Study of Stillbirth Claims

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Preface

This study is the work of many people. Fiona France, Chris King and Helen Vernon of the Technical Claims Unit extracted data from files and contributed greatly to discussions. Bob Arndtz also helped with data extraction. Alison Bartholomew and Sarah Nicholson assisted on risk management issues. Part 4 was written by Tracy Dilger and Susan Harris of DNV. Sonia Irvin created and maintained a spreadsheet for the data and was responsible for much of the other organisation. Graphs and tables were produced by Sonia Irvin and Emma Corbett. Professor Joan Higgins provided guidance and support throughout.

I would like to extend my grateful thanks to all the above, and to those organisations which have given encouragement and suggestions – SANDS, NICE, CEMACH and APIL.

Any errors are entirely my own.

John Mead
Technical Claims Director
30 July, 2009

1. Background

1.1. The NHS Litigation Authority (NHSLA) possesses a unique database of clinical negligence claims made against NHS bodies in England. This database has the potential to act as a source of learning for the NHS, and the Authority therefore decided in autumn 2008 to undertake an analysis of selected claims. It is hoped that this will be the first of a series of studies.

1.2. After detailed consideration of options, it was decided that the initial research should encompass claims arising from stillbirths. These are a readily identifiable group, the circumstances giving rise to which frequently cause extreme anguish to parents.

1.3. Several other organisations have an interest in this area, and some have recently published their own research. We have had very fruitful discussions with the following: SANDS (Stillbirth and Neonatal Death Society); APIL (Association of Personal Injury Lawyers); NPSA (National Patient Safety Agency); and CEMACH (Confidential Enquiry into Maternal and Child Health) [now known as CEMACE]. All of these organisations have been extremely supportive of our proposal and have made valuable suggestions.

1.4. We were advised by SANDS and APIL that seeking individual parental approval for access by external researchers to claims files would be traumatic for many parents. Accordingly, NHSLA approached PIAG (Patient Information Advisory Group) for advice on whether this study could lawfully be undertaken without express consent from individual parents. PIAG advised that because our proposal entailed only NHSLA claims staff accessing the relevant claim files and extracting anonymised data before any analysis could be undertaken, and since the purpose of the study was to feed learning back to the NHS (and elsewhere), the study would be lawful under the terms of the Data Protection Act.

2. Scope of Study

2.1. We decided to analyse the 100 stillbirth claim files logged on NHSLA's computer system on or before the 31st December 2007. Cases received more recently were excluded, on the basis that they were unlikely to contain sufficient information to be useful for the purposes of this analysis. We chose both open and closed files, in order to give a representative selection of cases.

2.2. Ultimately we excluded 10 of these 100 cases, either because they possessed inadequate detail or proved not to be stillbirth cases (in several, the child had lived for a few minutes or hours after birth). We therefore extended the study to the next available 10 cases.

2.3. The most recent event from the resultant group of 100 cases was on the 2nd July 2007; the oldest was 22nd January 2003. Distribution of years of death was as follows:

2007	2006	2005	2004	2003
3	25	33	21	18

2.4. It was decided not to study a "control" group additionally, owing to the difficulty in establishing one which was suitable. NHSLA only possess files on incidents which have become claims. We do not have material on stillbirths which have not resulted in claims, and even were we to obtain access to such papers legitimately, they would not contain information on many of the aspects which are being analysed in this study, e.g. damages paid and claimant costs.

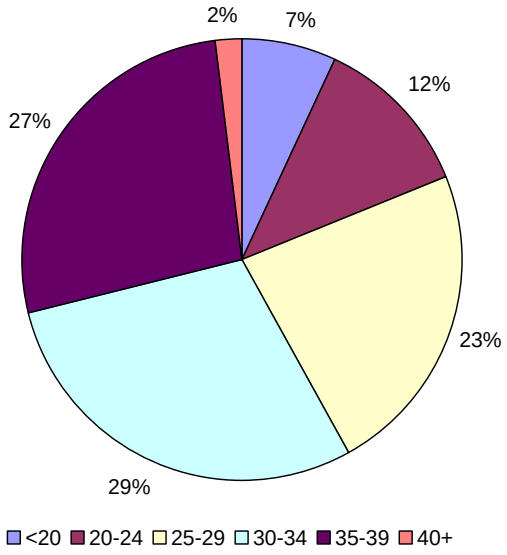
2.5. Five NHSLA claims handlers examined the relevant files and extracted the data from them onto a control sheet. A copy of this is attached at Appendix A. This sheet is anonymised: neither the patient's name nor the identity of the defendant trust is recorded, nor is the region in which the event occurred. The year of event is likewise omitted. The "case number" is not that used in day-to-day handling, but one allocated solely for the purposes of this study, in order to prevent easy identification. We are indebted to NPSA for valuable suggestions regarding factors to be recorded.

2.6. This report analyses most of the data extracted, but we have omitted the following factors: whether or not a consultant was present at the stillbirth; the number and designation of other staff present; and expert reports obtained. Information on the first two factors was not available on many files, and on others it was incomplete. The existence of expert evidence was problematical because NHSLA was often unaware of the complete range of reports obtained by the claimant's solicitors. Further, NHSLA did not obtain independent expert evidence on many files, relying instead upon reports from senior trust obstetricians and other clinicians. Consequently, we concluded that this factor could not be analysed usefully.

2.7. We are aware from other studies that the following factors are of significance in the incidence of stillbirths: ethnicity; birth weight; birth order; socio-economic group. Our claim files do not contain information on ethnicity or socio-economic group, which are irrelevant to considerations of legal liability. Rarely do our files provide information on birth weight, and only spasmodically on birth order. Consequently, none of these factors appears in our analysis. Further, we have not analysed the involvement of locum staff, because whether or not any particular clinician was a locum is often not apparent on claim files.

3. Findings

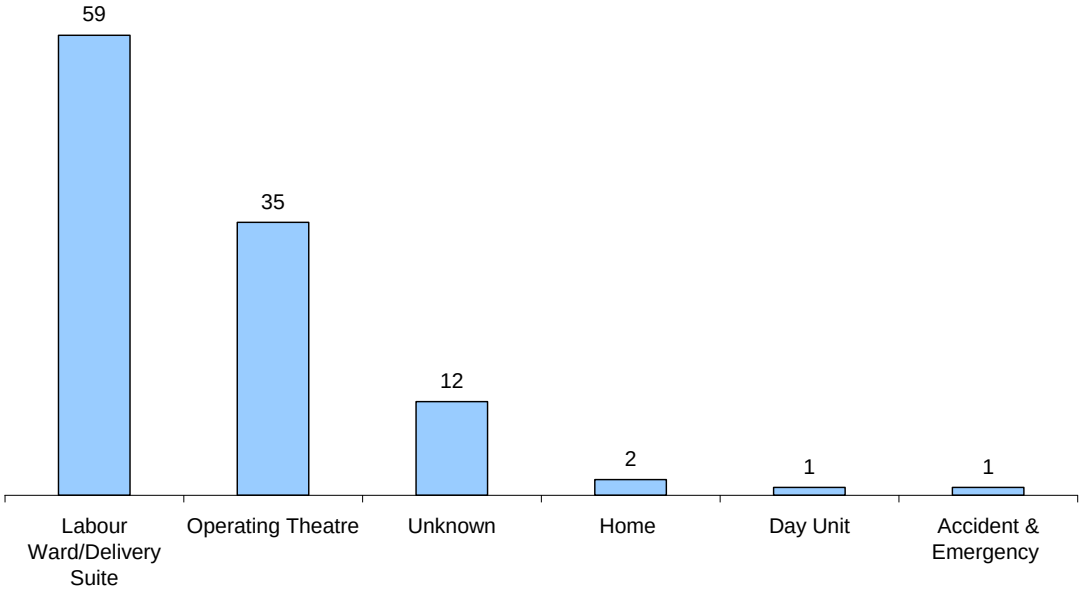
3.1. Age of mother



There is a reasonably close correlation between most of these findings and the relative proportions of <u>all</u> maternities by maternal age, cited by CEMACH (1) – page 39. However, there are two disparities: in our study, 27% of claims arose from mothers aged between 35 and 39; whereas CEMACH record that in 2007, only 16.6% of all births involved mothers in this age band. For mothers aged 40+, our study shows a figure of 2%; whereas the proportion of all births in 2007 was 3.6%.

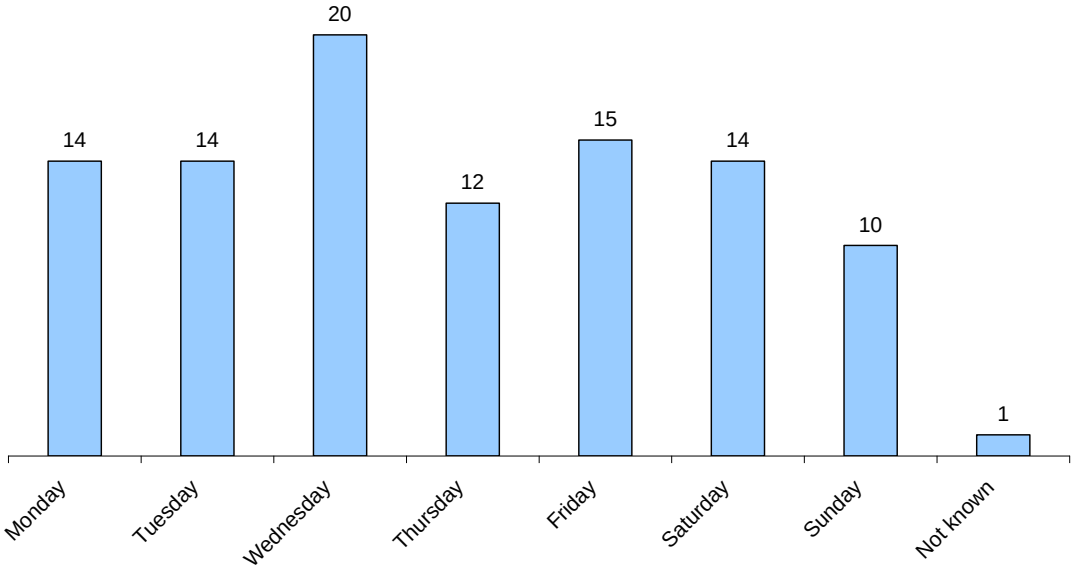
Stoneman (2) gives a figure of 30% for stillbirth claims involving mothers aged 40 and over, but her sample size is only 20.

3.2. Location



Many cases in the first two columns were planned inductions or Caesarean sections involving deaths which were already known to clinicians.

3.3. Day of Week



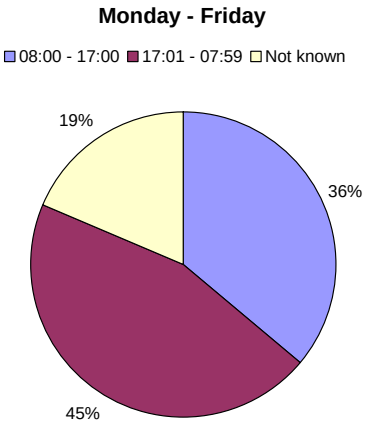
The fact that Wednesday accounts for 20% of the sample has no obvious explanation and is probably a statistical quirk. We anticipated, on commencing the study, that weekends would prove more “dangerous” than weekdays, but this proved not to be the case in terms of days of delivery. However, this conclusion may be slightly misleading because fetuses with complications discovered over a weekend were usually listed for delivery during the subsequent week.

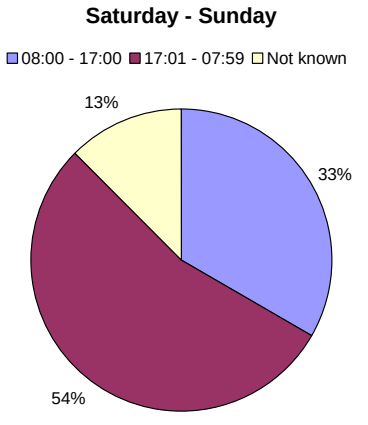
3.4. Month

Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total
7	2	7	4	8	13	9	8	16	7	8	11	100

There are peaks in June and September and a trough in February. Trainee NHS doctors usually start work in new departments in August and February, which means that peaks in these months, rather than June and September, might be predicted.

3.5. Time

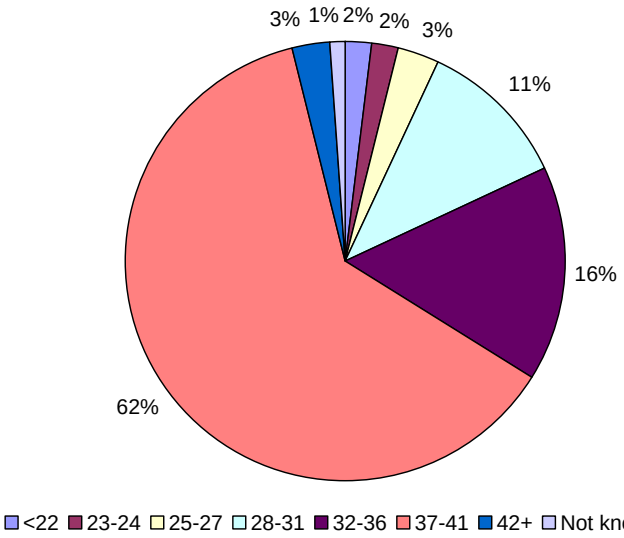




These charts illustrate the relative numbers of stillbirths during the conventional day shift and at other times. Perhaps surprisingly, they reveal more cases pro-rata to the number of hours during the former than the latter; but this is probably explained by the fact that complications during night shifts were either not spotted or resulted in planned deliveries between 08:00hrs and 17:00hrs.

These findings contrast with Stoneman (2), who found that 8 out of 20 cases involved weekend or holiday births. However, as previously noted, her sample size was small.

3.6. Gestation



Those cases involving less than 24 weeks gestation are technically not stillbirths, but we decided to include them in this study nonetheless in order to give as broad a picture as possible.

Using slightly different gestational groupings, 47% of cases were between 37 and 40 weeks; 18% were at 41 weeks; 53% were at 39+ weeks.

Accordingly, our study reveals a significant percentage of post-term cases. Stoneman (2) reported that 50% of her group were at 39+ weeks.

3.7. High-risk pregnancies

55% of our study involved high-risk pregnancies. 45 of these 55 were recognised as such by clinicians, albeit only at a very late stage in several cases.

The commonest factors were as follows:

Maternal hypertension	11
Twins	10
IUGR (Intra-uterine growth restriction)	8
Maternal Diabetes	6
History of pre-eclampsia	6
Previous Caesarean section	6
High maternal BMI	4

5 of the 8 cases of IUGR were not recognised, nor were 3 of the 6 cases of diabetes.

3.8. Misinterpretation of CTG Trace

This was accepted by the NHS as having occurred in 34% of cases.

Categories of clinicians involved were as follows:

Midwife	Registrar/Senior Registrar	Consultant	Unknown	Total
25	8	4	2	39

The total is not 34 because in several cases more than one category of clinician failed to interpret the CTG correctly.

Misinterpretation of a CTG trace was the most frequent example of negligence encountered in the study.

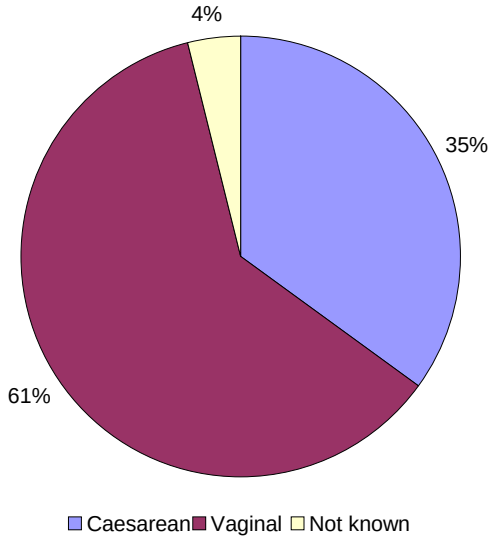
3.9. Other breach of duty issues

The interrelationship between allegations made and NHSLA's risk management standards is covered in detail in the analysis provided by DNV in part 4.

We have not undertaken a separate analysis of each of the 312 allegations recorded, since the majority of cases in the sample did not reach formal Letter of Claim/Letter of Response stage under the Pre-action Protocol for the Resolution of Clinical Disputes. It is only at that stage that allegations are refined and responses formalised. However, please see 3.13 for the numbers of allegations accepted or not.

By far the most frequently accepted allegation of negligence was failure to interpret a CTG trace correctly – see 3.8.

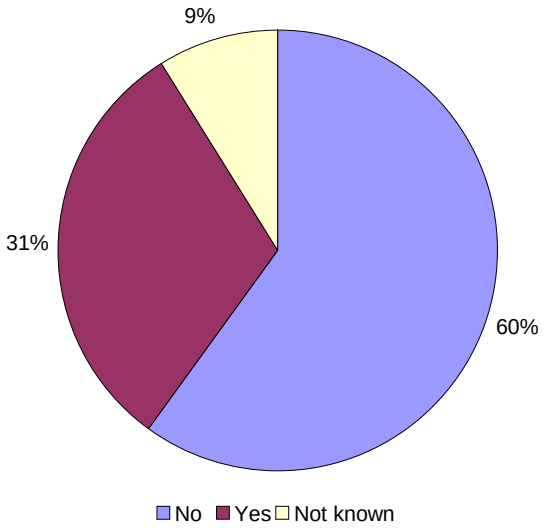
3.10. Mode of Delivery



The 35% Caesarean section figure in the study group contrasts with the average for all UK births in 2006 of 23%, as reported by NICE (www.nice.org.uk).

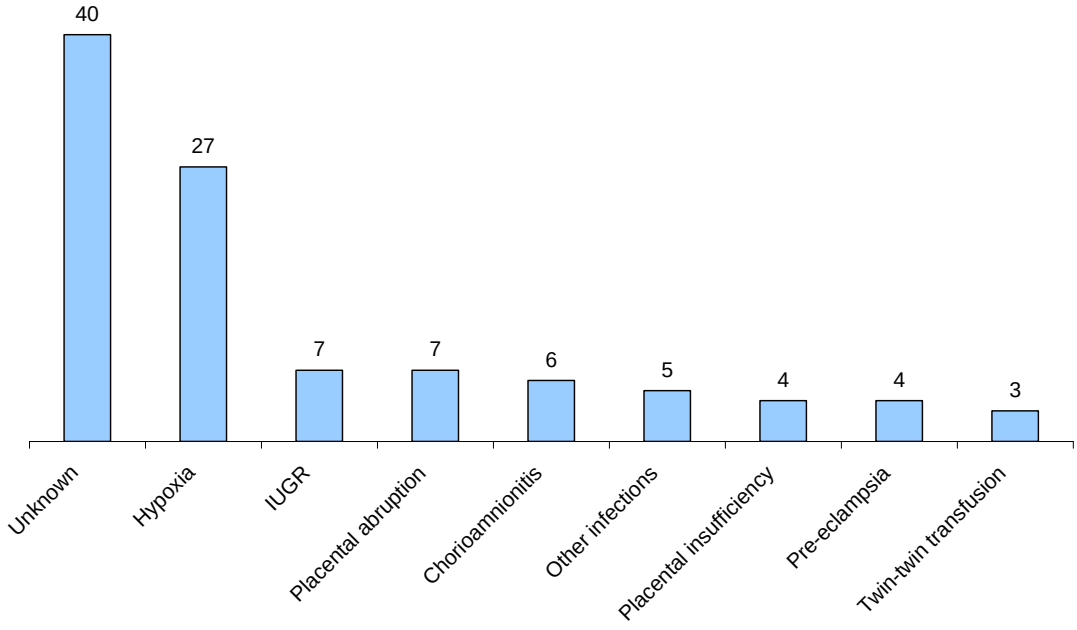
Further research would be required to explain this discrepancy, but mode of delivery appears largely not to have had a bearing on cause of death, given that it was realised in most cases in the study that the fetus was already dead prior to delivery.

3.11. Was fetus dead before mother entered hospital?



This question refers to the mother's last hospital visit immediately prior to delivery. The "yes" figure, at 31%, is surprisingly high; but many of these cases involved dead fetuses which were already known about, where the mother had a planned induction some days after discovery of the death.

3.12. Cause of death



The large number of unknowns is accounted for by the fact that many parents refused a post-mortem. In some other cases it was unclear from the claim file if a post-mortem had been offered or, indeed, if one had been performed.

CEMACH (page 58) (1) record that in 2007, post-mortems were only conducted in 45% of stillbirth cases.

The incidence of hypoxia (27%) is closely aligned with the number of cases in which it was accepted that a CTG was misinterpreted (34%).

3.13. Acceptance of breach of duty and causation by the NHS

	Yes	**No**	**Unclear**
Breach Accepted	58	39	3
Causation Accepted	49	49	2

As noted in 3.9, many cases had not reached Letter of Claim/Letter of Response stage, and therefore acceptance of breach and causation (or otherwise) was often on an informal basis. For the same reason the percentages listed under the “No” column are potentially misleading, because many claims were the subject of negotiated settlements even in the absence of formal admissions.

3.14. Psychiatric claims

Mother	76
Father	19
Others	0

The percentage of mothers making such claims is extremely high. However, this is arguably unsurprising given the traumatic nature of a stillbirth. There is room for argument, in law, as to whether mothers should be classified as primary or secondary victims in such circumstances. However, even if they are truly secondary victims, they will very frequently be able to recover damages for proven psychiatric trauma arising from the stillbirth under the criteria laid down by the House of Lords in A*lcock v Chief Constable of South Yorkshire* [*1991] 4 All ER 907.*

3.15. Other types of claim

There were 9 in total, each of a different nature:

- Rupture of previous Caesarean scar
- Cardiac arrest
- Hysterectomy
- Injury to pelvic floor
- Pelvic floor infection
- Human Rights Act – Bereavement Damages
- Loss of congenial employment
- Maternal fatality
- Failure to diagnose septicaemia

All are self-explanatory save perhaps the Human Rights Act claim. In law, stillbirths do not give rise to an entitlement to Bereavement Damages (fixed at £11,800 for deaths on or after 1 January 2008), and in the case in question an attempt was made to bring a claim under the Human Rights Act equivalent to the statutory bereavement award. This claim was resisted as it had no basis in law.

3.16. Financial cost

3.16.1. £1,761,638 damages were paid on 62 cases, an average of £28,413 per successful claim.

3.16.2. Claimant costs totalling £996,033 were paid on 49 claims, an average of £20,327 per successful claim.

3.16.3. Defence costs totalling £183,750 were paid on 47 cases, an average of £3,909 per case.

3.16.4. The highest damages payment was £225,000. This involved a significant psychiatric trauma to the mother and loss of earnings.

3.16.5. The highest payment for claimant costs was £102,500.

3.16.6. The highest payment for defence costs was £34,097 [on the same case as in 3.16.5].

3.16.7. Average claimant costs were 71% of average damages. Average defence costs were 14% of average damages.

3.16.8. 50 cases were closed with damages paid. 17 claims were closed at no cost, and 3 were closed with payment of defence costs only.

3.16.9. 30 cases remained open. 18 of these had outstanding damages reserves of £577,500, an average of £27,500 per case. 12 cases remained open for payment of costs only.

3.16.10. Total outstanding claimant costs reserves were £1.19m, an average of £39,666 per open file. Total outstanding defence costs were £341,900, an average of £11,397 per open file.

3.16.11. Total damages paid and reserved across all files were £2,339,138, an average of £23,391 per file.

3.16.12. Total claimant costs paid and reserved were £2,186,033, an average of £21,860 per file.

3.16.13. Total defence costs paid and reserved were £525,650, and average of £5,257 per file.

3.16.14. Average defence costs were therefore less than a quarter of average claimant costs.

3.16.15. The total paid and reserved overall was £5,050,821, an average of £50,508 per file.

3.16.16. Projecting from the figure of claims already paid (62%), across the cases still outstanding, the overall success rate will be 72%. This is much higher than the NHSLA average for clinical negligence claims of 53%.

4. Links to the CNST Maternity Standards

4.1. Scope

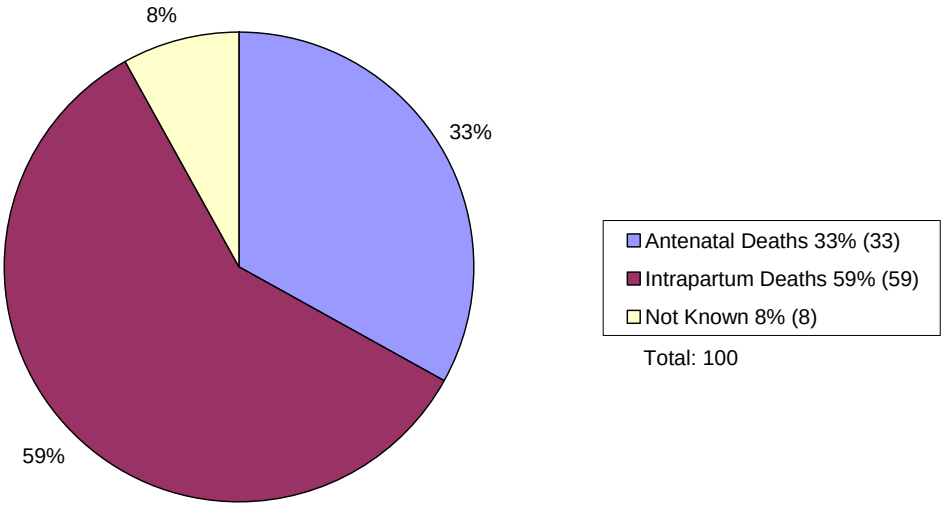
Det Norske Veritas (DNV) were asked to review the data in relation to:

- Mapping the list of alleged breaches of duty against the CNST Maternity Clinical Risk Management Standards 2009/10 (3) to determine whether or not there is a criterion or requirement in the current Standards which assesses the alleged breaches of duty.
- Identifying risk areas or themes not addressed by the current CNST Maternity Standards
- Correlating the identified themes with other reports, particularly the latest national confidential enquiry CEMACH (1).

4.2. Findings

4.2.1. Data on whether the fetus was dead before the woman entered hospital were used to determine whether the fetus had died during the antenatal or intrapartum period. This information is shown in Figure 1.

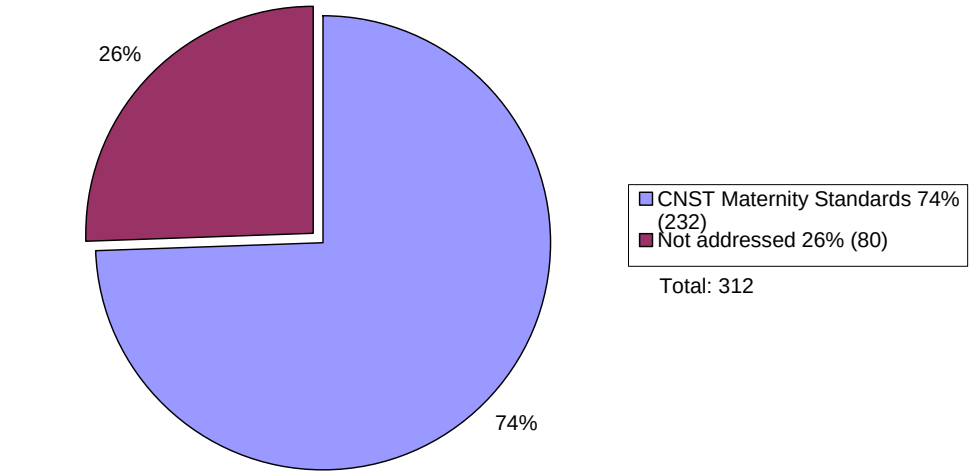
4.2.2. Figure 1: Whether death occurred during the antenatal or intrapartum period



Within the CNST Maternity Standards there is more of an emphasis on the risks associated with the intrapartum care than antenatal care.

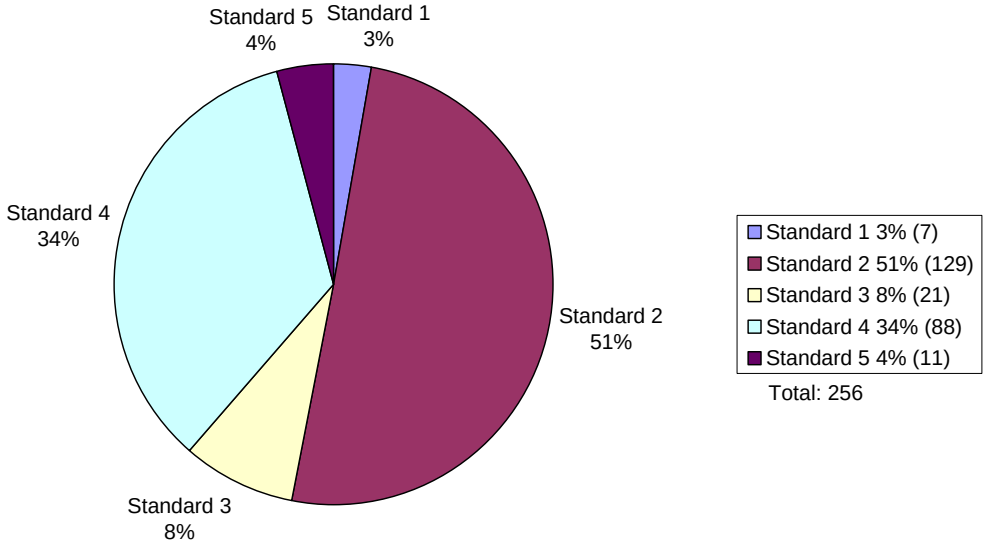
4.2.3. In total there were 312 alleged breaches of duty recorded for the claims reviewed. The number of breaches pertaining to each claim varied: in some claims only one breach was alleged, but the majority had two or more, and for one claim there were eight. Of the 312 alleged breaches, 232 are addressed by the CNST Maternity Standards but 80 are not, as shown in Figure 2. These 80 alleged breaches can be grouped into eight risk areas and are discussed later in this report.

4.2.4. Figure 2: Alleged breaches of duty addressed by the CNST Maternity Standards



4.2.5. Figure 3 illustrates where the criteria addressing the alleged breaches of duty can be found within the CNST Maternity Standards. (Please note that number shown i.e. 256, is higher than the actual number of alleged breaches i.e. 232, because some of breaches are addressed by more than one criterion.)

4.2.6. Figure 3: Alleged breaches of duty and the CNST Maternity Standards



4.2.7. A breakdown of the alleged breaches of duty by criterion is provided in Figure 4 which shows that some of the allegations are addressed in all five of the standards.

Figure 4: The number of alleged breaches of duty by standard and criterion of the CNST Maternity Standards

Criterion ➔ / Standard ⬇	1.3	1.4	1.7	2.1	2.2	2.3	2.4	2.5	2.6	2.10	3.1	3.3	3.9	4.3	4.5	4.7	4.8	5.1	5.2	5.8	5.9	5.10	Total
	Staffing Levels (Midwifery & Nursing Staff)	Staffing Levels (Obstetricians)	Maternity Records	Care of Women in Labour	Auscultation	Continuous Electronic Fetal Monitoring	Fetal Blood Sampling	Use of Oxytocin	Caesarean Section	Vaginal Birth after Caesarean Section	Severe Pre-Eclampsia	Operative Vaginal Deliver	Pre-Existing Diabetes	Clinical Risk Assessment (Antenatal)	Maternal Antenatal Screening Tests	Clinical Risk Assessment (Labour)	Handover of Care (Onsite)	Referral When a Fetal Abnormality is Detected	Neonatal Resuscitation	Support for Parents	Postnatal Care Planning	Postnatal Information	
Standard 1 - Organisation	4	1	2																				7
Standard 2 - Clinical Care				20	5	80	5	6	6	7													129
Standard 3 - High Risk Conditions											13	1	7										21
Standard 4 - Communication														61	8	17	2						88
Standard 5 - Postnatal and Newborn Care																		7	1	1	1	1	11
Total																							256

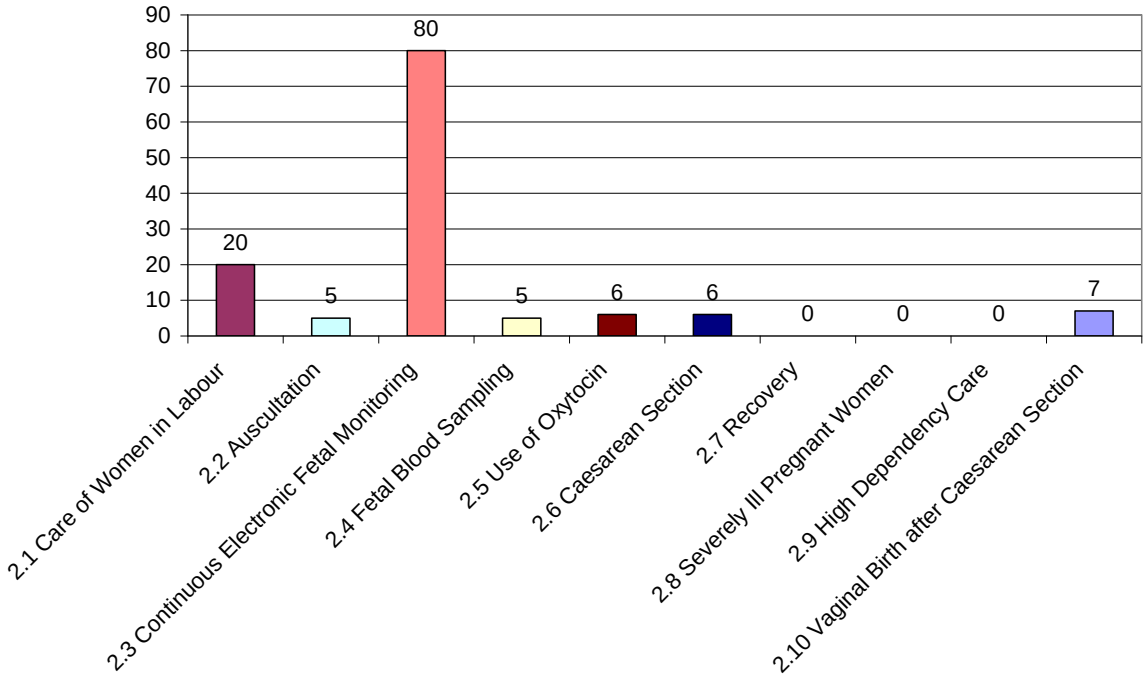
4.2.8. Standard 1 – Organisation

This standard has the lowest number of alleged breaches of duty (7), with poor record keeping (2) and staffing levels being inadequate or the necessary healthcare professional unavailable (5) being the relevant criteria.

4.2.9. Standard 2 – Clinical Care

The standard within the CNST Maternity Standards which addresses the highest number of alleged breaches of duty (129) is Standard 2 – Clinical Care. As can be seen in Figure 5, the criteria which address the highest number of alleged breaches in Standard 2 are 2.3 Continuous Electronic Fetal Monitoring (80) (Figure 6) and 2.1 Care of women in Labour (20) (Figure 7).

4.2.10. Figure: 5 – Alleged breaches of duty addressed within Standard 2 – Clinical Care of the CNST Maternity Standards by criterion



4.2.11. Figure 6: CNST Maternity Standard 2 – Criterion 3, Continuous Electronic Fetal Monitoring (Level 1 requirements, requirements highlighted in bold are carried forward for assessment at Level 2 and 3)

Standard 2 – Criterion 3: Continuous Electronic Fetal Monitoring	
The maternity service has an approved system for improving care and learning lessons relating to continuous electronic fetal monitoring in labour that is implemented and monitored.	
Level 1	**Minimum Requirements**
2.3	The maternity service has approved documentation for continuous electronic fetal monitoring (EFM), in all care settings, which as a minimum must include: a. date an and time checks on EFM machines following the guidance of NICE b. **the minimum data that should be recorded on the tracing, to include:** I. **woman's name** II. **date and time** III. **hospital number** IV. **any intrapartum events; which should be recorded at the time of the event signed and the time noted** V. **the requirement for those who provide an opinion on the tracing during labour to record this on the trace as well as in the health records** VI. **data to be included at the completion of the tracing following the guidance of NICE** c. when to monitor in labour d. **hourly systematic assessment of the trace following the guidance of NICE** e. **the actions to be taken in the event that the tracing is assessed as suspicious or pathological, following the guidance of NICE** f. **the expectations in relation to staff training as identified in the maternity service's training needs analysis** g. the process for audit, multidisciplinary review of audit results and subsequent monitoring of action plans.

4.2.12. Figure 7: CNST Maternity Standard 2 – Criterion 1, Care of Women in Labour (Level 1 requirements, requirements highlighted in bold are carried forward for assessment at Level 2 and 3)

Standard 2 – Criterion 1: Care of Women in Labour	
The maternity service has an approved system for improving care and learning lessons relating to the care of women in labour that is implemented and monitored.	
Level 1	**Minimum Requirements**

2.1	The maternity service has approved documentation for the care of women in labour, at term, in all care settings, which as a minimum must include the: a. observations to be carried out on admission following the guidance of NICE b. **observations to be carried out during established first stage of labour following the guidance of NICE** c. observations to be carried out during second stage of labour following the guidance of NICE d. observations to be carried out during third stage of labour following the guidance of NICE e. **documentation of observations following the guidance of NICE** f. guidance on duration of all stages of labour g. guidance on referral to obstetric care h. process for audit, multidisciplinary review of audit results and subsequent monitoring of action plans.

4.2.13. The two criteria above address 100 of the alleged breaches of duty and reflect the findings of the latest CEMACH Perinatal Mortality Report (1) that substandard intrapartum care has been found to be a high cause of both intrapartum related stillbirths and neonatal deaths occurring at term. This report suggests that there may have been avoidable factors during the labour and/or delivery which contributed to the outcomes of either stillbirth or neonatal deaths at term, although the latter were not part of this review.

4.2.14. The remaining 29 alleged breaches of duty in Standard 2 are also based on the care women and their fetuses should receive in labour including auscultation of the fetal heart (5) the appropriate use of fetal blood sampling (5), the appropriate use of oxytocin and the associated monitoring of both the woman and the fetus (6), the classification of the need to perform a Caesarean section (6) and finally care of women who have had a previous Caesarean section (7). All of these 29 alleged breaches would also fit into the category of substandard care being provided in labour.

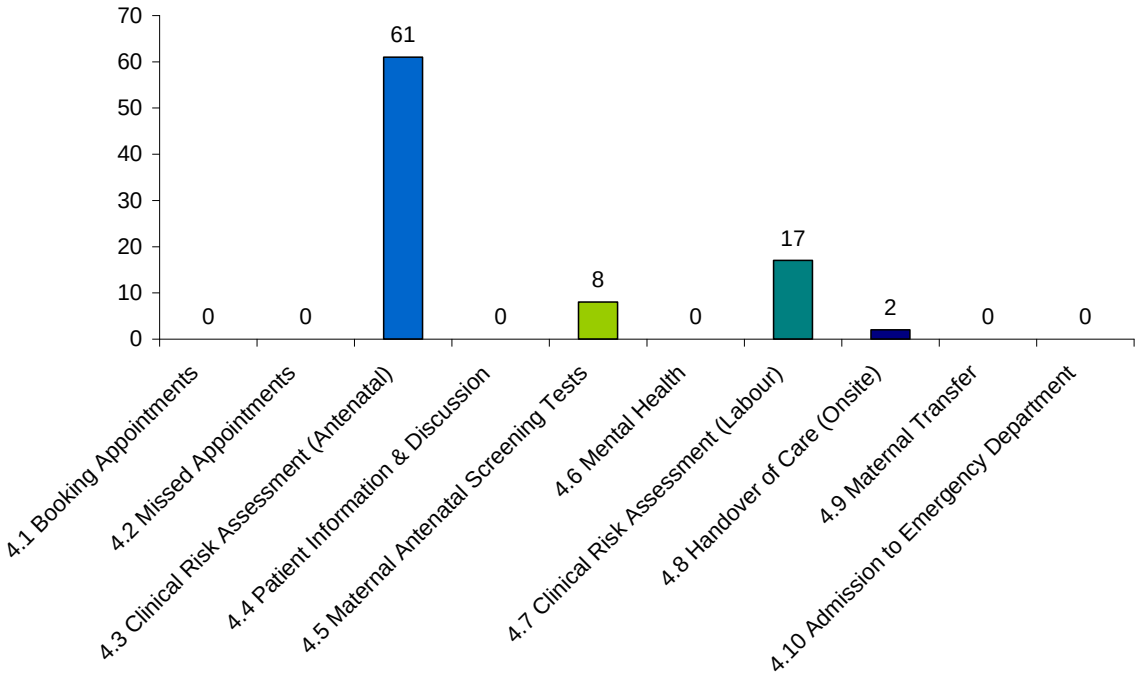
4.2.15. <u>Standard 3 – High Risk Conditions</u>

Within the alleged breaches of duty addressed by Standard 3 – High Risk Conditions (21), the criterion with the highest number is the management of severe pre-eclampsia (13). There are also alleged breaches attributed to pre-existing diabetes (7) and operative delivery (1). It is possible that the alleged breaches identified in Standard 3 could also be associated with criteria on risk assessment and screening tests within Standard 4.

4.2.16. Standard 4 – Communication

The standard within the CNST Maternity Standards which addresses the second highest number of alleged breaches of duty (88) is Standard 4 – Communication. As illustrated in Figure 8, the criteria which address the highest number of alleged breaches in Standard 4 both address risk assessment and are 4.3 Clinical Risk Assessment (Antenatal) (61) (Figure 9) and 4.7 Clinical Risk Assessment (Labour) (17) (Figure 10).

4.2.17. Figure: 8 – Alleged breaches of duty addressed within Standard 4 – Communication of the CNST Maternity Standards by criterion



4.2.18. As described in Figure 9, Criterion 4.3 examines clinical risk assessments during the antenatal period and requires that each episode is documented every time the woman is seen to ensure that any deviations from the norm are identified and acted upon. A failure to perform these assessments at the relevant time i.e. well in advance of delivery, can be significant when the woman goes into labour and may result in inappropriate or suboptimal care being provided to both the woman and the fetus. The consequences may include not identifying women with risk factors or, if the risk factors are identified, not acting upon them in a timely and suitable manner that is in line with national guidance.

4.2.19. Figure 9: CNST Maternity Standard 4 – Criterion 3, Clinical Risk Assessment (Antenatal) (Level 1 requirements, requirements highlighted in bold are carried forward to Level 2 and 3)

Standard 4 – Criterion 3: Clinical Risk Assessment (Antenatal)	
The maternity service has an approved documentation for the process of clinical risk assessment during the antenatal period that is implemented and monitored.	
Level 1	**Minimum Requirements**
4.3	The maternity service has approved documentation which describes the process of clinical risk assessment during the antenatal period, which as a minimum must include a description of the: a. timing of risk assessments b. medical conditions to be considered, including anaesthetic history c. factors from previous pregnancies d. lifestyle history to be considered e. identification of women who will decline blood and blood products f. risk assessment for appropriate place of birth g. **development of an individual management plan for women in whom risks are identified during the clinical risk assessment** h. **process for referral of women whom risks are identified during the clinical risk assessment** i. process for referral back to midwifery led care if appropriate j. process for monitoring compliance with all of the above requirements, review of results and subsequent monitoring of action plans.

4.2.20. As detailed in Figure 10, Criterion 4.7 reflects national guidance that expects all women to have a clinical risk assessment performed when labour commences to ensure they are labouring in the safest place for them and their fetus and have access to the appropriate healthcare professionals.

4.2.21. Figure 10: CNST Maternity Standard 4 – Criterion 7, Clinical Risk Assessment (Antenatal) (Level 1 requirements, requirements highlighted in bold are carried forward to Level 2 and 3)

Standard 4 – Criterion 7: Clinical Risk Assessment (Labour)	
The maternity service has an approved documentation for the process of clinical risk assessment when labour commences that is implemented and monitored.	
Level 1	**Minimum Requirements**
4.7	The maternity service has approved documentation which describes the process of clinical risk assessment when labour commences, which as a minimum must include a description of the: a. timing of clinical risk assessments b. medical conditions to be considered including anaesthetic history c. factors from previous pregnancies d. lifestyle history to be considered e. identification of women who will decline blood and blood products f. risk assessment for appropriate place of birth g. **development of an individual management plan for those in whom risks are identified during the clinical risk assessment** h. **process for referral of women those in whom risks are identified during the clinical risk assessment** i. process for monitoring compliance with all of the above requirements, review of results and subsequent monitoring of action plans.

4.2.22. In total, these two criteria address 78 of the alleged breaches of duty which again reflect the findings of the latest CEMACH Perinatal Mortality Report (published June 2009) (1). National guidance has been produced for both ante and intrapartum care by the National Institute for Health and Clinical Excellence (NICE) (4) & (5) with the aim of providing guidance to assist clinicians and women in making decisions about the most appropriate treatment for specific conditions, relating to the care of healthy women and their fetuses during childbirth. However, the need to perform risk assessments both during the antenatal period and at the commencement of labour is not new. Such assessments were recommended in previous reports e.g. CEMACH Why Mothers Die 2000-2002 (2004) (6), and it was hoped that the NICE guidance would aid the implementation of the desired clinical practice.

4.2.23. There are two other criteria in standard 4 which address alleged breaches of duty: namely maternal antenatal screening (8) and the handover of care (2). These are two areas where communication

between the relevant healthcare professionals is paramount to positive birth outcomes.

4.2.24. Standard 5 – Postnatal and Newborn Care

This standard has the second lowest number of alleged breaches of duty (11). The highest number concern referral when a fetal abnormality is detected (7) with the remaining four alleged breaches addressed by neonatal resuscitation criteria (1), support for parents (1), post natal care planning (1) and postnatal information (1)

4.3. Other Risk Areas

4.3.1. With the exception of support for parents, postnatal care planning and postnatal information all of the alleged breaches of duty discussed above have been addressed by the CNST Maternity Standards since their introduction as a pilot in 2002. However, 80 of the 312 alleged breaches of duty are not addressed by the current Standards. These allegations have been categorised and eight key risk areas identified as follows:

- Antenatal – Reduced fetal movements
- Antenatal – Spontaneous pre-labour rupture of membranes
- Antenatal – Ultrasound scanning
- Antenatal – Information leaflets and advice
- Antenatal – Induction of labour
- Antenatal – Gestational diabetes
- Intrapartum – Timing of delivery: both operative vaginal deliveries and Caesarean sections
- Twins

4.3.2. Figure 11 considers whether these risk areas were addressed in previous versions of the CNST Maternity Standards and whether a new requirement or criterion on the risk area should be considered for inclusion in future versions of the Standards.

4.3.3. When the stillbirths included in the claims data occurred, i.e. between 2003 and 2007, maternity services were assessed against a different set of CNST Maternity Standards to that used for this review and via a different assessment process. A notable difference is that the previous standards and assessments did not address the implementation and monitoring of key clinical guidelines to the same extent as the current approach.

Figure 11: Consideration of risk areas not addressed by the current CNST Maternity Standards

Risk Area	Discussion	Previous CNST Maternity Standards	Was the criterion removed?	Consider for inclusion?
Antenatal – Reduced fetal movements	• it would appear that women were not always asked about their perception of fetal well being • women were not always listened to when they provided information relating to their perception of fetal well being • there appears to be a delay or failure to act upon the information provided regarding fetal movements and activity	**Criterion 4.1.1** A guideline for the management of reduced fetal movements	**Yes – removed** It was one of 27 guidelines reviewed as part of the assessment. The claims data did not support it remaining as a criterion on its own.	Maybe – Although, talking to and listening to the woman should be a normal and important part of the antenatal risk assessment.
Antenatal – Spontaneous pre-labour rupture of membranes	• it would appear that women are not always asked whether they think their membranes have ruptured • it would appear women are not always examined when they provide a history of spontaneous pre-labour rupture of membranes • it would appear fetal wellbeing is not always assessed when women	Not in the previous standards	**Not applicable**	Maybe – Further research required, although this risk area should be part of antenatal risk assessment and information giving.

Risk Area	Discussion	Previous CNST Maternity Standards	Was the criterion removed?	Consider for inclusion?
	attend with a possible history of spontaneous pre – labour rupture of membranes			
Antenatal - Ultrasound scanning	• failure to perform ultrasound at identified stages of pregnancy • failure to follow up after previous ultrasound • failure to perform ultrasound for identified reason for example to assess fetal weight, liquor volume • failure to perform ultrasound requested	**Criterion 3.2.2** Ultrasound scanning was loosely included as part of the fetal anomaly screening but assessment of this element of the criterion was not as consistent as if ultrasound scanning was a standalone criterion.	**Not removed –** Although it appeared a problematic criterion for maternity services to monitor and audit, when the criterion was evaluated it appeared that the inclusion of the neonatal screening tests and reported results was the problematic area. Amended in current manual criterion 4.5 with reference to screening although ultrasound scanning may not be included in the screening programme by all maternity services	Maybe – Further research required, consider the possibility of specifically including ultrasound scanning.
Antenatal – Information leaflets and advice	• failure to provide adequate information to enable informed consent to be obtained • failure to advise women of the risks of self discharge • failure to advise women to attend for maternal and fetal assessment	**Criterion 3.1.1** A list of information was provided and the assessor would expect to see a minimum of five of the topics covered for compliance to be awarded.	**Not removed –** This criterion had been revised and is now criterion 4.4 – Patient Information and Discussion, with the focus moved to the information provided being documented when clinically indicated. Although there is a list of possible information leaflets they are all based on topics that require informed consent.	Yes – New minimum requirement within criterion 4.4. Many of the clinical guidelines could/should have supporting information or guidance for the women. This type of information is offered by NICE and the RCOG to complement their guidelines on a variety of topics. Maternity services should be expected to

Risk Area	Discussion	Previous CNST Maternity Standards	Was the criterion removed?	Consider for inclusion?
				develop and provide information to women when appropriate to complement the clinical guidelines they use.
Antenatal – Induction of labour	• failure to induce labour • failure to obtain informed consent prior to induction of labour	**Criterion 4.1.1** A guideline for the induction of labour – to include augmentation and the use of syntocinon and prostagladins.	**Partially –** The induction aspect and the prostaglandins aspect were removed as the claims data reviewed when the revised standards were developed did not support them being retained. The use of oxytocin is in the Standards as a standalone criterion i.e. 2.5.	No – However, the claims data should be reviewed to see if there has been an increase in claims related to induction. Realistically the use of syntocinon will cover the majority of inductions, but not the clinical decision to induce. The CNST standards and assessments have never questioned clinical judgement which is what it might be if a minimum requirement relating to the decision to induce was to be included.
Antenatal – Gestational diabetes	• failure to recognise symptoms of diabetes • failure to monitor for diabetes • failure to test for gestational diabetes • failure to diagnose diabetes • failure to properly assess fetal size in view of mother's	Not in the previous standards	**Not applicable** Criterion 3.9 of the current standards addresses pre-existing diabetes	Maybe – A review of the latest claims data and reports should be undertaken. However, although the NICE guideline Diabetes in Pregnancy includes gestational diabetes, there was insufficient evidence to suggest the inclusion of gestational

Risk Area	Discussion	Previous CNST Maternity Standards	Was the criterion removed?	Consider for inclusion?
	diabetes • failure to appreciate risks associated with diabetes			diabetes in the current Standards. The only reference to gestational diabetes in either the CEMACH Perinatal Mortality Report 2007 (June 2009) or CEMACH Perinatal Mortality Report 2006 (April 2008) is that older women are more likely to have a stillbirth and more likely to have antenatal complications although there is no direct correlation between the two.
Intrapartum - Timing of delivery both operative vaginal deliveries and caesarean sections	• failure to delivery fetus by operative vaginal delivery • failure to delivery by caesarean section as prescribe • failure to deliver by caesarean section in a timely manner	Not in the previous standards. **Criterion 3.2.4** The decision to delivery interval and classification of urgency in relation to caesarean section was in the previous standards	**Not removed –** Criterion 3.3 looks at operative deliveries and the expected associated care Criterion 2.6 Caesarean Section includes the care provided to women around the time of the caesarean section with the focus being on the emergency and the urgent caesarean sections.	Criterion 2.6 Caesarean Section does not assess whether the classification of urgency was correct. The CNST standards and assessments have never questioned clinical judgement which is what it might be if a minimum requirement relating to the decision to perform a caesarean section was not made quick enough or the classification of the necessity and timeliness misevaluated.
Twins	– 11 of the cases were a twin	**Criterion 4.1.1**	**Yes – removed**	Maybe – Further research

Risk Area	Discussion	Previous CNST Maternity Standards	Was the criterion removed?	Consider for inclusion?
	pregnancy	A guideline for the management of multiple births.	It was one of 27 guidelines reviewed as part of the assessment. The claims data did not support it remaining as a criterion on its own.	required, consider the possibility of including requirements specific to twins in the future.

4.4. Observations

4.4.1. On commencing an initial review of the sample data two of the cases revealed gestational ages of 20 and 22 weeks which do not meet the definition of a stillbirth *"a baby delivered with no signs of life known to have died at 24 completed weeks of pregnancy onwards"* (CEMACH, June 2009) (1) or the legal definition of a stillbirth *"A stillborn child is legally defined as a child born after the 24th week of pregnancy who did not show any signs of life at any time after being born*" (General Register Office, Home Office Identity and Passport Service, April 2004).

4.4.2. The perinatal mortality reports from CEMACH consider stillbirths in relation to socio-demographic data such as ethnic group. Unfortunately it was not possible to review this factor as part of this study because claims files do not include this information.

4.5. Local Action

4.5.1. All healthcare professionals must practise within the approved guidelines that have been agreed by the maternity service. Where there are adverse outcomes, an investigation into the compliance of the healthcare professionals involved with the relevant guidelines should be performed, as updating of the guideline and/or re-education or training of the healthcare professionals may be required.

4.5.2. Education methods such as drills and skills scenarios and objective structure clinical examinations (OSCE's) may enhance the use of approved guidelines.

4.5.3. Involvement of as many members of the maternity team as possible in the development and review of approved clinical guidelines may also propagate the spread of the rationale for the document as well as compliant practice.

4.5.4. Maternity services should review their own data in relation to stillbirths to identify substandard care, the cause of the substandard care and share the lessons learned.

4.6. CNST Maternity Standards Review

4.6.1. The foundation of the CNST Maternity Standards and assessment is that maternity services should have approved guidelines that provide direction for all healthcare professionals to follow in practice. For many of the alleged breaches of duty identified in this review of stillbirth claims, the risk area is already addressed by the Standards i.e. there is a requirement that an appropriate, approved guideline is in place (Level 1) within all

maternity services. However, it would appear that solely having approved guidelines does not ensure healthcare professionals will use them. Implementation (Level 2) of the approved guideline must be assessed and monitored (Level 3) to ascertain and facilitate compliance with the identified clinical practice to ensure the best possible care to women and their babies and so reduce the number of stillbirths and claims.

4.6.2. Where the possibility of an addition to the CNST Maternity Standards has been identified, further investigations need to be made by the DNV maternity project group, starting with a review of the latest claims data to see if there is further or new emerging evidence in claims other than those relating to stillbirths to identify whether the risk areas highlighted by this review are representative of the other maternity claims managed by the NHSLA.

4.6.3. If the risk is identified as high from a claims perspective, either due to the financial cost or the frequency of claims, recent and relevant research will need to be reviewed, the relevant stakeholder groups approached, and the case for a pilot minimum requirement or criterion put to the NHSLA. For a wholly new criterion to be included it will be necessary to remove an existing criterion to maintain a total number of 50 criteria but the addition of a new minimum requirement within an existing criterion does not create quite the same problem.

4.6.4. Finally, the opportunity should be taken to share real claims cases with healthcare professionals to help bring to life the areas where practice and performance have not met the standard expected within maternity services. This may be another way of trying to reduce the risk of reoccurrence for future women and their babies.

5. Conclusions

5.1. Introduction

5.1.1. It must be stressed that this is not a study of 100 typical stillbirths. Rather, it is an analysis of a very distinct (and relatively small) group of such cases, namely those which have been the subject of claims for damages against English NHS bodies.

5.1.2. Equally, this paper is not an academic clinical study.

5.2. Statistics

5.2.1. CEMACH (p.18) (1) report that in 2007 there were 4,037 stillbirths in the UK and 2,561 in England. The 100 cases in our study were recorded by NHSLA over a period of 21 months which equates to 57 per year. In other words, NHSLA received at the relevant time claims in respect of roughly 2.2% of stillbirths occurring in England.

5.2.2. Given our finding (3.16.16) that the overall success rate of claims in the study is likely to be 72%, this means that roughly 1.6% of all English stillbirths during the period in question will result in a payment of damages by NHSLA.

5.3. Risk Factors

5.3.1. The following findings are suggestive of enhanced risk:

- 18% of claims involved gestation of 41+ weeks
- 29% of claims involved mothers aged 35+
- 11% of claims involved maternal hypertension
- 10% of claims involved a twin
- 8% of claims involved IUGR
- 34% of claims featured admitted misinterpretation of CTG trace, most frequently by a midwife
- 27% of claims featured hypoxia as the known cause of death

5.3.2. These findings are very much in line with those of other studies.

5.3.3. The following factors, unexpectedly, did not demonstrate enhanced levels of risk in the sample chosen:

- Weekends
- Nights
- Mothers aged 40+
- February and August

However, given the relatively small size of our sample, coupled with the fact that many dead fetuses were not delivered immediately upon discovery, it would be wrong to conclude that these factors do not also increase risk.

5.4. Success Rates

5.4.1. As reported at 3.16, the overall success rate for claims in this sample is projected to be 72%, which is much higher than the average of 53% across the entire NHSLA clinical negligence portfolio. This was an unexpected finding. The most likely reason is good case selection by claimants' solicitors. Stillbirths are usually subject to detailed investigation and analysis by NHS Trusts, and the resultant reports are discloseable. Parents' solicitors will therefore see them on application before making a claim and be able to take informed decisions on whether or not to pursue the case. Only likely "winners" will be taken forward.

5.5. The Leading Factor?

5.5.1. If we had to point to one key finding, it would be that 34% of cases involved accepted misinterpretation of CTG traces, and that in 25 of these 34 the failure was by midwives.

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5. National Institute for Health and Clinical Excellence - *Intrapartum care: Care of healthy women and their babies during child-birth*. London, 2008. Available at www.nice.org.uk

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Still Birth Claims Study

Data Recording Sheet

Case No……...

Basic Details	
Age of Mother	
Location of Stillbirth (e.g. maternity suite)	
Day of week (if known)	
Date (omit year)	
Time (use 24 hour clock)	
Gestation (weeks)	
Staffing Issues	
Was consultant present at birth?	
How many staff were present at birth?	
What were their job titles? (e.g. midwife)	
Medical Issues	
Was this a high risk pregnancy? If so, why?	
Was it identified as such? If so, when?	
Was there misinterpretation of a CTG? If so, by whom (job titles)	

Breach of Duty Issues	List	Alleged (Y/N)	Admitted (Y/N)	Causative (Y/N)
Mode of delivery (e.g. vaginal, Caesarean)				
Was the fetus dead before mother entered hospital?				
Was mother monitored - by CTG - by stethoscope - other (please specify)				
Cause of death (if known)				
Legal Issues				
Was breach of duty admitted/accepted?				
Was causation admitted/accepted?				
Was expert evidence obtained from: - obstetrician - feto-maternal specialist - paediatrician/neonatologist - other (please specify)				
Was there a psychiatric injury claim from: - mother - father - other (please specify				
Were there any other claims (e.g. maternal injury)? If so, please specify				

Financial Cost		
	Paid	Outstanding Reserve
Damages Claimant costs Defence costs Total		
File Status		
Open / Closed		