Saving Babies Lives implementation)
- 2,230 mothers completed *postnatal questionnaire*
- 1,064 health professionals completed *staff questionnaire*

Implementing the Care Bundle

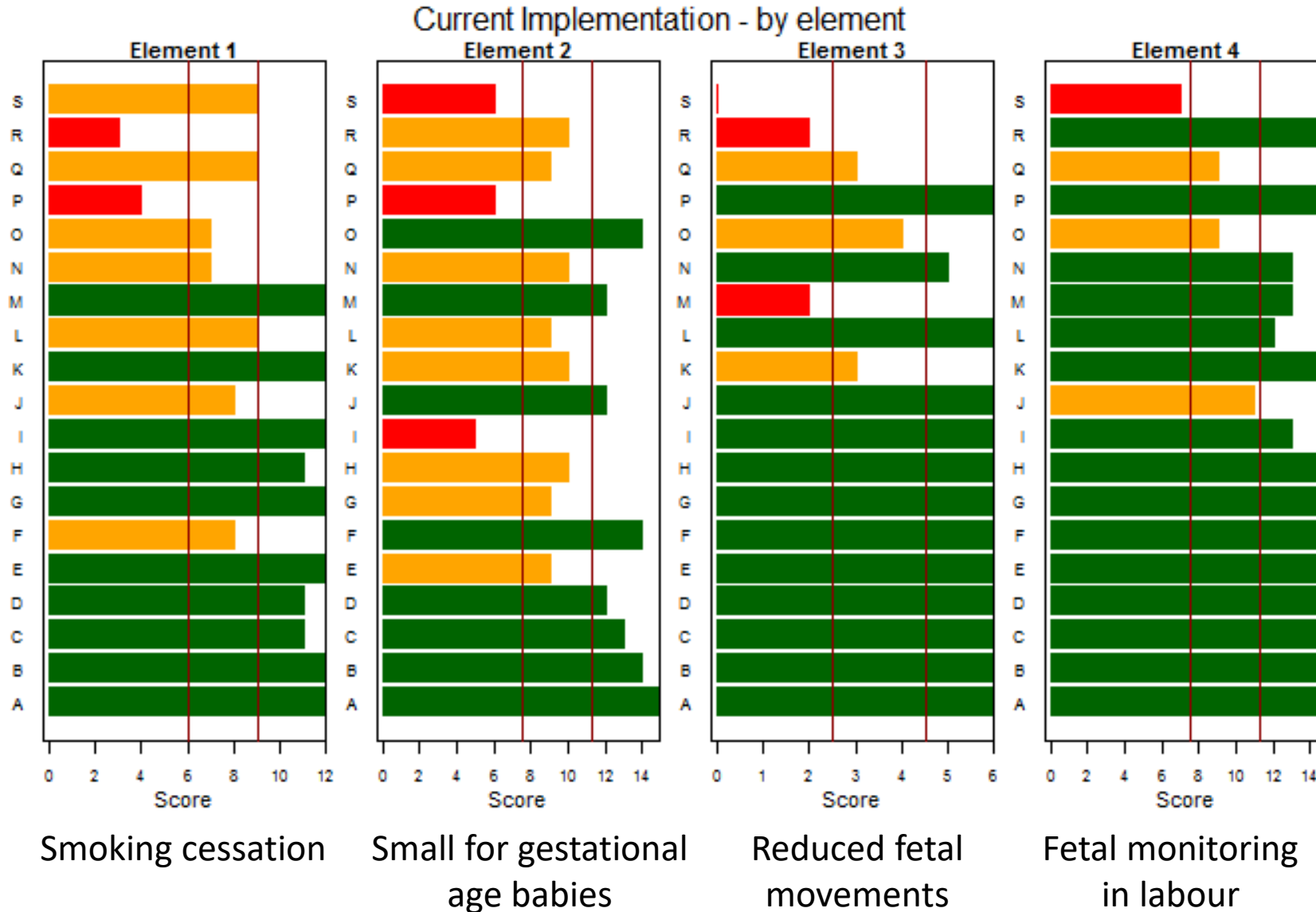
Overall Implementation Scores (% of maximum)

2013-
2014

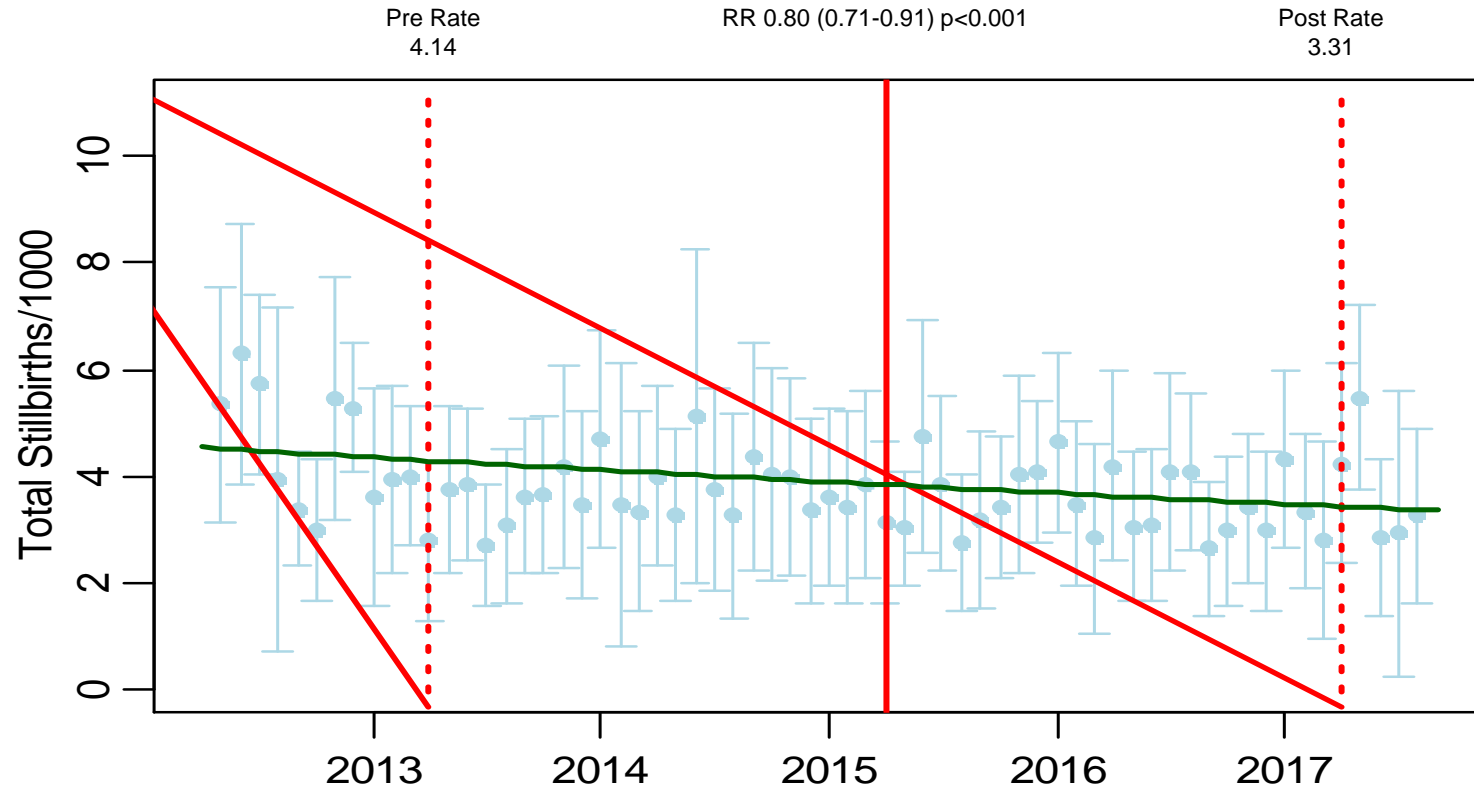


2017

Implementing Elements



Change in Stillbirth over time



- Pre/post SBLCB rates
- SBLCB launch in Early Implementers
- Trend over time

- Adjusted Relative Risk from 2013 to 2017 was ~5%

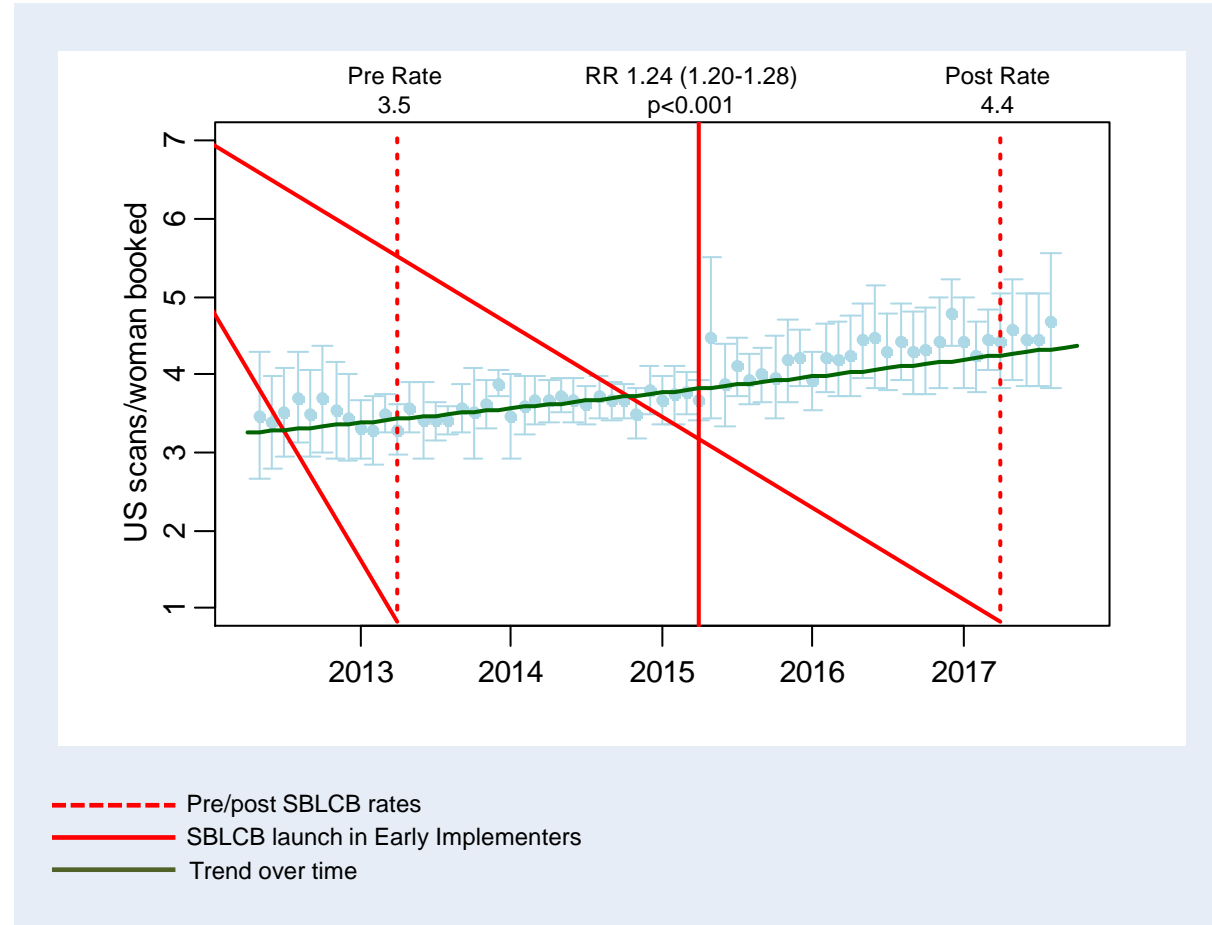
Secondary Outcomes – Change Over Time

Outcome	n	Number Deliveries	Pre Rate	Post Rate	RR (95% CI)	P value
Preterm births	17	446,378	7.42	7.90	1.06 (1.03-1.09)	<0.001
Preterm singleton births	17	446,378	6.3	6.6	1.05 (1.02-1.08)	0.002
Elective CS	17	452,944	9.86	11.78	1.20 (1.17-1.23)	<0.001
Emergency CS	15	386,817	13.7	15.0	1.10 (1.07-1.12)	<0.001
Induced Deliveries	18	473,889	26.3	31.4	1.20 (1.18-1.21)	<0.001
Instrumental Deliveries	18	473,889	12.3	12.4	1.01 (0.99-1.04)	0.245
Spontaneous Deliveries	18	473,889	63.4	60.4	0.95 (0.95-0.90)	<0.001
Ultrasound scans (per pregnancy)	14	449,357	3.5	4.4	1.24 (1.20-1.28)	<0.001
NICU admissions [§]	14	384,584	3.5	4.1	1.19 (1.11-1.26)	<0.001

n; number of Trusts providing data

[§]; from term singleton deliveries (per 100 births)

Element 2 – Number of Scans



- Increased SGA detected from 33.7% to 53.7% (RR 1.59 1.32-1.92, p<0.001)
 - Adjusted Rate Ratio of -0.14 (SE 0.06) SB per additional scan P=0.026

Element 3 – Management of RFM

Outcome	n	Number	% of women
RFM leaflet received	19	1735	74.4
RFM checklist used	17	339	52.2
Attendances for RFM	19	2171	36.5
Women with RFM who attended	19	1026	77.3
Scanned at every RFM visit	17	322	21.1
Scanned at any RFM visit	17	322	64.9
Women scanned for RFM (patient reported)	19	793	29.4
Heart trace for RFM	19	793	73.5
Monitoring at every RFM visit	17	339	97.4
Monitoring at every RFM visit	17	338	54.7
Women induced due to RFM	18	344	54.7

- 91% of women said they felt they received the right amount of information about monitoring baby's movements.
 - 96% said they monitored their baby's movements

Consideration of Resource Use

- Primary estimated cost of implementing care bundle/year is £93,116,650, or a~£140/birth.

A. Direct implementation cost				
Element	Resources included	Resources excluded	Cost (£)	
Element 1	i. 9 CO monitors/1000 births (£165 each) ii. D-pieces for monitors, to be replaced monthly (£3 each) iii. Mouthpieces for monitors, one per each woman booked (£0.25 each)	i. 10 minutes of midwife time to speak to women who smoke (9–24% of women in study) about smoking cessation and/or do referral ii. Calibration of monitors	£1,394,713	
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	£391,000	
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. Attendances with perceived RFM	£66,605	
Element 4	i. Online training course in CTG interpretation (£60) completed annually by midwives, consultants, and junior doctors	i. Staff time to complete training course	£1,798,039	
Direct Cost	£3,650,357 (4% of total cost)			
B. Secondary implementation costs				
Inductions	Induction rate increased from 26.27 to 31.40 per 100 births, costing £847.15 per induction.			£28,945,817 (31% of total cost)
Births		Before	After	Cost
	Normal (£1704.50)	63.42	61.94 ^b	-£16,802,227
	EMCS (£4553.41)	13.69	15.01	£40,033,063
	Instrumental (£3306.71)	12.25	12.41	£3,523,905
Scans	Number of scans per woman booked increased from 3.51 to 4.35 (24% increase), costing £52.94 per scan.			£33,765,735 (36% of total cost)
Secondary costs	£89,466,293 (96% of total cost)			
TOTAL	£93,116,650			

EMCS = emergency Caesarean section; *although the use of GROW software to generate customised growth charts was not specified in the care bundle, only 2 out of 19 Trusts included in the analysis said that they did not use it therefore it was included in the costs.

<https://doi.org/10.1371/journal.pone.0250150.t005>

NHS England Saving Babies' Lives Care Bundle – V2

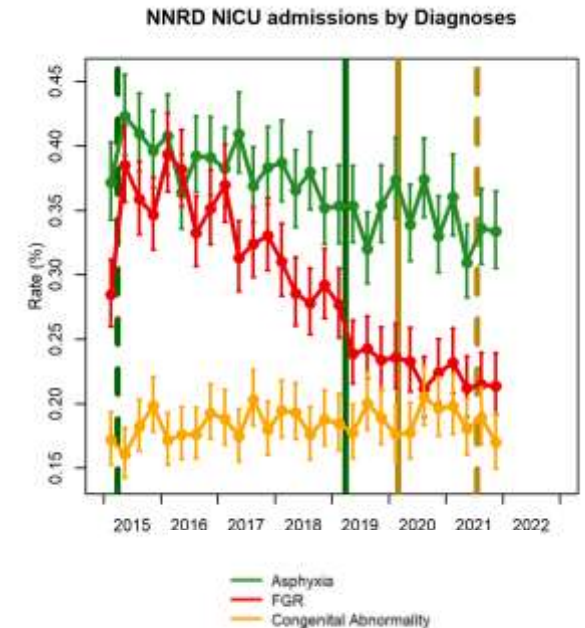
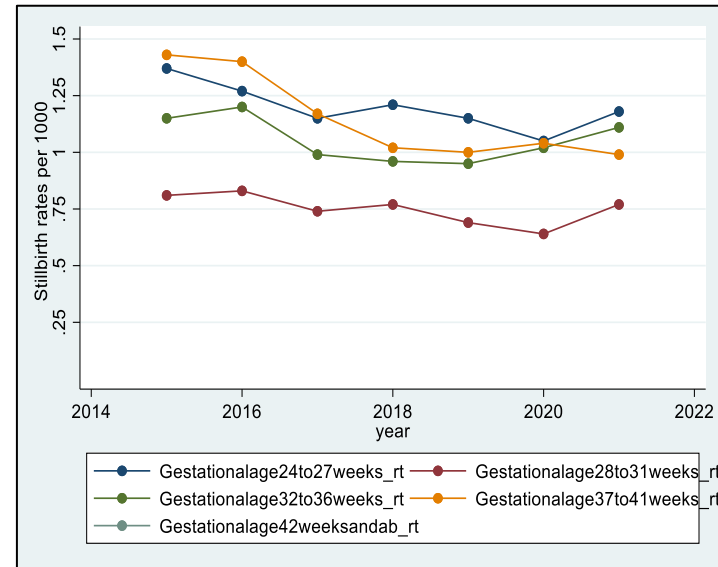
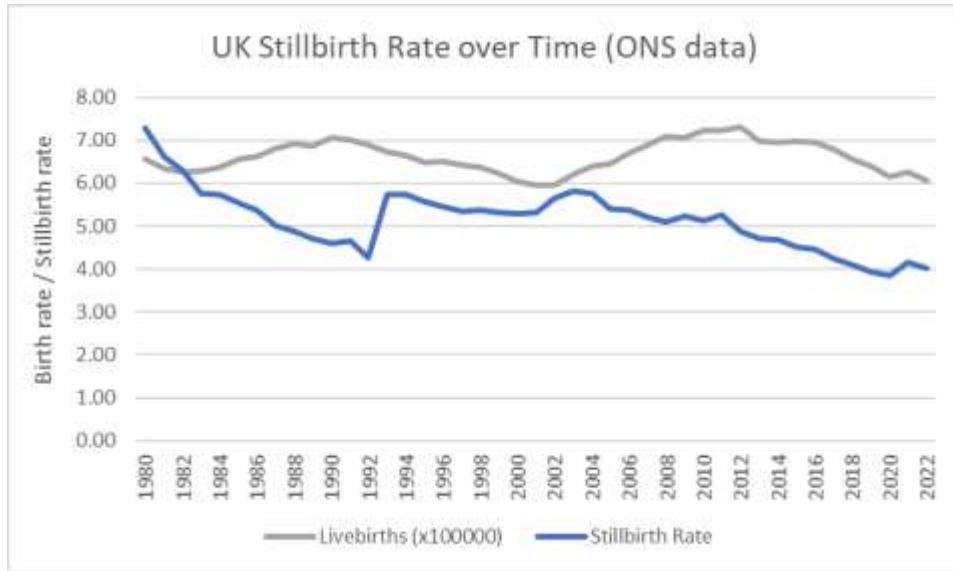
Launched by NHSE in March 2019 to reduce stillbirth rates and implement learning from evaluation of Version 1

Brings together **five** key elements of care that are recognised as evidence-based and/or practice:

1. Reducing smoking in pregnancy
2. Risk assessment and surveillance for fetal growth restriction
3. Raising awareness of reduced fetal movements
4. Effective fetal monitoring during labour
5. **Reducing preterm birth**



Changes in UK Stillbirths (ONS data)



- Stillbirth rates increased in 2021 after sustained reduction, likely COVID-effect
- Term stillbirths were not increased (prime goal of the Care Bundle)
- Reduction in neonatal admission from fetal growth restriction and asphyxia

Element 2 – Fetal Growth Restriction

Patient Reported Outcome	No. Responses	Percentage
Aspirin prescription offered	295/1140	25.8
Took aspirin daily	220/295	74.5
SFH measured	888/1140	77.8
Suspected SGA/FGR	345/1140	30.2
Women scanned	308/345	89.3
Scanned every 1-2 weeks	144/308	46.7
Scanned every 3-4 weeks	79/308	25.6
Scanned from 28 weeks	204/345	59.1
Scanned from 32 weeks	114/345	33.0
Scanned on 3 or more occasions	155/240	64.5
Appointment with fetal medicine	57/345	16.5

Element 2 – Fetal Growth Restriction

Staff reported	No Responses	Percentage
SBLCBv2 algorithm for prescribing aspirin	267/384	69.5
Risk assessment pathway for FGR		
Growth Assessment Protocol	180/387	46.5
SBLCBv2 Algorithm	178/387	46.3
In-house algorithm	68/387	17.5

Staff views about growth scans

	Strongly disagree	Disagree	No feelings	Agree	Strongly agree	Mean*
Staff views about growth scans						
We have enough ultrasonographers to scan all women referred	33 (23%)	35 (24%)	25 (17%)	47 (32%)	5 (3%)	-0.15
The demand for ultrasound scans has increased	5 (3%)	3 (2%)	1 (1%)	45 (31%)	91 (63%)	+0.75
Women are being referred for scans unnecessarily	2 (1%)	28 (19%)	46 (32%)	52 (36%)	17 (12%)	+0.20
The demand for uterine artery Doppler scans has increased	1 (1%)	1 (1%)	23 (16%)	71 (49%)	49 (34%)	+0.55
We don't have enough staff trained to carry out uterine artery Doppler scans	12 (8%)	28 (19%)	36 (25%)	41 (28%)	28 (19%)	+0.15
In your opinion (N=366)	Greatly worsening	Slightly worsening	Not changed	Slightly improving	Greatly improving	Mean*
How do you feel the care bundle has influenced antenatal detection rates of SGA/FGR babies in your organisation?	0 (0%)	3 (1%)	38 (10%)	172 (47%)	153 (42%)	+0.65

Communication is key to implementation

- **Prescribing Aspirin** - *So they offered me aspirin. They just told me... it could 'help blood flow through the placenta to the baby', but I'd never had an issue with this... so I was like, I'm probably not gonna take it, as I didn't understand the potential risk factors... it just felt like it was a bit of a tick box exercise...*
- **When having a scan** - *I always felt nervous going to a scan. You've seen your baby, but you want to make sure everything's alright. But you feel quite uneasy when they're not talking to you, so making sure that people understand what's happening in those scans, as they're happening, would be more comforting.*

Communication is key to implementation

- Sometimes we need bring birth forwards, when an ultrasound scan shows there may be a problem with the position of the baby, or baby's growth;
- Need to listen to service users needs and preferences, to be able to help guide them to what's needed for the best outcome for their baby.
- *After an earlier growth scan, they'd tried to talk me out of doing what I wanted for the birth and talk me into what they wanted... so at my last growth scan, I went in ready for an argument... but then the consultant was really supportive of my plans and I felt really listened to.*
- *He's small and he's breech, and when the doctor scanned me, she said "oh, he's still breech, C-section it is I think I was given enough information.*

Conclusions

- UK needs to address stillbirth rates (alongside other challenges in maternity care)
- Focus on care for groups at highest-risk of stillbirth and neonatal death
- Saving Babies Lives implemented by majority of early adopter units, initial implementation variable, but now more embedded
- Reduction in the rate of stillbirth over time (until COVID); changes in other important secondary outcomes
- Scanning is a key tool to reducing perinatal morbidity and mortality
- Communication between staff and patients – focus for improvement

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