Saving Babies in North England (SaBiNE)

Final Report – October 2016

EXECUTIVE SUMMARY

A four month intensive training programme of the Growth Assessment Protocol was implemented across 3 North of England regions in 2015, with the help of designated clinical midwives seconded for the duration of the project. The intervention resulted in significant increases in antenatal referral and detection of babies born small for gestational age. During the same period, the stillbirth rates in each of the three regions dropped to their lowest ever levels and resulted in 84 fewer deaths, while there was no change in the rest of England. The project was also highly cost effective in terms of savings in direct and indirect costs, with an estimated 14 fold overall return on investment.

CONTENT

1. BACKGROUND

The majority of normally formed stillbirths are associated with fetal growth restriction (FGR) [1]. Stillbirth risk is reduced significantly once FGR is detected without increasing prematurity rate, as most of these deaths occur at relatively mature gestations; yet the majority of these at-risk babies go undetected during the antenatal period [2].

To address this issue, the Perinatal Institute has implemented in most units across the UK a programme for improved antenatal detection of small for gestational age (SGA) babies called the 'Growth Assessment Protocol' (GAP). GAP is based on principles consistent with RCOG and NICE guidelines and has been responsible for significant reductions in stillbirths in some NHS regions as well as in England overall [3].

The main requirement for implementation is staff training and assessment in theory and practice to achieve the required competencies [4]. However maternity services are often overstretched and unable to allocate sufficient time for staff training. As a result, implementation is often incomplete, preventing the benefits of the programme to be fully realised.

2. AIMS

SaBiNE was an NHS North England funded initiative to achieve more comprehensive implementation of the Growth Assessment Protocol (GAP), as a pilot of the 'Fetal Growth' element of the NHS England 'Saving Babies Lives Care Bundle' for stillbirth prevention [5].

This was to be achieved through:

➢ A comprehensive programme including the introduction of early pregnancy risk assessment using the new NHS England algorithm

➢ Enhanced training in standardised fundal height measurement, plotting on customised growth charts and indications for referral

➢ Audit of antenatal referral and detection rates of babies born small for gestational age (SGA)

➢ Implementation of a 'missed case' audit tool to identify causes for undetected SGA, through standardised clinical outcome review and evaluation (GAP-SCORE).

3. METHOD

The project commenced in June 2015 and included 40 Trusts from across the North East, North West and Yorkshire & The Humber regions – with 35 Trusts already using customised GROW charts, and 5 new ones.

- 52 Designated Clinical Midwives (DCMs) funded at AfC band 7 were seconded for 135 hours (18 days), which could be taken flexibly to suit the service needs over a 4-month period
- Two intensive GAP training workshops were held for over 150 staff from all units, including DCMs and other midwives, heads of midwifery, obstetricians, ultra-sonographers and SCN leads.
- A further workshop was held for DCMs and clinical governance midwives to introduce GAP-SCORE for near-miss audit
- DCM's were issued with a training pack containing key performance indicators, a project plan, reference material and key documentation. Each DCM was required to be in contact with the Perinatal Institute either via WebEx or telephone at least once a month
- Twice weekly WebEx sessions were arranged to offer on-going guidance and support and an opportunity to discuss practice issues with other DCM's across the North of England

Role of the Designated Clinical Midwife

- Provide cascade training to ensure staff competency in use of GROW charts and referral
- Support audit of post-delivery data for assessment of detection rates
- Review current Trust guidance on management of SGA/FGR and update to correspond with supplied template protocol, based on RCOG/NHSE/PI recommendations
- Ensure staff have access to e-learning and ensure completion of modules
- Implement the GAP-SCORE tool for 'missed case' audit of 10 randomly selected SGA births per 6 month period

4. RESULTS

1. <u>Training:</u>
   - 40 Trusts and 52 DCMs participated - this represented all Trusts across the 3 North of England regions with the exception of Bradford
   - Training workshops were cascaded rapidly within each Trust
   - This was supported by e-learning: from May to October 2015, enrolments across the three regions increased from 4858 to 8214 midwives, obstetricians and ultrasonographers.

2. <u>Data entry:</u> There was a rapid increase in routine post-delivery audit of SGA referral and detection, which resulted in a total of 139,612 records since the beginning of the project (Figure 1).
   To date, 35 of the 40 Trusts in SaBiNE have established routine postnatal audit of all deliveries, with an average ascertainment rate of 90.3%.

   Fig 1: Cumulative graph of post-delivery data entry for SGA referral and detection audit
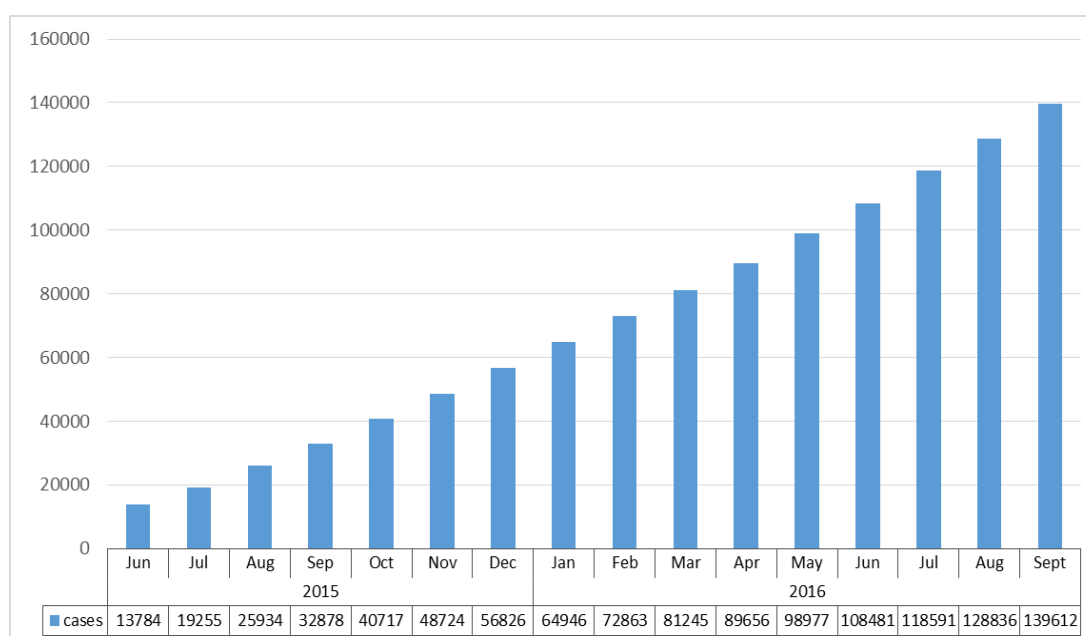
3. <u>SGA referral and detection rates</u>

This rolling audit was undertaken using the GROW app electronic audit form. The tool records information on birthweight, gestation at delivery, antenatal scan referral for suspected SGA, and identification of SGA by ultrasound estimated fetal weight (EFW).

To establish a baseline, a retrospective audit of 3698 deliveries was undertaken in ten maternity units. Post-implementation, data were obtained from 40 participating trusts, representing deliveries from the latest quarter (Jul - Sept 2016, n= 31,131) (Table 1).

Table 1: Referral and detection rates pre-and post-implementation

	Baseline audit (before May 2015) N = 3698	Latest quarter (Jul - Sept 2016) N= 31,131
	N (%)	N (%)
Referred for scan; birthweight SGA (TP)	36.5	53.1
Referred for scan; birthweight not SGA (FP)	15.9	17.1
SGA according to EFW; birthweight SGA (TP)	18.5	42.7
SGA according to EFW; birthweight not SGA (FP)	1.6	7.0
TP = True Positive; FP = False positive		

As shown in Table 1, implementation of the programme resulted in a near 50% increase, from 36.5 to 53.1%, in antenatal referral for suspected SGA (true positive), while false positive referrals (where the baby's birthweight was not SGA) stayed essentially the same (15.9 and 17.1%). At the same time, the antenatal detection by scan-EFW increased 2.3 fold, from 18.5 to 42.7%. Both of these improvements were statistically significant. In the best units, antenatal detection rates increased to over 60%. False-positive diagnosis of SGA according to EFW rose too, but only to 7.0%. The average improvement in referral and detection rates are illustrated in Figure 2.

Fig 2: SGA referral and detection rates before and after implementation of GAP

	Baseline (pre SaBiNE)	Current (July-Sept 2016)
Referral (%)	36.5	53.1
Detection (%)	18.5	42.7

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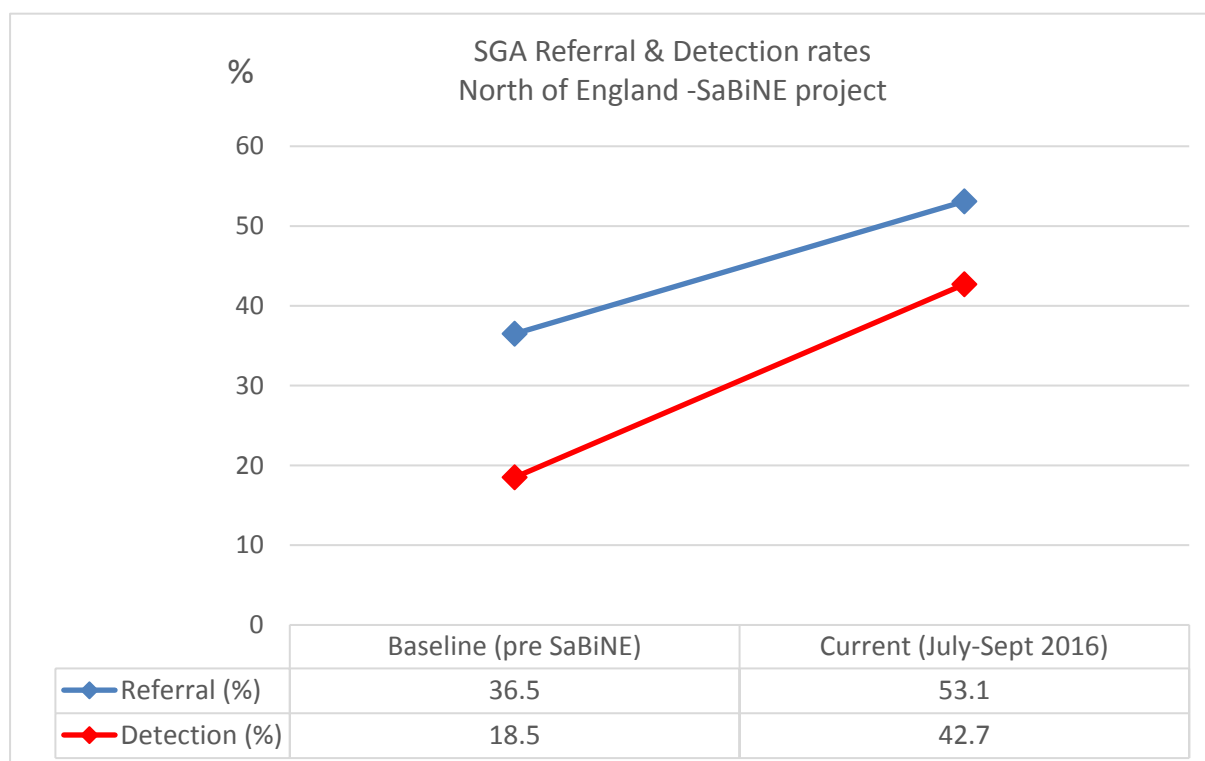
5. MISSED CASE AUDIT

Audits of undetected SGA cases were undertaken following training and implementation of GAP SCORE, a web based audit tool designed to assist clinicians in the review of clinical care for 'missed cases' of SGA. The audit utilises key information from the care during pregnancy to ascertain the reasons why SGA was missed antenatally, identify any training issues and failures in service provision, and provide evidence for commissioning.

GAP SCORE audits were undertaken in 20 Trusts, with a total of 480 missed SGA cases entered since October 2015 (average 24 cases per Trust).

A. Pregnancies with risk factors

i.   Indications.   Detailed review of indications for scan at booking showed that in 265 of the 480 pregnancies (55.2%) there were one or more risk factors at booking which would indicate serial scans according to NHSE Care Bundle guidelines [5]. Table 2 lists the frequency of these risk factors (in order of the published NHSE algorithm).

Table 2: Risk factors for SGA

Risk Factors at booking	N	%
Maternal age $\geq$40	12	2.5
Smoker (any)	146	30.4
Drug Misuse	6	1.3
Previous SGA	103	21.5
Previous Stillbirth	2	0.4
Chronic Hypertension	4	0.8
Diabetes	5	1.0
Renal Impairment	2	0.4
Antiphospholipid Syndrome	0	0.0
BMI $\geq$35	45	9.4
Large Fibroids	2	0.4
Multiple Pregnancy	5	1.0
Other	48	10.0

ii.   Scans: Only 143 (54%) of the 265 mothers with risk factors had one or more growth scans. In the 122 (46%) of pregnancies that had no growth scans, the predominant indications that were ignored were smoking or high BMI. The relative frequency of the scans undertaken varied with unit protocol and is listed in Table 3.

Table 3: Scan frequencies in 265 pregnancies with risk factors

Scans	%
0	46.0
1	2.6
2	15.5
3	24.2
4	9.1
5+	2.7

Including all high risk pregnancies, the average number of scans per pregnancy was 1.6 (mean) and 2 (median). In pregnancies designated to have one or more growth scans, the average number of scans was 2.9 (mean) and 3 (median). The average time interval from last scan to delivery was 20.7 days in high risk pregnancies and 27.5 days in low risk pregnancies that had one or more scans.

B. Pregnancies without risk factors

215 of the 480 missed SGA cases (44.8%) had no risk factors at booking.

- In 106 of these pregnancies, one or more referrals for growth scans were made for indications arising during pregnancy but resulted in no antenatal prediction of the eventual SGA outcome.

- In the remaining 109 'low risk' cases, monitoring with fundal height measurements did not lead to a referral for growth scans during pregnancy

The 4 categories of risk and scan are summarised in Table 4 and the pie chart.

Table 4: Main categories of 'missed' SGA births; n=480

	n	%
High Risk and had growth scans	143	29.8%
High Risk, but had no growth scans	122	25.4%
Low risk, but referred for scan(s)	106	22.7%
Low risk and had no growth scan	109	22.1%
Total	480	100.0%

Figure 3: Main categories of 'missed' SGA births; n=480
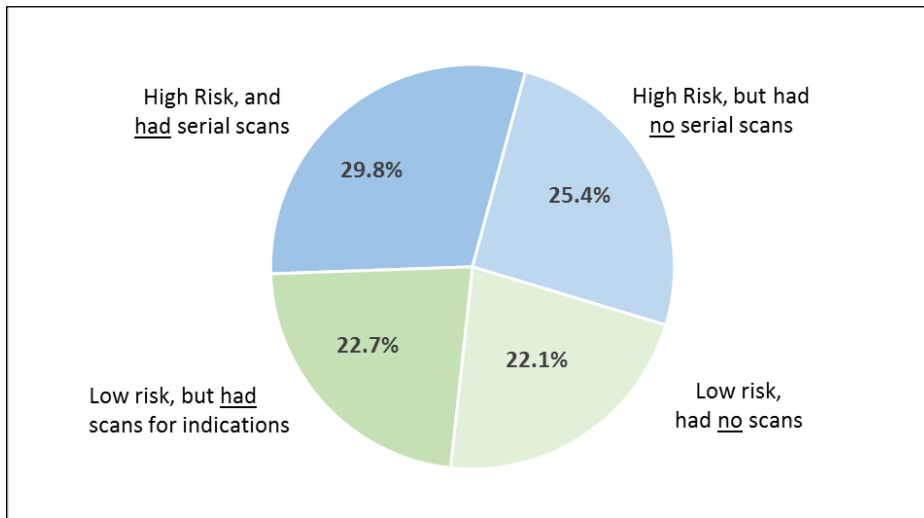
The chart illustrates that failure to suspect SGA and refer for scan on the basis of fundal height measurement accounted for only 22.1% of missed cases. In the remaining 77.9%, scans were either not done despite the presence of indications, or were done but failed to detect SGA.

Key points

- The majority of missed SGA cases had risk factors in early pregnancy
- Almost half of these cases had no serial scans, contrary to NHSE guidelines
- Over half of missed SGA cases did have scans but SGA was still not detected
- This is likely to be due to too few scans, and an average 3-4 week delay from last scan to delivery
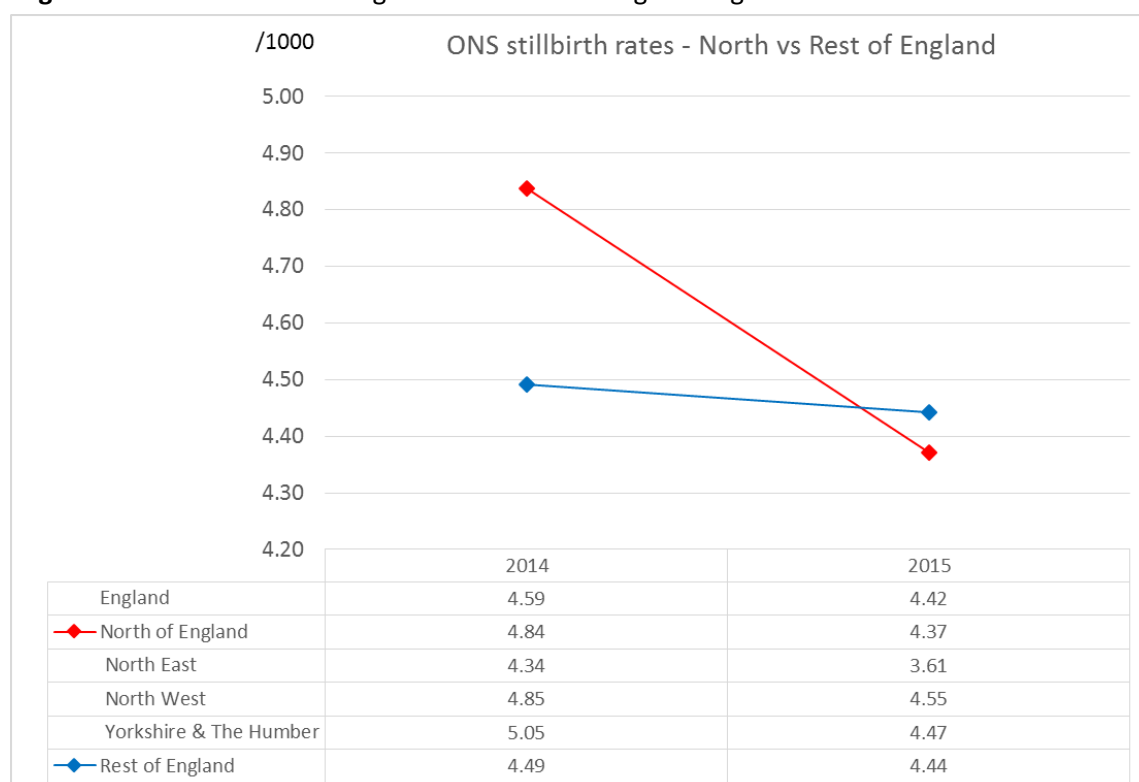
6. EFFECT ON STILLBIRTH RATES

Source: ONS [6], released 13 July 2016

The overall rate (per thousand) of stillbirths for England has fallen from 4.59 in 2014 to 4.42 in 2015
Table 5 and Figure 3 below show a breakdown of these figures for the North and the Rest of England

Table 5: ONS Births and Stillbirths (SBs)

	2014			2015				
	All Births	**SBs**	**SB rate**	**All Births**	**SBs**	**SB rate**	**Diff.**	**P value**
North of England	179,006	866	**4.84**	178,878	782	**4.37**	-0.47	<0.05
Rest of England	485,537	2,181	**4.49**	488,473	2,170	**4.44**	-0.05	NS

Fig 4: ONS Stillbirth rates – England and North of England regions

ONS stillbirth rates - North vs Rest of England

	2014	2015
England	4.59	4.42
North of England	4.84	4.37
North East	4.34	3.61
North West	4.85	4.55
Yorkshire & The Humber	5.05	4.47
Rest of England	4.49	4.44

Key points

- The national reduction in stillbirth rates is mostly due to a fall in the North of England, an area with traditionally higher than average mortality rates.
- Each of the three participating regions (North East, Yorkshire and the Humber, North West) reduced their stillbirth rates to the lowest ever level in their respective region.
- In contrast, such changes were not evident in other English regions, which suggests that the fall in stillbirths in the North was caused by the implementation of SaBiNE during 2015.
- Taken together, the three regions had a reduction in stillbirth rate from 4.84 to 4.37 / 1000. This is statistically significant, i.e. not due to chance, and represents a 10% reduction in a single year.
- This drop equates to 84 fewer stillbirths which, when extrapolated to the whole of England, would represent 313 fewer deaths per year.
- The study also highlighted that even more stillbirths could be prevented by addressing the chronic shortages of ultrasound provision in pregnancies at increased risk of fetal growth restriction.

7. COST-BENEFIT

Funding received for the SaBiNE project was just under £200k, or a lay-out of less than £2400 for each of 84 stillbirths saved.

It is impossible to estimate, nay fathom the magnitude of loss to the parents concerned. There is also the inestimable loss of life potential of the stillborn baby. The cost of a stillbirth to the health service and society can however be estimated, as has been done in the recently published authoritative study commissioned by the Stillbirth Foundation of Australia [7]. The Sterling equivalent was approximately £34,000 based on direct costs (health service, investigations, counselling; ca. £8000) and indirect costs (funeral, absenteeism, loss of productivity; ca. £ 26,000).

For the 84 fewer stillbirths, these estimates would mean a total saving of over £672k in direct costs alone, or a more than 3-fold return; and a total saving of £2.8M when indirect costs are also included, equivalent to a 14-fold return on the 200k investment.

8. FEEDBACK

The designated clinical midwives (DCMs) valued the training and reported positive effects from their role as GAP lead within the Trust. There appeared to be an overall improved confidence and competence in clinicians dealing with fetal growth screening and assessment. Case examples were presented at follow-up meetings which demonstrated increased detection of 'at-risk' cases.

Among challenges identified, about a third of DCMs reported that despite their secondment, which should free up dedicated time, there were often competing priorities including clinical commitments and concurrent audits which could hamper progress. This was ameliorated when there was good support within the unit and/or external backing by SCN leads, the LSAMO and the Perinatal Institute.

Although there was a rapid rise in postnatal recording of birthweight centiles and referral and detection rates, uptake was patchy, as several units persisted in assessing neonatal weight according to the WHO-UK (Red Book) birthweight charts currently still used by many neonatologists.

9. CONCLUSIONS & RECOMMENDATION

SaBiNE was able to demonstrate proof of principle, substantial benefits as well as cost effectiveness of an enhanced GAP programme in support of the NHS England Care Bundle for stillbirth prevention.

The project showed that:

- Designated midwives can be seconded to lead local implementation of unit based training
- This has led to demonstrable improvement in antenatal recognition of growth problems
- Performance could be monitored through a rolling programme of postnatal data collection, and missed case audits were rapidly established and able to identify the main hurdles to be overcome.
- Anecdotal reports of adverse outcomes prevented were supported by ONS data which showed a significant fall in stillbirths across the three regions, resulting in 84 fewer deaths in one year
- This reduction of stillbirths across the North of England was mainly responsible for the national reduction in the 2015 stillbirth rates in England.
- However more work needs to be done to implement the programme fully

We recommend that

➢ similar programmes should be introduced in other regions, to enhance antenatal detection of at risk pregnancies;
➢ such initiatives should be accompanied by requirements for a rolling audit of performance, as stipulated in the NHS England Saving Babies Lives Care Bundle;
➢ there is an urgent need to address shortages in ultrasound resources, to ensure that service provision is commensurate with NHS recommendations and able to meet quality and safety standards.

10. AUTHORS

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11. ACKNOWLEDGEMENTS

12. REFERENCES

1. Gardosi J. Kady SM, McGeown P, Francis A, Tonks. Classification of stillbirth by relevant condition at death (ReCoDe): population based cohort study. *BMJ* 2005 12;331:1113–7.

2. Gardosi J, Madurasinghe V, Williams M, Malik A, Francis A. Maternal and fetal risk factors for stillbirth: population based study. *BMJ* 2013;346:f108–f108.

3. Gardosi J, Giddings S, Clifford S, Wood L, Francis A. Association between reduced stillbirth rates in England and regional uptake of accreditation training in customised fetal growth assessment. *BMJ Open* 2013;3(12):e003942

4. Clifford S, Giddings S, Southam M, Williams M, Gardosi J. The Growth Assessment Protocol: a national programme to improve patient safety in maternity care. *MIDIRS Midwifery Digest* 2013;23(4):516–23.

5. NHS England - Saving Babies Lives: Care Bundle for Stillbirth Prevention 2016
    https://www.england.nhs.uk/ourwork/futurenhs/mat-transformation/saving-babies/

6. Office for National Statistics: ONS Death Registrations Summary Tables, England & Wales 2015
    www.ons.gov.uk/peoplepopulationandcommunity/ birthsdeathsandmarriages/deaths/datasets/
    deathregistrationssummarytablesenglandandwalesreferencetables Table 4; July 2016.

7. Stillbirth Foundation of Australia & PwC. The economic impacts of stillbirth in Australia. 2016
    http://stillbirthfoundation.org.au/wp-content/uploads/2016/10/Economic-Impacts-of-Stillbirth-2016-PwC.pdf