NHS
Litigation Authority

Ten Years of Maternity Claims

An Analysis of NHS Litigation Authority Data

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Contents

1. Executive Summary

This report provides an analysis of the various clinical situations that have led to maternity claims and it is hoped that the information provided will be helpful to those professionals responsible for ensuring the provision of safe care for women and their babies.

Maternity claims represent the highest value and second highest number of clinical negligence claims reported to the NHS Litigation Authority (NHSLA). This is a report of the findings of a project which analysed ten years of maternity claims with an incident date between 1st April 2000 and 31st March 2010 i.e. 5,087 maternity claims with a total value of £3.1 billion. During a similar time period from 2000 to 2009 inclusive, there were 5.5 million births in England.[1] Thus, less than 0.1% of these births had become the subject of a claim, indicating that the vast majority of births do not result in a clinical negligence claim.

The report starts by providing data on the number and value of clinical negligence claims managed by the NHSLA on behalf of NHS organisations. It then describes the role of the NHSLA and sets out the legal background to the claims which form the basis of the project. The methodology used is explained, including the limitations of the dataset. The report goes on to explain the Primary and Secondary Level Studies undertaken as part of the project and the results of those Studies.

The Primary Level Study involved an analysis of the frequency of certain types of maternity claims and the associated financial costs, based on information recorded on the NHSLA's database. This showed that the three most frequent categories of claim were those relating to management of labour (14.05%), caesarean section (13.24%) and cerebral palsy (10.65%). Two of these categories, namely cerebral palsy and management of labour, along with CTG interpretation, were also the most expensive and together accounted for 70% of the total value of all the maternity claims.

Information sheets to support learning have been prepared on each of the categories of claims identified and are appended to this report. These provide details of the number and total value of claims in each category, reference the guidance available to help manage the associated risks, and consider whether management of the risk is adequately addressed in the CNST Maternity Standards.[2] There is a close correlation between the categories of maternity claims identified in the project and the CNST Maternity Standards and a summary document showing the links is also provided.

The Secondary Level Study comprised a detailed review of claims files for four of the categories of maternity claims identified; antenatal ultrasound investigations; CTG interpretation; perineal trauma; uterine rupture. It was thought that this type of analysis may identify factors that could be used to make risk management recommendations, to prevent incidents of harm and reduce the severity of those that do occur. The claim files were reviewed by the solicitors managing the claims on behalf of the NHSLA, using

questionnaires. The results of these reviews are set out in detail in Section 7 within this report.

The key risk management themes to emerge from the project are discussed. Namely, the need to: engage with the risk management process at all levels; provide suitable learning and training; ensure appropriate supervision and support; have in place up-to-date protocols and guidance with which staff are familiar; learn lessons from claims.

The report concludes that the most effective way to reduce the financial and human cost of maternity claims is to continue to improve the management of risks associated with maternity care, focusing on preventing incidents involving the management of women in labour, including the interpretation of CTG traces.

2. Introduction

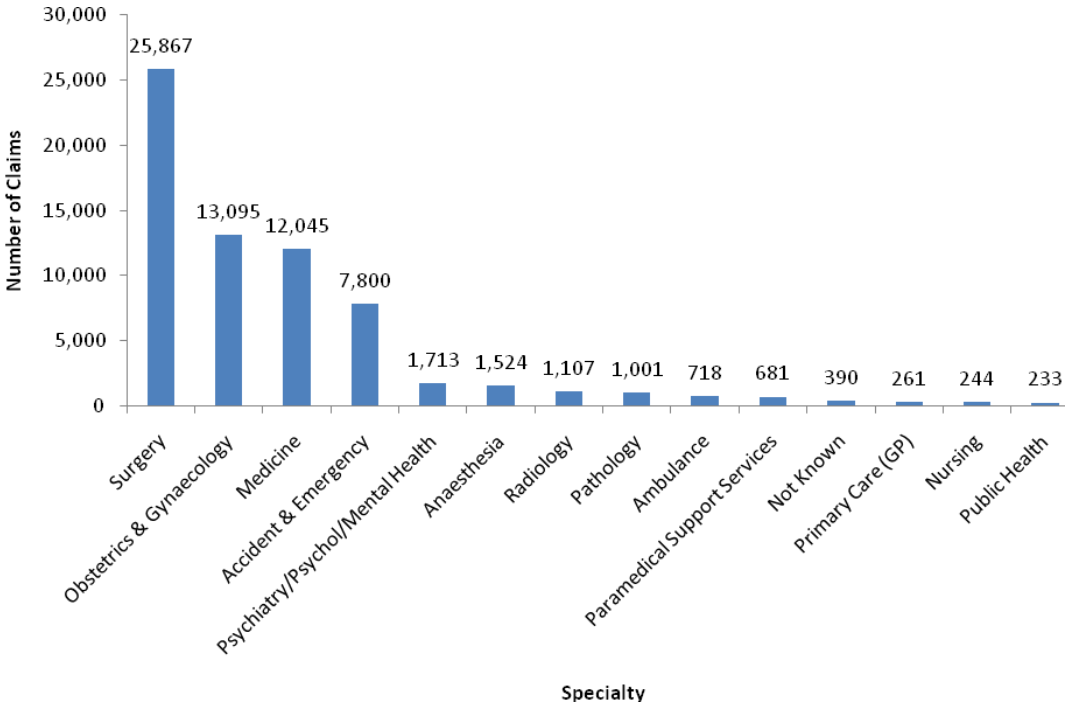
Maternity claims account for the highest value, and the second highest number, of claims under the Clinical Negligence Scheme for Trusts (CNST), a risk pooling scheme for NHS organisations managed by the NHSLA. By the end of March 2011, more than 13,000 obstetrics and gynaecology claims, with a total estimated value in excess of £5.2 billion, had been notified to the NHSLA under the CNST since it started in 1995. As can be seen in Figures 1 and 2, while obstetrics and gynaecology claims totalled approximately half of the number of surgical claims during the same period, the "total value" (see Glossary) was more than double the total value of surgical claims and in fact exceeded the joint total value of claims from the next three biggest specialities, namely "Surgery", "Medicine" and "Accident and Emergency". Overall, obstetrics and gynaecology claims account for 20% of the number of all clinical negligence claims notified to the NHSLA and 49% of the total value, as illustrated in Figures 3 and 4.

This study analysed 5,087 maternity claims on the NHSLA's claims database as at 1st April 2010 with an incident date in a ten year period between 1st April 2000 and 31st March 2010. The total value of these claims was £3,117,649,888. The nature and financial scale of harm reported from maternity units was assessed, to ascertain what lessons can be learned from litigation concerning maternity claims. The aim was to consider data on maternity claims meaningfully from a risk management perspective and to produce information to support learning to improve safety for women and their babies. It was recognised from the outset, however, that the claims dataset had various limitations and these are described in the methodology in Section 5.

An initial review was undertaken by a single researcher of all maternity claims in the ten year period. This formed the Primary Level Study. Litigation files in four specific areas were then considered as part of a Secondary Level Study and questionnaires in those four areas were completed by the NHSLA's solicitors' panel (see Glossary). This gave the study a qualitative as well as a quantitative perspective. To support learning lessons to improve safety, it is intended to use the findings of the study to inform the maintenance and revision of CNST Maternity Standards and design of a better system for coding maternity claims, to assist ongoing analysis and support further learning.

The Primary Level Study provided an analysis of the frequency of certain types of maternity claim and the financial cost of claims in different aspects of maternity care. This financial cost to the NHS is measured in terms of the money paid, and expected to be paid, by the NHSLA for compensation and for claimant and defence legal and other costs (see Glossary) on claims that have been reported to the NHSLA. Thus, the "total value" (see Glossary) includes both payments made and estimates for future potential payments. It does not take into account the "human" cost, to both patients and staff, arising as a result of error and the extra treatment costs incurred by the NHS due to harm which a patient may have suffered.

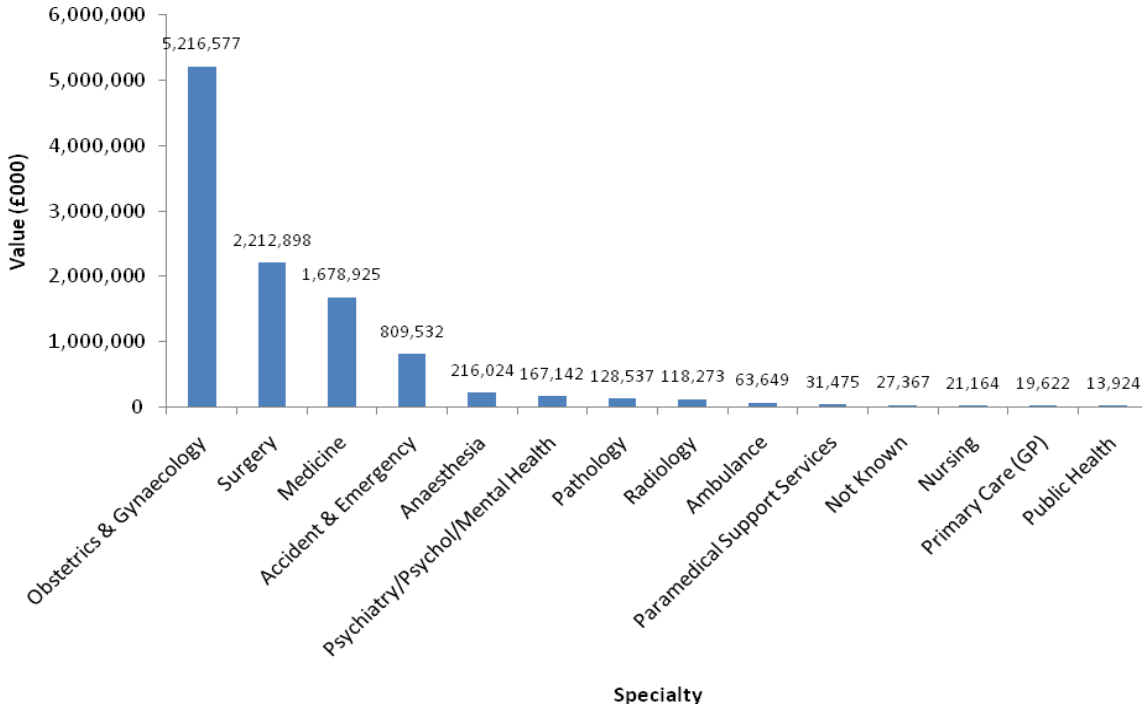
Figure 1 – Total number of reported CNST claims by specialty 01/04/95 to 31/03/11



Note: Excludes below excess claims handled by trusts prior to 01/04/2002

Source: NHSLA Factsheet 3: information on claims (2010/11)[3]

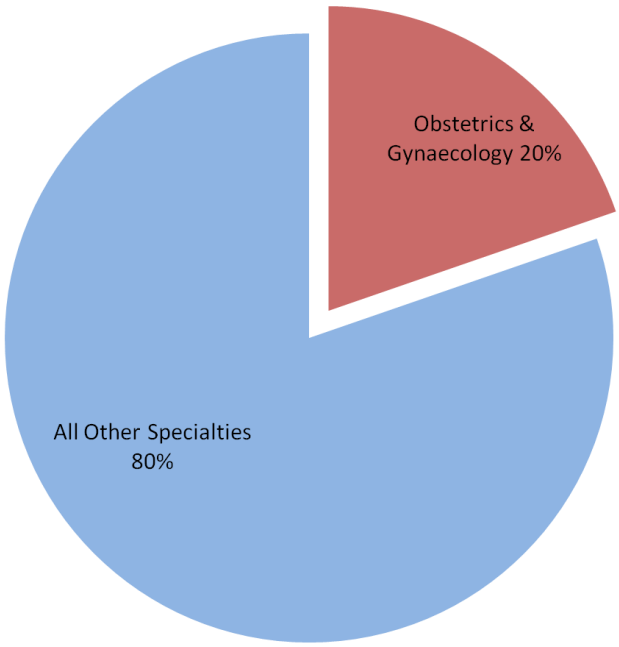
Figure 2 – Total value of reported CNST claims by specialty 01/04/95 to 31/03/11



Note: Excludes below excess claims handled by trusts prior to 01/04/2002

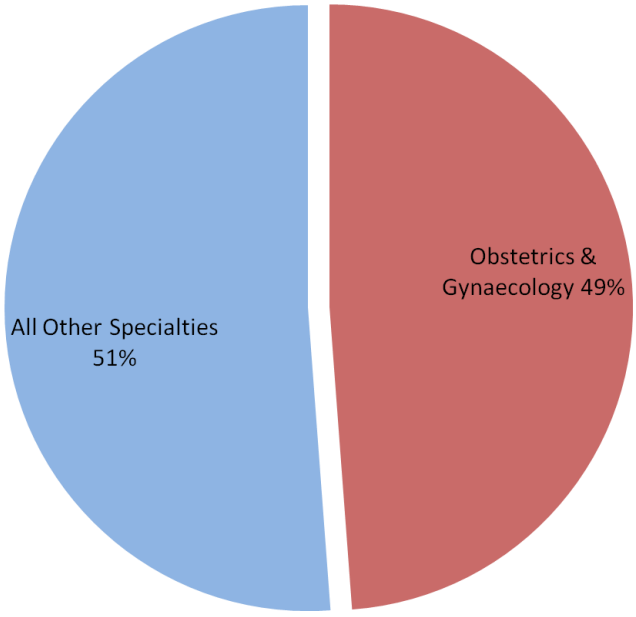
Source: NHSLA Factsheet 3: information on claims (2010/11)[3]

Figure 3 – Total number (%) of reported CNST claims by specialty 01/04/95 to 31/03/11



Note: Excludes below excess claims handled by trusts prior to 01/04/2002
Source: NHSLA Factsheet 3: information on claims (2010/11)[3]

Figure 4 –Total value (%) of reported CNST claims by specialty 01/04/95 to 31/03/11



Note: Excludes below excess claims handled by trusts prior to 01/04/2002
Source: NHSLA Factsheet 3: information on claims (2010/11)[3]

3. NHS Litigation Authority (NHSLA)

The NHSLA is a Special Health Authority which administers risk pooling schemes (similar to insurance) for the NHS, including the CNST which provides a means for organisations to fund the cost of clinical negligence claims. All NHS organisations in England providing maternity services are members of CNST, although membership is voluntary. In administering the schemes, the NHSLA has a remit to contribute to raising the standards of risk management in the NHS by supporting the learning of lessons from claims, to improve safety.[4]

CNST is funded on a pay-as-you-go, non- profit basis. Actuaries predict the total amount expected to be paid by the NHSLA on behalf of all scheme members in each financial year and then apportion this figure between members. For maternity, the number of births is used as the basis to determine contributions. The total gross CNST maternity contribution in 2011/12 was £571 million.

Organisations receive a discount on their contributions when they have demonstrated compliance with the relevant NHSLA risk management standards at assessment. The standards focus on issues which arise in claims and the requirements are based on guidance, and recommendations issued by relevant bodies e.g. National Institute for Health and Clinical Excellence (NICE). All NHS organisations providing labour ward services are assessed against the CNST maternity standards. The CNST maternity standards manual, information on the levels achieved by maternity services in the standards, and copies of assessment reports are all published by the NHSLA on its website at www.nhsla.com.

In addition to this study, the NHSLA has completed another review of maternity claims, publishing a detailed Study of 100 Stillbirth Claims[5] in 2009. Since February 2010, solicitors on the NHSLA's clinical panel have been preparing risk management reports on claims on behalf of the NHSLA, which are sent to the healthcare organisation against which the claim was made, to consider and take appropriate action in respect of the risk issues identified. The NHSLA follows up the reports to ensure that actions have been taken and also collates all the information, to share lessons with the wider NHS. A report[6] has been published on the first year of this initiative, which includes separate findings on maternity claims.

4. Legal Background

Litigation arising from clinical negligence, whilst representing only the tip of the iceberg of claims, complaints, incidents and mistakes which do not result in harm, nevertheless provides a valuable retrospective analysis on the anatomy of error. Legal claims represent only 0.7% of incidents reported to the National Reporting and Learning System (NRLS).[7] Part of the NHSLA's role is to contribute to improvements in risk management in the NHS. Learning from the claims which the NHSLA manages helps towards improving risk management.

Claims for clinical negligence should generally be brought within three years of the incident date, or the date of knowledge of potential negligence, if later. Claims involving children should have court proceedings issued, if necessary, no later than three years from the child's eighteenth birthday. However, where the claimant (see Glossary) does not have capacity, e.g. children who have suffered brain injury, there is no such time limitation (see Glossary) period. It is therefore very likely that a proportion of claims with incident dates within the period covered by the project are yet to be issued. In brain injury claims involving children, investigations may not be started for a number of years and Court proceedings are sometimes only issued once the child has reached an age when it is possible to make an assessment as to prognosis.

For all settled CNST maternity claims, the average time from the incident date to the date the trust was notified of a claim is 1.79 years. For those claims with damages above £1 million, the average time from incident to notification date is 1.72 years. However, these figures are averages and in some cases the time between the incident date and notification of a claim can be considerably longer. For example, the NHSLA still receives notifications of new maternity claims which pre-date the establishment of CNST in 1995.

Once a claim is intimated, it is for the claimant to establish that there has been breach of duty i.e. that the standard of care fell below that to be expected and the clinicians did not act in accordance with what would be considered appropriate by a responsible body of medical opinion. The claimant must also establish causation (see Glossary) by showing that this failure has "caused" or "materially contributed" to the claimant suffering injury, loss or damage. In birth injury claims, for example where a child is left brain damaged, this involves the claimant proving that, on the basis of the CTG trace, delivery should have been earlier than it was on the basis of evidence of fetal heart monitoring or the CTG trace and that this would have prevented some, if not all, of the injury. Unless the claimant is able to establish this causative link between the alleged breach and the damage, the claim will fail.

Compensation awards comprise damages (see Glossary) for pain, suffering and loss of amenity for the injury itself, as well as damages for past and future pecuniary losses. These can include loss of earnings, the cost of care and assistance, technology and physiotherapy needs, aids and equipment as well as the cost of alternative accommodation. The claims reviewed in this study cover injury to both women and babies. A compensation

award of many millions of pounds may be recovered on behalf of a neurologically impaired baby, because of the requirement for continuous care over the lifetime of that individual.

Historically, claims have been settled by way of a single “lump sum” payment to cover the injury itself as well as all past and future losses. However, it is now more common for the higher value claims to be settled by way of lump sum for the injury, past losses and some future costs such as suitable accommodation and equipment (amongst other things), with future care and case management costs dealt with through annual “periodic payments” (see Glossary). Periodic payments represent an annual payment for life in respect of the future care that will be required to ensure that all needs are met and the injured person is adequately compensated. It is index linked to protect against inflation. The security of knowing that a regular payment will be made means that the claimant’s family do not need to seek specialist investment advice to ensure that suitable returns are made to cover inflation.

For all settled CNST maternity claims, the average time from the incident date to the date when the claim was resolved by the NHSLA is 4.32 years. For claims with damages above £1 million, the average time from incident date to resolution is 8.57 years. The longer time taken to resolve the higher value claims reflects the complex nature of these cases.

5. Methodology

No previous study has looked directly at all the data held by the NHSLA on maternity claims over a ten year period. In considering which claims to include in this study, only claims with an incident date within ten years prior to the start of the project were chosen as it was felt that they would be more relevant to current clinical practice. Claims were initially categorised on the basis of the year in which the incident occurred, in order to establish the number of claims per annum. 5,087 claims notified to the NHSLA as at 1st April 2010 with an incident date in a ten year period between 1st April 2000 and 31st March 2010 were analysed using the descriptive information on the NHSLA claims database. The total value of these claims was £3,117,649,888. Categories describing the clinical situation within which the circumstances giving rise to each claim occurred were identified using a free write description field. Where the coded fields within the NHSLA database provided more detail as to the circumstances of the incident this field was also used to categorise the claims. The resulting quantitative analysis provides details of the number and total value of maternity claims per year over the ten year period covered (Figure 5) and the total number and total value of these claims by descriptor (Figure 6). This formed the Primary Level Study and provided data to analyse specific categories of claims in more detail by way of a Secondary Level Study.

In the Secondary Level Study four categories of claim – those involving antenatal ultrasound investigations, CTG interpretation, perineal trauma and uterine rupture – were selected for a detailed qualitative analysis, in which NHSLA panel solicitors reviewed the claim files. The four categories were chosen subjectively, following discussions with stakeholders, on the basis that not only were they suitably diverse and allowed a review of some of the most expensive claims, but that they were also claims involving both women and their babies. Antenatal scanning is relevant to all maternity units and uterine rupture is becoming a greater risk, given the increase in caesarean sections. In regard to claims concerning women, perineal trauma is one of the largest areas of litigation. Finally, in addition to claims categorised as CTG interpretation, it was felt that CTG interpretation was likely to have been a factor, or the subject of an allegation of negligence, in a number of claims in three other categories, namely management of labour, cerebral palsy and caesarean section. Whilst cerebral palsy accounted for the largest total value, it is not in itself a ‘cause’ but rather a ‘condition’ arising out of a cause and was therefore not chosen for further study. It may, however, be a risk area which merits separate review in due course.

For each of these four categories, questionnaires were prepared following consultation with project stakeholders and these are included at Appendices 21 - 24. The questionnaires were then sent to the ten solicitors firms on the NHSLA clinical panel. The solicitors were asked to complete questionnaires only on those claims with an incident date on or after 1st April 2000 where a Letter of Claim was served or Court proceedings had been served, if there was no Letter of Claim. The files for review included both open and closed claims. In respect of claims involving CTG interpretation, panel solicitors were asked to include only

those claims where an admission of breach of duty had been made within claims reviewed, in order to limit the claims to those where there were accepted failures in care from which lessons could be learnt. The completed questionnaires were analysed and full details of the findings in each of the four risk areas are set out in Section 7. Common themes and learning points from the categories of claims reviewed as part of the Secondary Level Study are considered in the results and discussion below.

It was accepted at the outset that this study had a number of limitations, including:

1. Clinical practice has developed during the ten year period, especially in relation to ultrasound and prenatal diagnosis, and it could be argued that only the most recent claims are relevant for learning purposes. However, a review of the last five years of claims would not have produced sufficient numbers of claims for the study to be of any real value, especially as incidents arising in the last three to five years may not yet have been notified to the NHSLA. A further study in, say, 2015 may provide a clearer perspective on the current position.
2. The NHSLA claims database, which formed the basis of the project, is used primarily for the management of claims and to provide accurate financial reserving for future liabilities. It was not designed to provide an analysis of the clinical situation from which claims arise. There is a basic risk management coding system for all claims reported to the NHSLA but, as with any similar system, use of different operators to enter information into the database may have resulted in some inconsistencies in classification. Additionally, the complex nature of the allegations made in many clinical negligence claims cannot be adequately reflected in the coding. Thus, whilst the NHSLA claims database serves a risk management function, it does not, at this point, provide sufficiently detailed information for specific clinical recommendations to be made. A project is underway, however, with a view to improving the value of the database for learning purposes.
3. Only a limited number of questionnaires were returned in each of the four areas in the Secondary Level Study. Some claims may have been closed and the claims files archived. Furthermore, in a number of claims the results were prepared without reference to the patient's medical records, as the relevant information was available from expert reports which had themselves been prepared from a thorough review of the medical records.
4. In claims such as those relating to management of labour, the allegations were wide ranging and overlapping. They could, for example, include a failure to properly interpret the CTG trace and/or proceed to a caesarean section promptly and/or properly manage the labour, which cumulatively have resulted in a child suffering cerebral palsy. Thus, in terms of coding, such a claim could fall into any one of a number of categories. Where this was the case, the category which most closely described the clinical situation giving rise to the claim was selected. In order to gain as much information as possible from the data, and reduce the number of claims in the broad "management of labour" category, some clinical outcomes have been included in the categories, for example cerebral

palsy. It should also be appreciated that the nature of the allegations can change on more than one occasion during the lifetime of a legal claim.

5. The claims considered included those which were either unsuccessful or withdrawn, and the study therefore took into account claims where the allegations could not be substantiated. NHSLA data indicated that between 1st April 2000 and 31st March 2010, 37.69% of claims (24,050 out of 63,804 open claims) were abandoned by the claimant. In a large number of claims, no admission will have been made and the claim may have been settled on a discounted basis to reflect the risk which each party had of their case not succeeding. While around 40% of all clinical negligence claims brought against the NHS do not result in a payment to the claimant, and others are resolved by way of a reduced payment if a litigation risk exists to both parties, there may still be learning points arising from some of these claims.

6. Results – Primary Level Study

In the initial primary level analysis of the NHSLA claims database, all claims with any links to maternity services (i.e. not just those coded as "obstetrics and gynaecology") were reviewed for their relevance to the project. Following this exercise, 5,087 maternity claims were included in the study. Of these claims, 3,469 had been closed, 1,413 remained open, and 205 were incidents which had been notified to the NHSLA where no formal claim had been made, but one was nevertheless anticipated.

A list of descriptors was then assigned to the data using the most commonly occurring clinical categories seen within the information on the database. An additional category of "Other" was used where the situation occurred very infrequently and detailed analysis was unlikely to provide useful data or risk management recommendations. A single descriptor was assigned to each claim using the limited information available. So, each claim only appears once in the subsequent analysis, even where more than one category may have been relevant.

The total number of maternity claims with an incident date in each financial year and the total value of the damages and costs reserved for, or paid out, in those claims as at 31st March 2010 is set out in the table at Figure 5. These numbers comprise all claims made, though around 37% of all claims are resolved by the NHSLA without any damages being paid to the claimant.

Figure 5: Total number and value of maternity claims by financial year as at 31st March 2010

Financial Year	Number of claims	Total value
2000/2001	692	£315,077,262
2001/2002	643	£297,746,799
2002/2003	690	£439,990,329
2003/2004	683	£368,912,614
2004/2005	649	£459,091,400
2005/2006	588	£455,233,188
2006/2007	517	£371,968,190
2007/2008	362	£226,580,089
2008/2009	222	£148,455,956
2009/2010	41	£34,594,061
Total	**5,087**	**£3,117,649,888**

While the results in Figure 5 show a reduction in the number of claims from 2005/2006 onwards and a reduction in the total value for these claims it should be appreciated that additional claims will be reported for the financial years from 2005/6 onwards (and earlier years too) in due course. Claims relating to birth injury may take a number of years to be investigated by the claimant's representatives and brought to the attention of the NHSLA, particularly if the claimant's representatives have not completed their investigation into liability, or the age of the child does not allow an accurate assessment of condition and prognosis to be made.

The Primary Level Study then looked at the number and total value of claims according to the different descriptors, as set out in Figure 6. The three most frequent categories of claim were those relating to management of labour, caesarean section and cerebral palsy. Interestingly, two of these categories namely cerebral palsy and management of labour were also the most expensive along with CTG interpretation. These categories of claims include high value claims where a child has been left with a significant brain injury due to alleged negligence at birth. Although the study included cerebral palsy as a category of claim, this essentially referred to the condition that arose as a result of alleged negligence rather than the cause itself and was one reason why this category was not chosen for the Secondary Level Study on this occasion. What is most striking from Figure 6 is that three categories of claim (CTG interpretation, management of labour and cerebral palsy) account for approximately 70% of the total figure of £3.1 billion, paid out on or expected to be paid, for all maternity claims. Figure 7 shows the top 10 categories of claims by number and Figure 8 the top 10 by total value.

Information Sheets providing: details of the number and total value of claims in each category; guidance, including reference sources, available to help manage the associated risks; and details to consider whether management of the risk is addressed in the CNST Maternity Standards, can be found at Appendices 1 - 19. These Information Sheets are intended to assist with learning and training.

Figure 6: Total number and value of claims by category between 1st April 2000 and 31st March 2010 as at 31st March 2010

Category	Number of Claims	(%)	Total value	(%)
Accident	58	1.14	£728,796	0.02
Anaesthetic	172	3.38	£19,249,853	0.61
Antenatal care	391	7.68	£144,811,665	4.64
Antenatal investigations	230	4.52	£149,986,770	4.81
Bladder	72	1.41	£8,824,269	0.28
Caesarean section	674	13.24	£216,167,223	6.93
Cerebral palsy	542	10.65	£1,263,581,324	40.52
CTG interpretation	300	5.89	£466,393,771	14.95
Drug error	83	1.63	£8,759,430	0.28
Management of labour	715	14.05	£424,039,651	13.60
Maternal death	38	0.74	£20,253,906	0.64
Nursing care	35	0.68	£511,700	0.01
Operative vaginal delivery	160	3.14	£93,659,223	3.00
Other	265	5.20	£40,252,783	1.29
Perineal trauma	441	8.66	£31,202,836	1.00
Postpartum haemorrhage	111	2.18	£3,024,833	0.1
Psychological	28	0.55	£681,791	0.02
Retained swabs	186	3.65	£3,021,910	0.1
Shoulder dystocia	250	4.91	£103,520,832	3.32
Stillbirth	251	4.93	£15,712,695	0.50
Uterine rupture	85	1.67	£103,264,627	3.31
Total	**5,087**		**£3,117,649,888**	

Figure 7: Top 10 categories of claims by number between 1st April 2000 and 31st March 2010 as at 31st March 2010

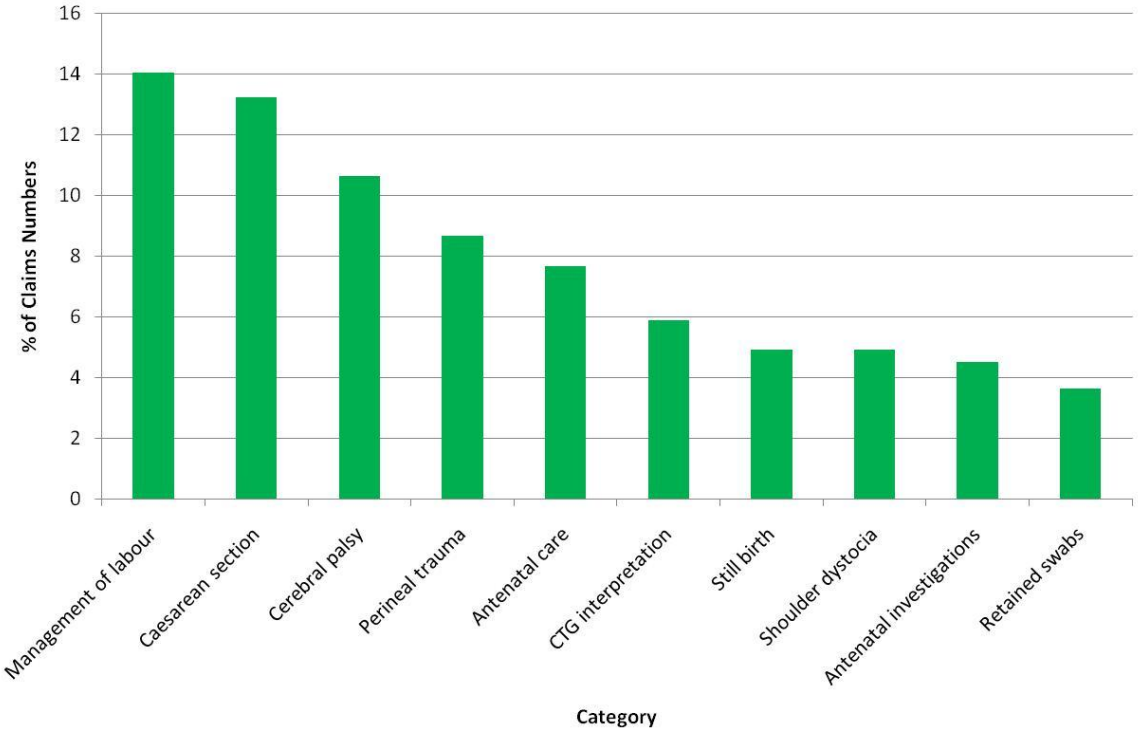
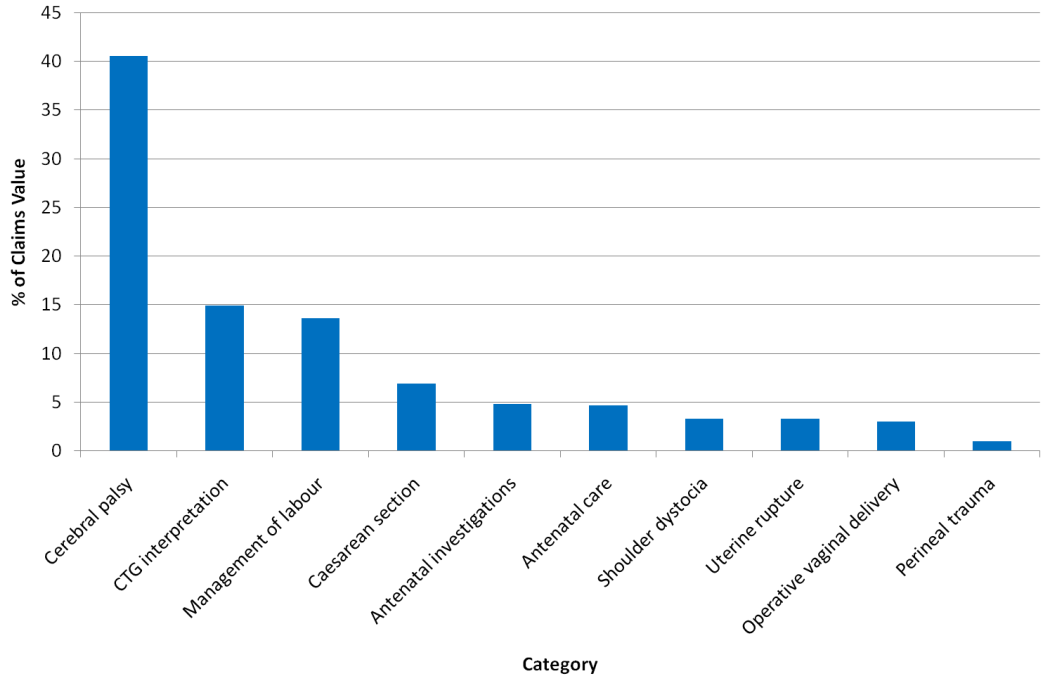


Figure 8: Top 10 categories of claims by total value between 1st April 2000 and 31st March 2010 as at 31st March 2010



The CNST Maternity Standards and assessments were introduced by the NHSLA in 2003 in response to the number and value of maternity claims, with the aim of improving the safety of women and their babies. The Standards provide a framework within which to focus risk management activities, and encourage and support maternity units in taking a proactive approach to improvement. Since they were introduced, the Standards and assessment process have undergone a fundamental review and are updated on an annual basis. There is a close correlation between the categories of maternity claims identified in the project and the risk areas addressed by the Standards, and a summary document showing the links is provided at Appendix 20.

7. Results – Secondary Level Study

A more detailed review of specific claims in respect of antenatal ultrasound investigations, CTG interpretation, perineal trauma and uterine rupture was undertaken. Some of the key findings from the Secondary Level Study can be summarised as follows:

a. Antenatal Ultrasound Investigations

Forty questionnaires were returned out of a possible 92 reported incidents. These 92 were chosen from 230 claims concerning antenatal investigations as they related solely to ultrasound scanning as opposed to any other investigation. The majority of claims related to interpretation by ultrasonographers (42.5%) although some involved specially trained midwives (25%) and obstetricians (27.5%). The Royal College of Obstetricians and Gynaecologists (RCOG) recommended, in 2008[8], guidelines for a minimum standard for the 20 week anomaly scan, but practice remained variable across the country until 2005 when additional guidance[9] was issued. In only 60% of claims could it be said with any certainty that there was a protocol in force, and this analysis highlighted the need to ensure that protocols are up to date with national guidance and that staff follow such protocols. In 72.5% of the claims, human error in the interpretation of the scan was felt to be the most common cause for the failure to detect the anomaly in question. Whilst improved training will address knowledge-based mistakes, effective audit of claims and discussions within units of difficult scans is also likely to assist in combating mistakes in interpretation of scans.

b. CTG Interpretation

The largest number of completed questionnaires, 170, was from claims handled in this category. With an admission in these claims that there had been a failing in the standard of care provided, this category allowed a more informed view to be taken as to the reason for the failings and measures needed to improve safety. The main allegations centred on the failure to recognise an abnormal CTG and act on it. Only 35 (21%) of the claims involved high risk pregnancies, indicating the importance of the effective monitoring of all women. As to the timing of the events in question, 103 claims (60%) related to an incident which took place “out of hours” i.e. 8:00pm to 8:00am between Monday and Friday or during the weekend, but it is possible that within this category the mother may have been admitted to hospital between 8.00am and 8.00pm on a week day. There was no clear correlation between the material event and when it occurred. In 49 out of the 50 claims involving midwives, it was argued that obstetric assistance was required but only in 16 was it actually sought. It is thought that the main reason for this is that in the 33 remaining claims the midwife thought that the CTG was normal and obstetric intervention was not needed. As may be expected, the majority of the claims related to pregnancies at term. Interestingly, however, the highest number of claims occurred at 40 and 41 weeks of pregnancy. Based

on the experience of the project group, it is likely that issues concerning CTG interpretation also arose in a number of the claims in the management of labour, caesarean section and cerebral palsy categories.

c. Perineal Trauma

Eighty-three risk management questionnaires were returned. The questionnaires reviewed who conducted the delivery, the repair and post-delivery follow-up, whether the tear was identified, and if the correct grading of the tear was recorded in the records. Damages paid to women in the cohort of 83 claims totalled £9.4 million. Allegations of negligence included failure to consider a caesarean section or perform or extend the episiotomy, and failure to diagnose the true extent and grade of the injury including failure to perform a rectal examination. Failure to perform the repair and the adequacy of the repair itself were also raised as allegations in this cohort of claims. The RCOG has produced Guidelines[10] in this area and in doctor-managed deliveries a tear was identified in all 44 claims, although there were allegations as to whether the severity of the injury was correctly identified. In 23 of the midwife-managed claims and 29 of the doctor-managed claims, allegations were made that the grade of the tear had been incorrect. This analysis showed that the experience of those managing the delivery and repair is relevant in these claims. Thirty-seven claims related to occurrences between 8:00am and 8:00pm Monday to Friday and 46 occurred outside these hours, effectively indicating no difference between care provided in and out of hours.

d. Uterine Rupture

Of the 45 claims considered, analysis of the claims data linked 19 to vaginal birth after caesarean section (VBAC). The total value for these claims was £103,264,627. In 47% of the claims one of the main allegations was that there was a delay in recognising rupture or impending rupture, and in 24% of claims there was an alleged failure to offer maternal counselling as to the mode of delivery. In 49% of the claims there had been a consultant obstetrician or a consultant midwife involved in the discussion concerning the mode of delivery, but only in 22% of claims did a discussion as to the mode of delivery take place in a VBAC clinic. In only 18 out of 45 claims was an approved guideline in place, with 6 claims having no guideline and 21 claims where it was not known if there was a guideline. Finally, out of 45 claims, delivery took place between 8:00am and 8:00pm in 24 claims and outside these hours in 18, with 3 unknown. Again, suggesting no difference between care provided in and out of hours.

a. Antenatal Ultrasound Investigations

Contents

1. Overview

This study analysed clinical negligence claims reported to the NHS Litigation Authority (NHSLA) which related to ultrasound scanning, to consider what could be learned from a risk management perspective. 40 claims concerning allegations of negligence relating to antenatal ultrasound scans and reported to the NHSLA with an incident date between 1st April 2000 and 31st March 2010 were reviewed and questionnaires addressing key themes were completed by the NHSLA panel solicitor handling the claim.

Whilst only a very small proportion of routine fetal examinations by ultrasound result in legal claims, the financial cost to the NHS is significant. In the majority of the claims settled it was felt that human error was the main contributing factor for the failure to detect the abnormality. This study highlights the need for continued training, supervision and improved systems to combat mistakes in interpretation of ultrasound scans to detect fetal abnormalities which result in legal claims for "wrongful birth".

Over the ten year period of the study more units will have implemented national guidelines, thereby changing local practice. However it was the introduction of National Screening Standards in 2010[1], which clearly defined which fetal parts should be examined and how images should be captured and stored, that are likely to have had the greatest impact.

2. Introduction

Compared to the estimated total number of antenatal ultrasound investigations undertaken in maternity units across the country, only a very small number of scans resulted in litigation because of an alleged failure to detect a fetal anomaly. Nevertheless, such claims can result in awards of damages totalling many hundreds of thousands of pounds in addition to the emotional, psychological and practical effect on a family who have a child born with a disability which could have been detected. Some abnormalities are not detectable and in a proportion of claims considered the central issue was whether the abnormality was visible to the reviewer when the scan was undertaken. Legal claims in such cases can be brought by the mother of the child who is born with the abnormality on the basis that, had it been detected, she would have been offered counselling and the option of termination and would have chosen to terminate the pregnancy. Such claims are commonly known as "wrongful birth" claims.[2] Compensation is sought to cover the additional cost to the parents of bringing up a disabled child. Whilst there have been a number of studies on the effectiveness of routine ultrasound for the identification of fetal abnormalities, there has not been any research linked to legal claims for compensation arising from a failure to detect such abnormalities.[3] This study describes a survey of such claims arising from alleged negligence, in order to determine what risk management lessons can be learned, and what measures might be put in place to limit future claims.

3. Study population

During the period covered by the study, 230 claims were identified as relating to antenatal investigations, of which 92 related to ultrasound scans in the antenatal period. Standard questionnaires (Appendix 21 - 24) were sent to the solicitors handling these 92 claims on behalf of the NHSLA.

4. Questionnaire design

The questionnaire for this study was designed to determine specific details of the pregnancy and scan, for example the gestation at which the alleged negligent scan(s) were undertaken, the nature of the abnormality, whether there were mitigating factors such as maternal obesity, previous abdominal surgery and scarring, reduced liquor volume, and whether the scan was undertaken during the working day (8:00am to 8:00pm) or out of hours. NHSLA panel solicitors were also asked to identify the title and seniority of the person who undertook the scan, whether the scan took place at a district general hospital or a tertiary centre, and if any fetal ultrasound scanning protocol was in place. Finally, they were asked to identify the main contributory factor(s) in the failure to detect an anomaly, for example human error, systems failure, communication failure or equipment failure. From a legal perspective, the study identified the nature of the allegations, whether an admission of breach of duty for the failure to detect the abnormality was made, and the level of damages and legal costs either paid or reserved.

5. Results

Of the 92 claims identified in the NHSLA database, completed questionnaires were returned for 40 (43%) claims. Failure to return questionnaires may have been because some claim files were closed and archived. The key findings from the data analysed were as follows:

- 20 of the claims considered arose between 2005 and 2008 with the largest number occurring in 2005. There is no identifiable reason why a greater number of claims occurred during this three year period. As the claim is that of the child's mother, to whom a duty of care was owed, it must be brought within three years of the date of the alleged negligence. It is therefore unlikely that any further claims where the scan was undertaken in 2008 or earlier will now be brought.

- 29 claims (72.5%) occurred on Monday to Friday between 8:00am and 8:00pm, with nine incidents occurring out of hours and two unknown.

- 19 claims (47.5%) involved a sonographer or trainee sonographer, and 10 (25%) a suitably trained midwife (see Figure 9).

- 35 (87.5%) of the claims stemmed from a scan undertaken at a district general hospital, with 3 scans in a tertiary centre and 3 not classified.

- Scanned images were saved in only 21 (52.5%) of the cases that were litigated. In most of the claims, unit scanning protocols did not include the requirement to store images if the operator considered all key structures had been examined and appeared normal.

- 15 (37.5%) of the scans in question were performed at 20 weeks, 10 between 21 and 30 weeks, and 15 after 30 weeks. A number of these scans were repeat scans as the relevant health professional had not been able to obtain a clear image on the first scan or time had not allowed for all of the structures to be clearly visualised.

- In 25 (62.5%) of the claims a scanning protocol for the examination of the fetus existed, and a referral procedure was also in place in the event that an anomaly was identified. However, in 14 of the claims the solicitor reviewing the file was unclear whether a protocol was in force and, in one case, there was no ultrasound scanning protocol in place.

- Specialist expertise from an obstetrician or radiologist with an interest in ultrasound scanning was noted to be available but not necessarily requested in 18 (45%) of the claims involved. In 22 (55%), it was not known whether the clinician performing the scan could seek specialist expertise elsewhere within the hospital. However, if the operator felt that the scan itself was normal then it is unlikely that they would seek to obtain a senior specialist opinion.

- Figure 10 sets out the nature of the anomalies which were subsequently found to exist. The most common conditions were "development/septal defects/multiple anomalies" and spina bifida, which together accounted for 27.5% of the claims reviewed.

- From a legal perspective, the most common allegation was failure to identify the abnormality. It is accepted that a referral to a tertiary centre would be needed to make some of the diagnoses, but the claimant’s case is very often that had a secondary abnormality been identified, referral would have been made and the more serious primary abnormality would have been diagnosed. This allegation arose in 12 (30%) claims. In 5 claims (12.5%) it was alleged that there was a failure to provide senior review or ensure that senior staff were available to assist. Other allegations included failure to advise of the implications of the abnormality and/or offer termination.

- In 12 (30%) of the claims considered there was a formal admission of breach of duty made for the failure to detect the abnormality. In other claims, where the evidence indicated that there was a litigation risk, settlement was agreed without a formal admission but not at the full value of the claim. At the time the questionnaires were submitted, £10,080,500 had been paid in damages to claimants falling within this category of claim, with a further £39,994,773 reserved for claims yet to be concluded. In addition to this, legal costs of £1,793,735 had been paid to claimants' solicitors and experts, and £667,746 had been paid to solicitors and experts acting on behalf of

the NHSLA. A further £3,706,452 was reserved for claimant costs and disbursements, and £1,715,265 reserved for defence costs and disbursements. There will of course also be additional costs which are not quantifiable, for example ongoing medical treatment and the cost involved in NHS staff handling legal claims.

- In 29 claims (72.5%) human error resulting in incorrect interpretation of the scan was identified as one of the contributing factors, with a system failure occurring in six and communication failure in five claims. In only two claims was there thought to be a possible equipment failure.
- In 16 claims (40%) the pregnancies were identified as being high risk pregnancies although the questionnaire did not seek to ascertain the reason for this.

Figure 9

Job title of health professional (some claims involved multiple scans and a variety of professionals)

Job title	Number of claims	% of claims
Sonographer	17	42.5%
Midwife	10	25%
Registrar	7	17.5%
Consultant	6	15%
Unknown	4	10%
Senior House Officer	2	5%
Trainee Sonographer (supervised by senior)	2	5%
Obstetric Registrar Trainee (supervised by Sonographer)	1	2.5%

Figure 10

Nature of structural anomaly (where identified)

Number of claims	% of claims	Nature of anomaly
6	15%	Developmental/septal defects/multiple anomalies
5	12.5%	Spina bifida
3	7.5%	Small baby
3	7.5%	Absent/short radius or ulna
2	5%	Twin to twin transfusion syndrome
2	5%	Unilateral renal agenesis
1	2.5%	Septo-optic dysplasia and schizencephaly Abnormal fetal spine Distended bladder/fluid filled bowel loops Exomphalos Vasa previa Right anophthalmos Severe left microphthalmos Malformation of brain including Dandy-Walker variant Bladder exstrophy Mono-amniotic twins Sacrococcygeal teratoma Tetralogy of Fallot Ventriculomegaly AVSD and hypoplastic aortic arch Lumbosacral agenesis Abnormal head shape (Chiari malformation)

Case Study 1

In August Mrs B had her 20 week scan. The sonographer was unable to identify the fetal bladder. A second sonographer was asked to assist but she was also unable to locate the fetal bladder. Mrs B was advised to return to the hospital for a further scan a few days later. Five days later, Mrs B underwent a further scan and on this occasion the sonographer noted that the bladder had been seen. No abnormality was reported.

Mrs B gave birth to her son in December. Shortly after delivery it was noted that his genitalia were abnormal and following a paediatric review he was diagnosed as suffering from bladder exstrophy.

Having obtained expert evidence it was accepted that the antenatal failure to diagnose bladder exstrophy breached the duty of care owed.

6. Discussion

Ultrasound screening is part of the routine antenatal care for pregnant women and is used to screen for and diagnose fetal anomalies which may, in some cases, result in a termination being offered. Whilst the first scan, usually undertaken before 14 weeks, is to establish gestational age, viability, fetal number and increasingly to measure nuchal translucency as part of the combined screening test for Down's syndrome, the routine 20 week anomaly scan is used to screen for a range of structural abnormalities which the fetus may have. It has been shown that routine ultrasound scanning performed by sonographers in low risk populations is effective in detecting many structural malformations and up to 80% of severe or lethal anomalies.[4] In high risk populations, scanned in tertiary units, the detection rate is reported to be higher.[5] Of the claims reviewed here 40% were noted to be high risk pregnancies although it is not known how this may have impacted on the detection in each particular case. The fact that legal proceedings were issued or intimated to the NHSLA in only 92 cases involving antenatal ultrasound scans, during the study period of ten years, would suggest that policies and practices, both in terms of scanning skills, communication and other aspects of a good service, are in place for the majority of routine antenatal scans. This may reflect the recommendations from the RCOG in 2000 suggesting guidelines for a minimum standard for the 20 week anomaly scan[6], although practice across the country remained variable at least until 2005.[7] It will be interesting to repeat this study in a few years time as the UK National Screening Committee set standards for the 20 weeks scan, with a requirement for implementation across England, in 2010.[8] However, those few scans which do result in litigation carry high costs, both in financial, social and emotional terms.

The main limitation of this study is that it involved only a very small number of claims i.e. 92, and the response rate to the questionnaires was only 45%. A further limitation is the quality and variability of the data available both in the questionnaires that were returned and the NHSLA claims database itself, which is focused on coding the different types of maternity

claim and providing financial data on the case. Finally, for reasons of confidentiality, data was ascertained by a survey of different solicitors managing and holding the individual claims rather than anyone with clinical expertise. Nevertheless, although the sample of cases analysed is small, a number of important learning points arise, including:

- *Protocols*: The use of minimum national standards for a 20 week anomaly scan, which form the basis of local protocols, provide clear parameters for sonographers. In only 60% of the claims could it definitely be said that there was a protocol in force. There is a need to ensure that protocols are in place in every unit, that they are effectively implemented and updated, and that staff are aware of how they should be used.

- *Human Error*: In 72.5% of claims, a failure by the individual sonographer to identify the anomaly was considered to be the main contributory factor in the incident. In cases where the sonographer believes the scan to have correctly examined all fetal parts mentioned in the protocol, there may be instances of knowledge-based mistakes. This highlights the need for regular audit to identify systematic errors. Effective audit of cases within a unit will also assist in identifying whether the mistake is a knowledge-based one requiring further education and training or a violation, such as a failure to follow a protocol appropriately.

- *Training*: It has been shown that detection rates rise substantially with training and greater experience[9]. Failure to identify an abnormality may reflect inadequate experience and training. In addition to audit, training programmes should be in place to ensure regular updates are available for all staff performing fetal ultrasound. This should include review of complex cases, to familiarise staff with common problems as well as rarer cases.

- *Requesting assistance from senior colleagues*: Whilst in many units senior supervision was available, the central issue is often recognising when to request such assistance. Again, audit can help identify how a systems approach can be taken to ensure supervision is given as needed.

- *Equipment*: Whilst no specific allegations of equipment failure were established, equipment used can affect the results obtained, and units must ensure that equipment is up-to-date, regularly serviced, and staff are fully trained in the use of the equipment. An RCOG Working Party has previously recommended that ultrasound examinations for fetal anomaly detection should be carried out on equipment no older than five years.

- *Lack of documentation*: Images were only available in 52.5% of cases. This may reflect the lack of a definitive guideline suggesting image storage, as RCOG guidelines in 2000 recommended storage of images showing an abnormality but not where the fetus appeared normal. It may also reflect the fact that until recently hard copy image storage was the main option and these degrade relatively quickly over time. With increasing access to electronic image storage, it would be helpful if images of all fetal parts examined were stored, normal and abnormal. The National Screening Committee in its 2010 standards recognises this need and clearly defines which fetal parts should be

examined and states that all required images should be captured, stored and archived for the purposes of a complete maternal record and to fulfil medico-legal requirement.

7. Conclusion

This study showed that, when compared to the potential number of routine antenatal ultrasound scans taken every year, only a small proportion result in litigation and any payment of compensation. A number of cases which are initially investigated by patient representatives may not proceed to the stage of being reported to the NHSLA due to lack of evidence. The implementation of national minimum standards, as recommended by the RCOG Working Group, has meant that in general, standards are such that the incidence of harm and of litigation is kept low. However, the data we present here suggest that further improvement may reduce the level of successful litigation. The 2010 National Screening Committee Fetal Anomaly Screening Programme standards attempt to address many of the issues raised above, concerning image capture of all fetal parts examined and storage of these images. It is to be hoped that widespread implementation and adherence to those standards by maternity units across England will not only further reduce these incidents and in turn claims, but also assist patients and Trusts alike with access to the relevant images in the event of a claim. It will be interesting to see whether the investment in high standards of service delivery, including training and audit, will further minimise error in ultrasound screening for fetal abnormalities and reduce the financial, human and psychological cost of such errors.

8. References

1. UK National Screening Programme and NHS Fetal Anomaly Screening Programme: Standards and Policies http://fetalanomaly.screening.nhs.uk/standardsand policies

2. "B v South Tyneside Healthcare NHS Trust": [2004] EWHC 1169 (QB)

   The claimant's case was that, with competent care, partial sacral genesis should have been detected during an ultrasound scan at 19 weeks gestation and if the claimant had been advised of this she would have asked for and been offered a termination prior to 24 weeks. The court did not find any negligence on the part of the defendant

3. Smith NC, Hau C. A six year study of the antenatal detection of fetal abnormality in six Scottish health boards. Br J Obstet Gynaecol. 1999 Mar; 106(3):206-12.

4. Chitty LS, Hunt GH, Moore J, Lobb MO. Effectiveness of routine ultrasonography in detecting fetal structural abnormalities in a low risk population. BMJ. 1991 Nov 9;303(6811)1165-9

5. Carrera JM, Torrents M, Mortera C, Cusi V, Muńoz A. Routine prenatal ultrasound screening for fetal abnormalities: 22 years' experience. Ultrasound Obstet Gynecol. 1995 Mar;5(3):174-9

6. Routine Ultrasound Screening in Pregnancy: Protocol, Standards and Training Supplement to Ultrasound Screening for Fetal Abnormalities. London : RCOG 2000

7. Antenatal Ultrasound Screening. Ultrasound survey of England 2002. UK National Screening Committee 2005

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9. Tegnander E, Eik-Nes SH. The examiner's ultrasound experience has a significant impact on the detection rate of congenital heart defects at the second-trimester fetal examination. Ultrasound Obstet Gynecol. 2006 Jul;28(1):8-14

b. Cardiotocograph (CTG) Interpretation

Contents

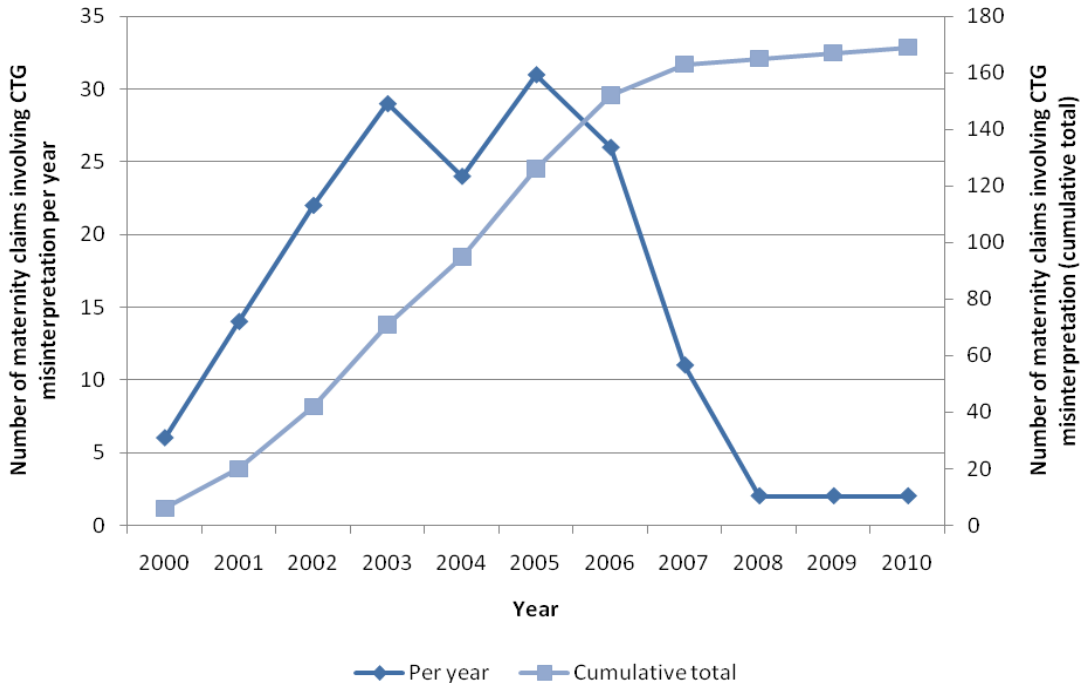
1. Overview

This analysis of CTG claims is based on the information obtained from the responses to a questionnaire, sent out to the NHSLA's panel solicitors in relation to maternity claims with an incident date between 1st April 2000 and 31st March 2010, that have involved alleged CTG misinterpretation or poor management of the results of CTGs. A copy of the questionnaire can be found in Appendix 22. It should be noted that the data obtained from the responses were variable in quality and have only been used where they added value. It should also be noted that there have been many developments in guidance, training and assessment over this period of time. For example, the National Institute for Health and Clinical Excellence (NICE) Intrapartum Care Guidelines[1], and the introduction of the CNST Maternity Standards in 2003[2], which have both been introduced during the period covered in this report.

2. CTG interpretation claims

170 completed questionnaires were returned by the panel solicitors. The questionnaire looked at both human and organisational factors surrounding the 170 claims, as well as the total costs of litigation in this category. Figure 11 shows the number of claims relating to alleged CTG misinterpretation over the ten years. This chart reflects the date of the alleged incident rather than the date the claim was made. As it may take some considerable time for incidents involving CTGs to become claims, it may appear that there have been a reduced number of claims since 2005 but this is not necessarily the case.

Figure 11 – Maternity claims allegedly involving CTG misinterpretation by year of the alleged incident and cumulative figures for 2000-2010



2.1 File status and financial detail

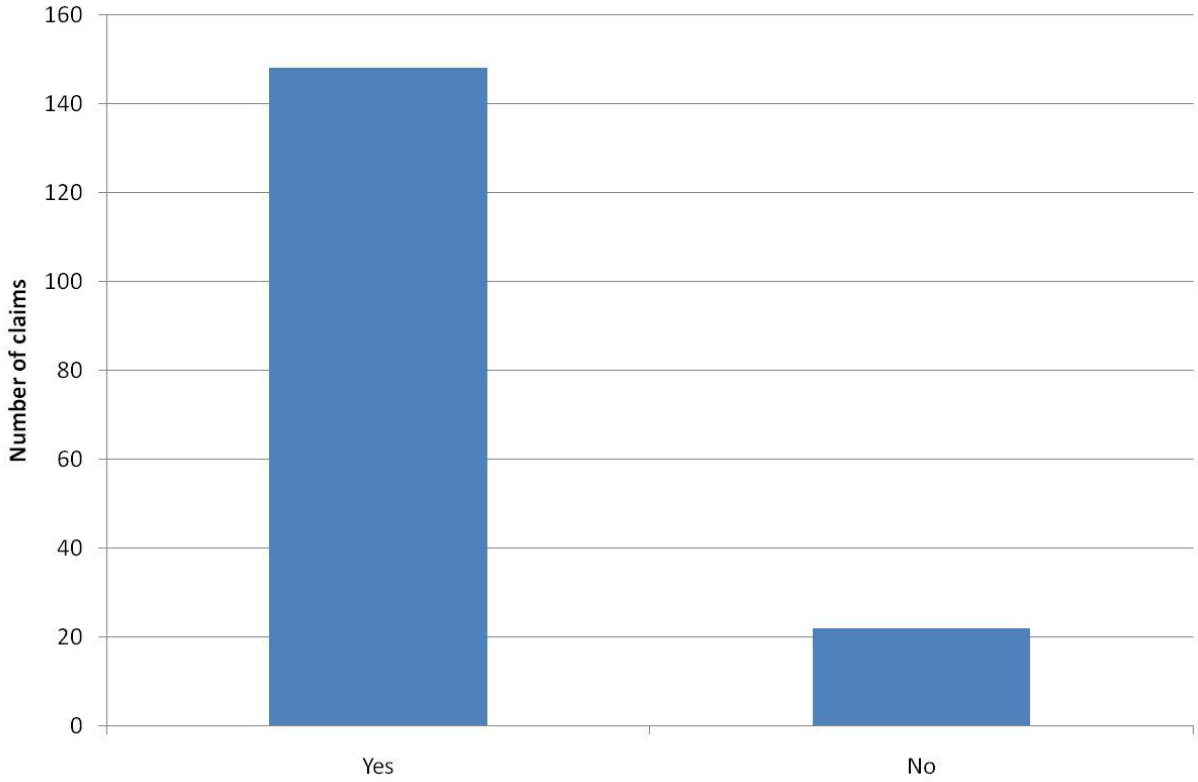
In the ten years covered by the study, 300 claims involving alleged CTG misinterpretation were reported to the NHSLA. The total value of these claims is estimated to be in the region of £466million.

Of the 170 CTG claims analysed, 39 had been closed. Of the remaining 131, some are the subject of Periodic Payments and will remain open for the rest of the claimant's life.

2.2 Misinterpretation of a CTG

In response to the question "Was there a misinterpretation of a CTG?", as shown in Figure 12, 148 of the 170 claims state that there had been a misinterpretation of a CTG. The remaining 22 claims either state that the allegations were not admitted, or that the case related to auscultation of the fetal heart rather than CTG monitoring. However, in the text of the responses, all but one of the claims alleges that abnormal CTGs had not been acted upon. It should be noted that in many units until the NICE Intrapartum Care Guidelines were published in 2007[1], low risk women had their fetus monitored using CTG monitoring rather than intermittent auscultation.

Figure 12 – Was there a misinterpretation of the CTG?

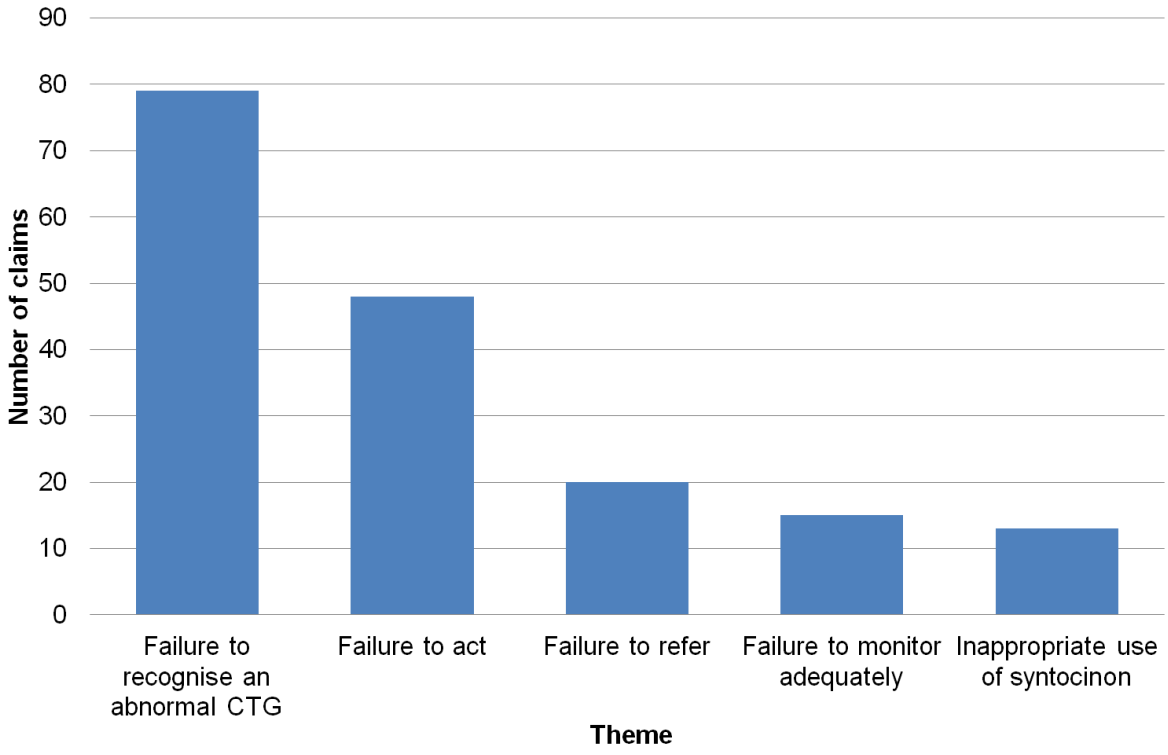


Further analysis of the data showed the following themes:

- failure to recognise an abnormal CTG
- failure to act on an abnormal CTG
- failure to refer appropriately
- continuing to prescribe or administer Syntocinon in the presence of an abnormal CTG
- failure to monitor the fetal heart adequately (mistaking maternal pulse for the fetal heart, failing to recognise 'doubling' on the CTG)
- inadequate documentation

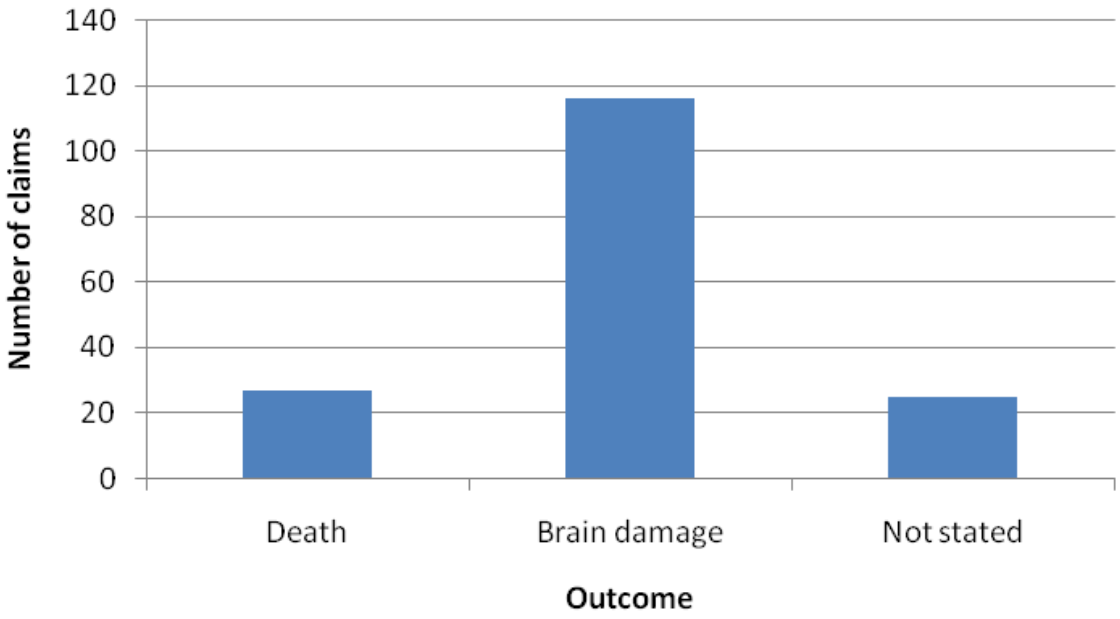
Figure 13 shows the types of misinterpretation and the number of times it was alleged to have occurred in the 170 claims. Some of the themes occur in conjunction with other themes and therefore the total number of incidents on the chart total is more than 148. For example, a claim may involve failure to recognise an abnormal CTG, as well as failure to refer to an obstetrician.

Figure 13 – Themes of misinterpretation of CTG



The outcomes as a result of the alleged misinterpretation of the CTG or auscultation of the fetal heart rate can be seen in Figure 14. One hundred and seventeen claims were for babies born with neurological problems, including cerebral palsy, quadriplegia, hemiplegia and developmental problems. Twenty-seven claims were for the death of a baby or child.

Figure 14 – Outcomes in relation to misinterpretation of a CTG or auscultation of the fetal heart



Case Study 2

A 31 year old woman with a pregnancy at term plus 10 days.

The CTG showed a significant bradycardia down to 40 bpm and 3 late decelerations with slow recovery and reduced variability.

The midwife incorrectly identified the bradycardia as 'reactive'.

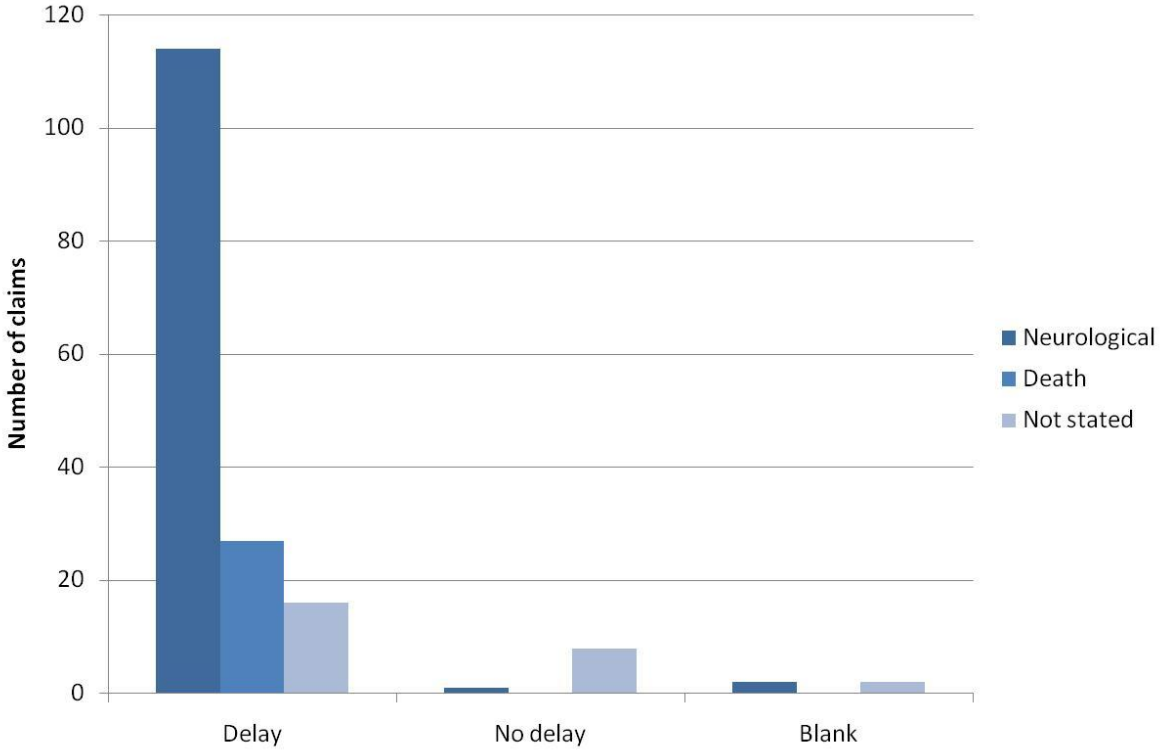
The registrar prescribed syntocinon despite the CTG trace showing no accelerations, reduced variability, significant bradycardia and unprovoked decelerations.

The midwife then increased the dosage of syntocinon several times despite the abnormal CTG trace.

Whilst the claimant has normal tone with no spasticity, ataxia or dystonic posturing, they will have significant cognitive impairment and be incapable of independent living. The claimant shows speech delay, is microcephalic and suffered from complex febrile seizures.

Figure 15 shows the clinical outcome for the baby where delivery was delayed. Unfortunately, the data were insufficient to indicate the reason for the delay.

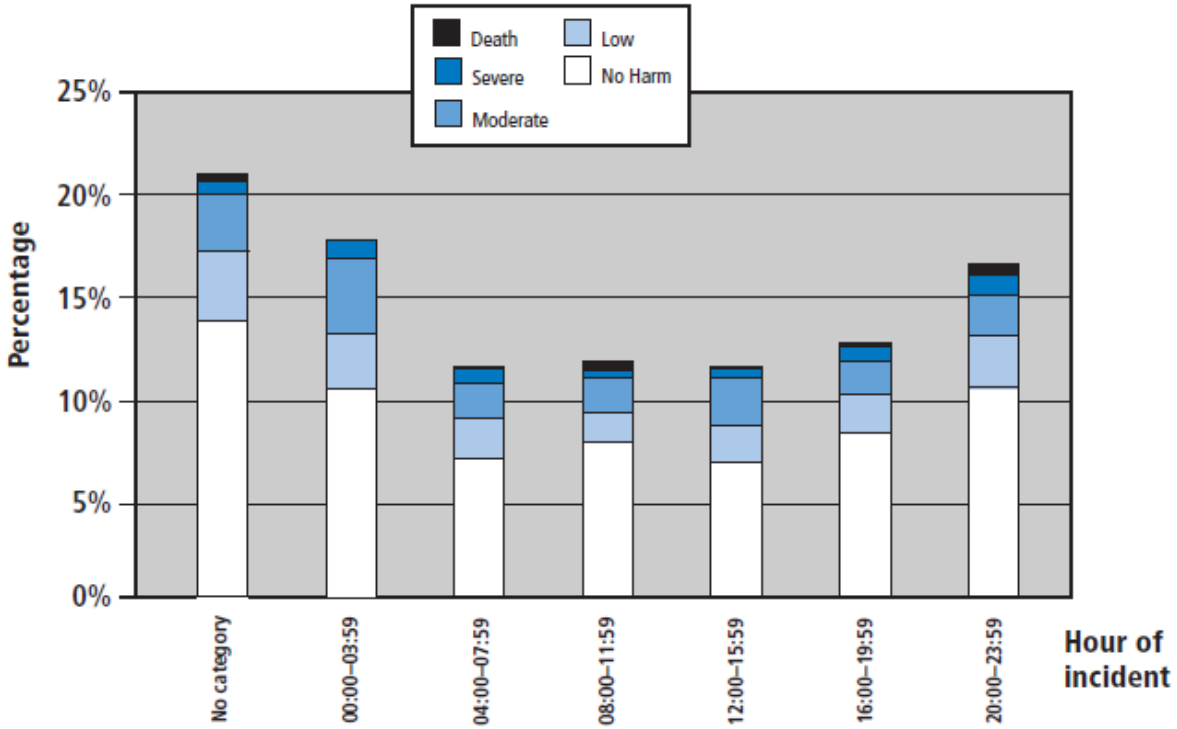
Figure 15 – Outcome in relation to delay in delivery



2.3 Time of alleged negligence

National Patient Safety Agency (NPSA) National Reporting and Learning System (NRLS) data from 2009, published in *Safer Childbirth*[3], showed that approximately the same percentage of reported fetal compromise incidents occurred between the hours of 8:00am and 8:00pm and between 8:00pm and 8:00am, although the data did not distinguish between weekdays and weekends and over 20% of data did not specify the time. A graph of the data is reproduced at Figure 16.

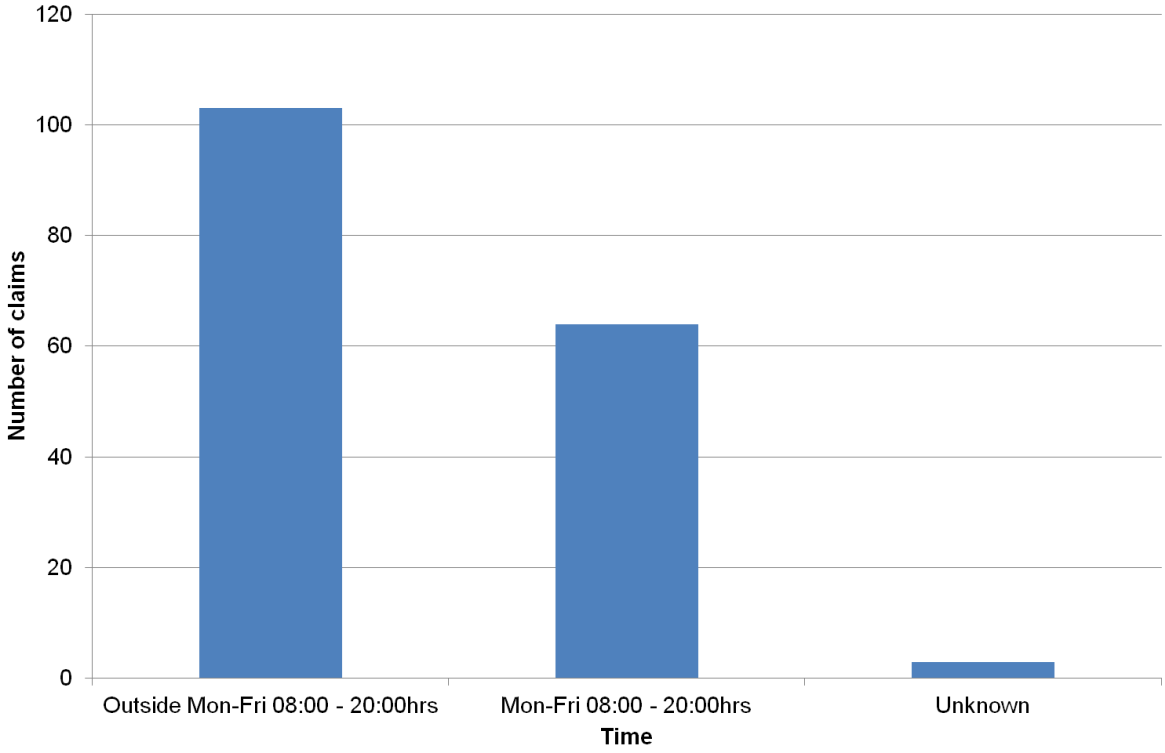
Figure 16 – Fetal compromise incidents reported to NPSA (degree of harm by hour of incident)*



* taken from *Safer Childbirth*[3]

Analysis of the claims data relating to the timing of the event, and whether or not it occurred during the time period of Monday to Friday between the hours of 8:00am and 8:00pm, showed that 103 (60%) of the claims relate to an incident that took place out of hours. These data are illustrated in Figure 17. However, when the number of hours in a week are split between in and out of hours and taken as a percentage, 64% of the time is out of hours. So there is no difference between the rates of errors in and out of hours in the claims reviewed. This finding does, however, need to be treated with some caution, as the time recorded on claims will often be the time of birth and may not be the time when the error(s) which resulted in the claim occurred.

Figure 17 – Time of the alleged incident



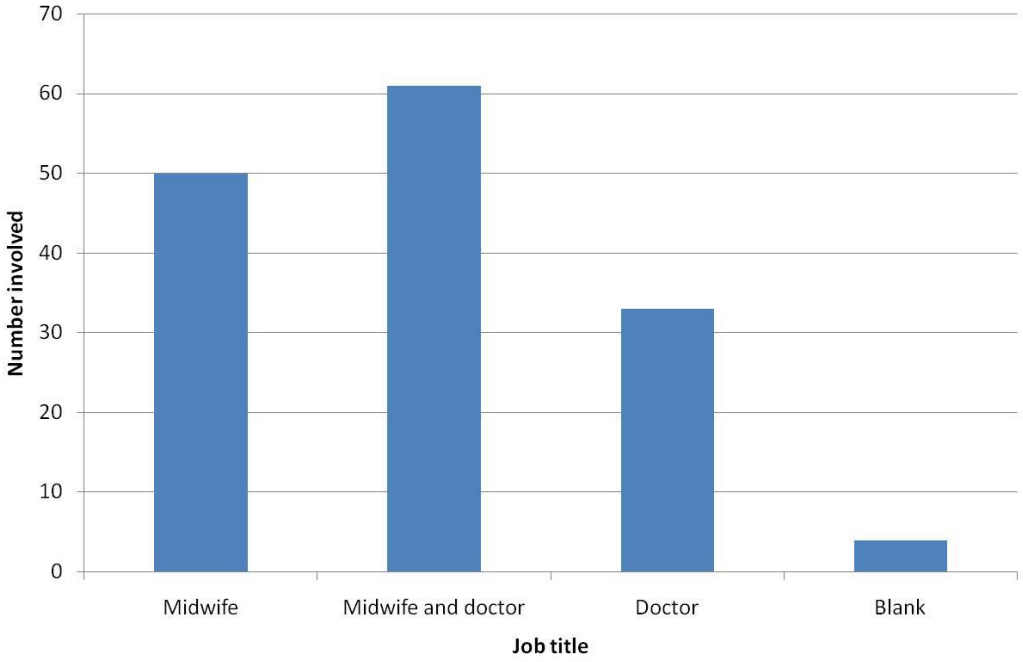
Changes to the working patterns of junior doctors and the standards for labour ward consultant presence mean that in future there will be an increase in obstetric consultant cover out of hours in the largest maternity units.[4] In addition to obstetric cover, *Safer Childbirth*[3] outlines the suggested midwifery staffing levels necessary to maintain safe care in all midwifery settings, not just on the labour ward.

Job title of the staff

When analysing the job title of the staff alleged to have misinterpreted the CTG, there is a variety of staff involved and in many cases there is more than one healthcare professional involved in the alleged misinterpretation (Figure 18). The largest single group is midwives, who alone are the subject of 50 of the claims which reflects that midwives care for all women in labour. A combination of midwives and various grades of doctors are named in 61 claims, and various grades of doctors alone in 33 claims.

Of the 50 claims involving midwives, it was suggested that obstetric assistance was required in 49 claims, but in only 16 of those claims was assistance sought, mostly because in the remaining 33 claims the midwife thought that the CTG was normal and obstetric intervention was not required.

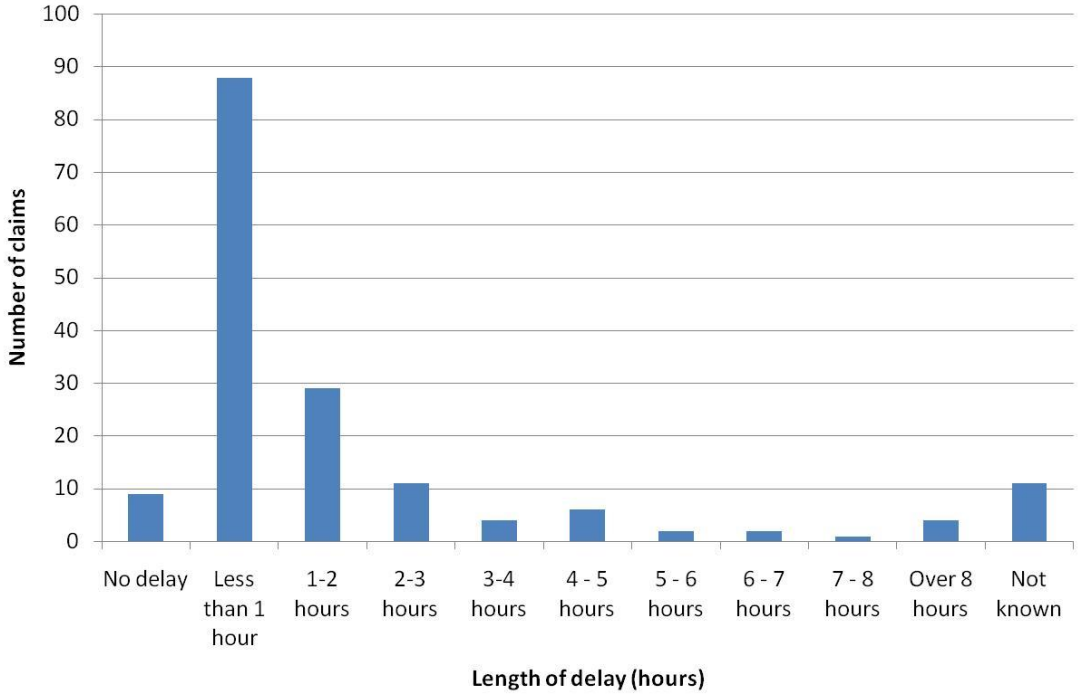
Figure 18 – Job title of those involved in the misinterpretation of CTGs



2.4 Delay in delivery

Whether or not the misinterpretation of the CTG led to a delay in delivery, cannot be identified from the data available. However, Figure 19 shows the scale of the alleged delays.

Figure 19 – Length of alleged delay

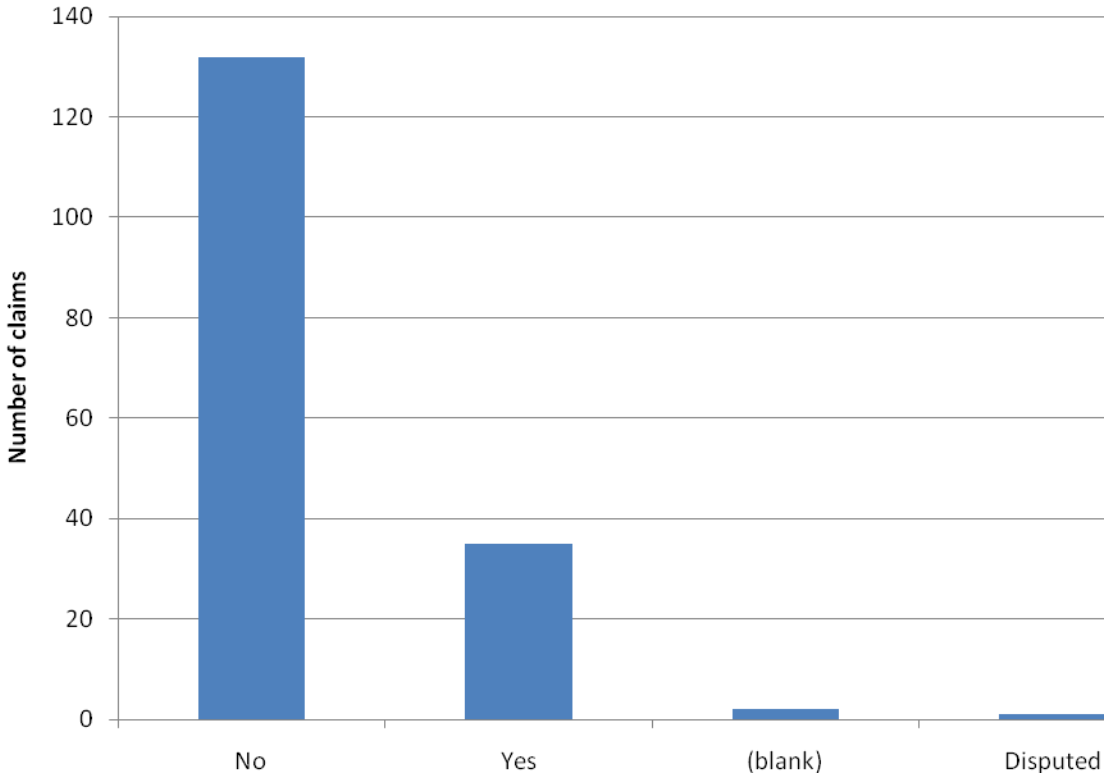


2.5 Was this a high risk pregnancy

Although there appears to be no universal definition of a "high-risk" pregnancy, it is generally thought of as one in which the mother or the developing fetus has a condition that places one or both of them at a higher-than-normal-risk for complications, either during the pregnancy , during delivery, or following the birth[5].

As shown in Figure 20, only 21% (35) of the claims involved high risk pregnancies. Of these 35 claims, five had not been identified as being high risk.

Figure 20 – Was this a high risk pregnancy?



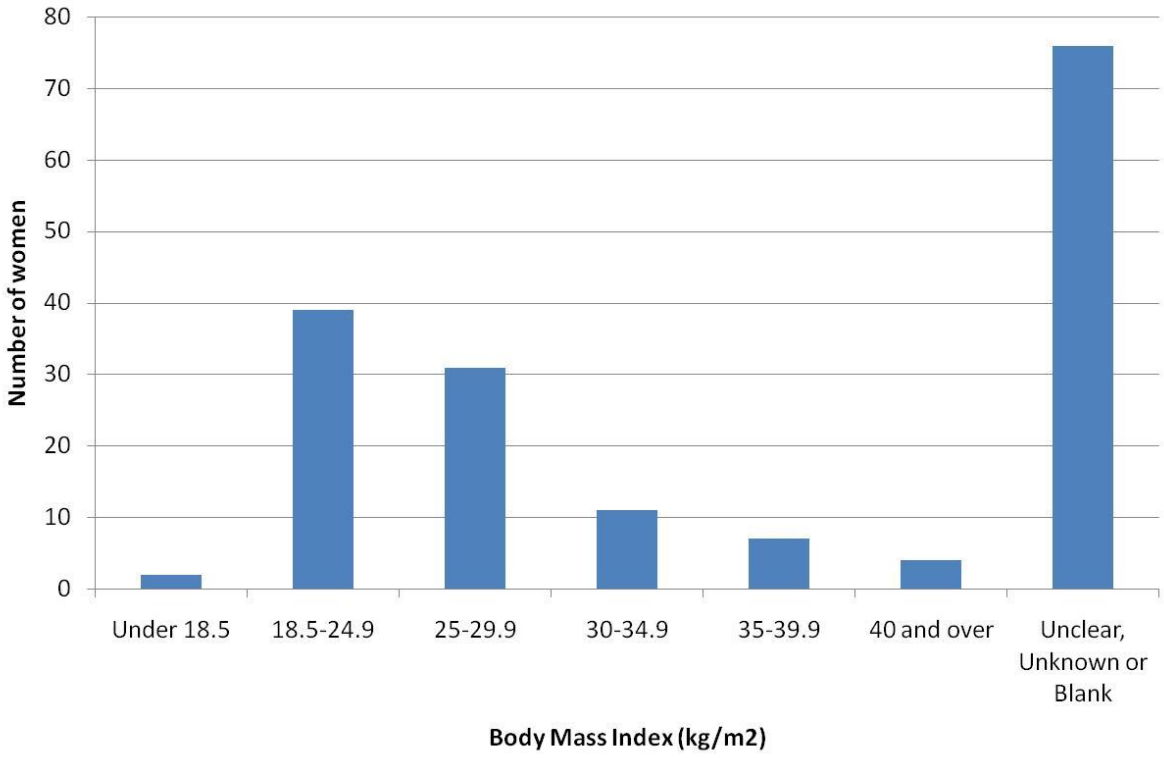
3. Background data

3.1 Body Mass Index (BMI)

In *Saving Mothers' Lives*[6], maternal obesity has been highlighted as a risk factor for maternal death, and it cites Office for National Statistics (ONS) data and work done by Helsehurst et al to show that as the overall prevalence of obesity has increased in the general population so it has in pregnant women. In 2007, it was estimated that 24% of women in the UK aged 16 years or more were obese.[7] This is an increase from the 16% calculated for 1993.[8]

Figure 21 shows the BMI of the women in the maternity CTG interpretation claims data, categorised according to NICE classifications.[9] 23% of the women were in the "healthy weight" category. More than 50% of the claims either showed no BMI data or the information was unclear or unknown but this may be due to the fact that recording of BMI had not always been routine practice, until the introduction of the NICE Antenatal Care Guidelines in 2003.[10]

Figure 21 – Recorded BMI of women in the CTG claims data



Case Study 3

A 30 year old woman with a BMI of 42.

There was no clinical guideline at the time for the management of meconium stained liquor.

No observation chart was commenced and no blood pressure (BP) measurements were taken overnight.

There was inadequate exchange of information on the shift change, so the night staff were unaware of the risk factors identified on admission despite these being recorded in the notes.

The senior midwife was unaware of all of the risk factors.

It was alleged that obstetric staff were called to review the woman, but they reviewed the early CTGs in isolation and did not examine her or document the review it in the notes.

There was a delayed transfer to the labour ward and the claimant was not examined by an obstetrician on transfer to the labour ward.

The specialist registrar was not informed of the hypertension and reduced fetal movements when asked about a possible epidural.

There was alleged failure to recognise and act upon the significance of the decelerations of the fetal heart rate and in the meantime continuing Syntocinon.

The midwife did request obstetric assistance, but from the senior house officer.

Baby was stillborn.

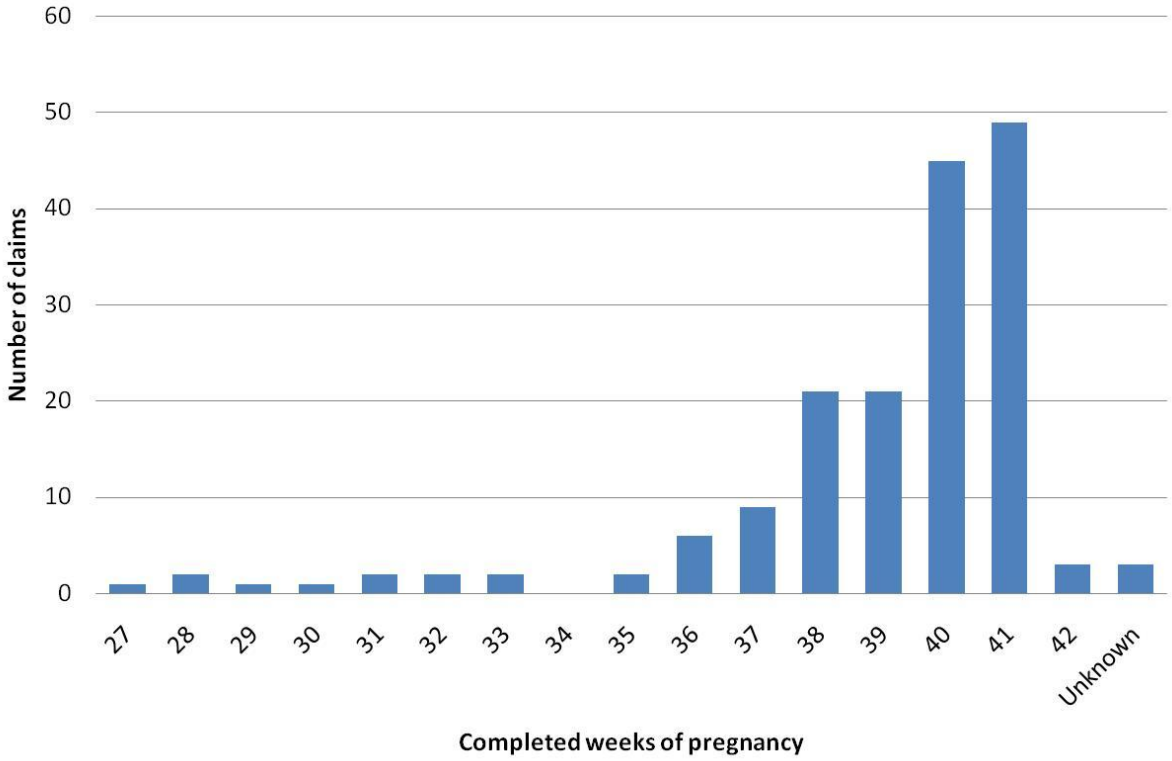
Notes were written retrospectively for the last two hours of labour.

3.2 Gestation (weeks) at time of negligence

The data for the gestation in weeks at the time of the alleged negligence were recorded in various ways, which made it more difficult to interpret, and therefore some assumptions had to be made regarding the number of weeks through pregnancy the alleged incidents occurred. Gestation ranged from 27 weeks to 42^{+6} weeks.

From Figure 22 it can be seen that where the gestation was known, 11% of pregnancies were preterm (less than 37 completed weeks), 1% occurred when the pregnancy was post-mature and the remaining 86% occurred when the pregnancy was between 37^{+1} and 42^{+0} weeks gestation. Interestingly, the highest number of alleged incidents of negligence occurred at 40 and 41 weeks. By looking at the completed weeks of the pregnancy at the time of the alleged negligence, it can be seen that the majority of the claims relate to pregnancies at term, which is not unexpected as the claims relate to CTG interpretation in labour.

Figure 22 – Completed weeks of pregnancy at the time of the alleged negligence



3.3 Birth weight

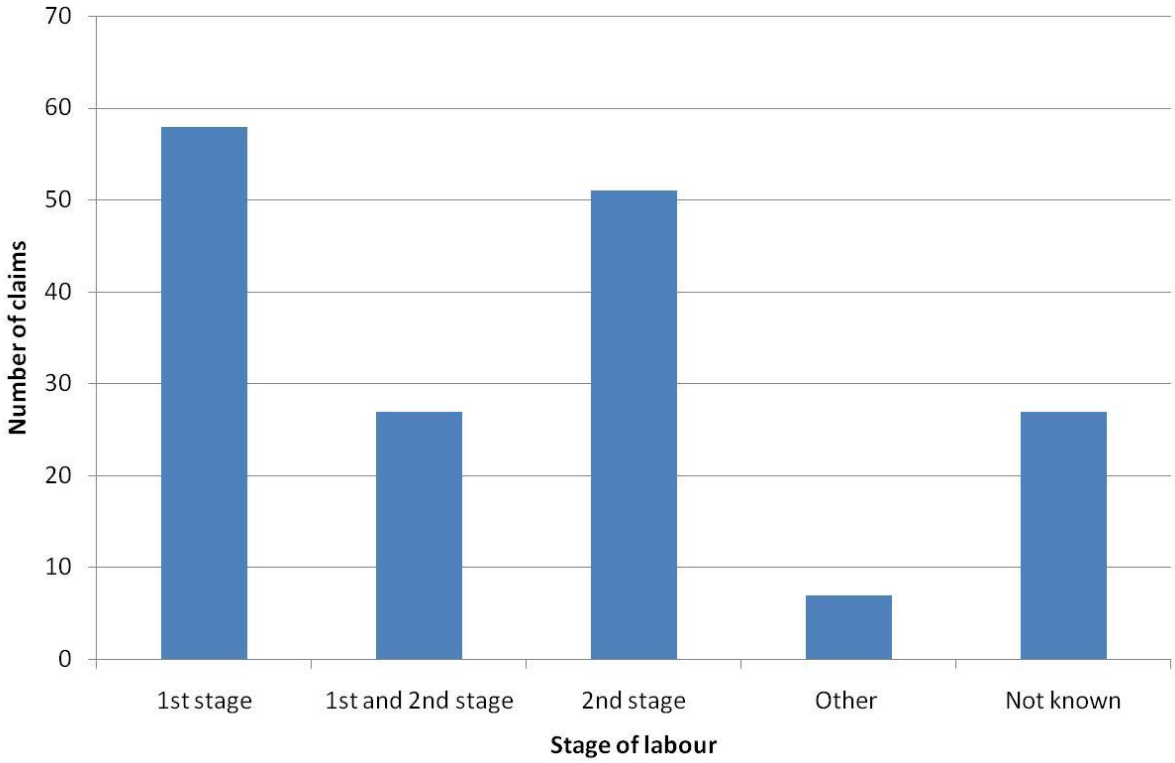
As with gestation, the data about birth weight have been described in various ways, including imperial weights which have been converted to grams.

Birth weights ranged from a baby that weighed 835g when it was born at 28 weeks gestation following two hours of a pathological CTG trace, to a baby weighing 5,283g at 40 weeks gestation, where there was a failure to ascertain a reliable CTG and the child now has cerebral palsy.

3.4 Stage of labour

As shown in Figure 23, 109 of the claims relate to incidents that occurred in either the first or second stage of labour. However, 27 claims allege that both the first and second stages of labour were affected by an alleged misinterpretation of a CTG.

Figure 23 – Stage of labour in which the alleged misinterpretation occurred



Nine "Other" claims relate either to the antenatal period, induction of labour, or it was unclear at what stage the CTG had been used.

4. Conclusion

The rationale for the criterion (2.3, 2011/12) on Continuous Electronic Fetal Monitoring in the CNST Maternity Standards[2] states that the aim of monitoring the fetal heart in labour is to identify hypoxia before it is sufficient to lead to long term poor neurological outcome for babies. This is an analysis of 170 claims made because it was alleged that babies had been harmed as a result of misinterpretation of that monitoring.

CTG misinterpretation is still a major reason behind a large number of the maternity clinical negligence claims received by the NHSLA. Key points identified by the analysis of some of these claims are:

- Only 21% (35) of the 170 claims involved high risk pregnancies, indicating the importance of the effective monitoring of all women
- There appears to be a range of professionals involved in these claims, but the majority relate to the midwife either failing to identify an abnormal CTG correctly or thereafter failing to act on the abnormality. However, this is not unexpected as most of the pregnancies were not regarded as high risk and the midwife would have been the primary healthcare professional responsible for the woman's labour and delivery.
- The majority of the claims relate to pregnancies at term, which is to be expected as the claims relate to CTG interpretation in labour, but interestingly the highest number of alleged incidents of negligence occurred at 40 and 41 weeks.
- The claims analysed show no difference between the rates of errors in and out of hours but the time recorded on claims will often be the time of birth and may not be the time when the error(s) which resulted in the claim occurred.

The results of this review of CTG claims aims to provide the basis for training materials which, alongside the CNST Maternity Standards[2] and the RCOG/Royal College of Midwives (RCM) e-learning resource[11] can be used to help professionals to provide safe maternity care.

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c. Perineal Trauma

Contents

1. Overview

It was felt that it was important to analyse in detail a category of claims which are brought as a result of injury and damage caused to the women in labour, to see if lessons could be learned to improve both levels of overall care and help reduce the volume of these claims in future. This study reviews claims involving obstetric anal sphincter injuries - third and fourth degree tears to the perineum.

During the review period for this project, from 1 April 2000 to 31 March 2010, the NHSLA's claims data identified the receipt of 441 claims in which allegations of negligence were made arising out of perineal damage (principally third and fourth degree tears) caused during labour. The total value of those claims, including both damages and legal costs, was estimated to be £31.2million.

The CNST Maternity Clinical Risk Management Standards 2011/12 include Criterion 3.5: *Perineal Trauma*. This includes specific reference to the management of third and fourth degree tears including who can repair these, standard of record-keeping and training. Level 2 requires the implementation of approved documentation.

The panel of solicitors who are instructed by the NHSLA on clinical negligence claims were asked to respond to a detailed questionnaire, attached at Appendix 1, which had been formulated with assistance from key stakeholders, including the RCOG and the Care Quality Commission.(CQC) The analysis of the data is published in this report.

2. Incidence

Up to 90% of women tear to some extent during childbirth. Most tears are classed as first degree (small, skin-deep tears which heal naturally) and second degree (deeper tears affecting the muscles of the perineum which require suturing). "Severe perineal tears … are identified in 0.6-9.0% of vaginal deliveries where a mediolateral episiotomy is performed."[1]

The RCOG *Guidelines for the Management of Third and Fourth Degree Perineal Tears* document[2] was published in June 2007 (and reviewed in 2010 when it was felt that no revisions were necessary). The introduction states:-

The overall risk of obstetric anal sphincter injury is 1% of all vaginal deliveries. With increased awareness and training, there appears to be an increase in detection of anal sphincter injury. Obstetricians who are appropriately trained are more likely to provide a consistent, high standard of anal sphincter repair and contribute to reducing the extent of morbidity and litigation associated with anal sphincter injury. Obstetric anal sphincter injury encompasses both third- and fourth-degree perineal tears. A third-degree perineal tear is defined as a partial or complete disruption of the anal sphincter muscles, which may involve either or both the external (EAS) and internal anal sphincter (IAS) muscles. A fourth-degree

tear is defined as a disruption of the anal sphincter muscles with a breach of the rectal mucosa.

Issues of training, classification of extent of the tear and surgical competence are all referred to in the Guidelines as representing the main issues which need to be addressed, to reduce the overall incidences of such injuries and, in turn, the number of litigation claims being brought. The Guidelines acknowledge that there has been a steady rise in the number of litigation claims being brought in the area and this study provides a comprehensive review of the reasons why such claims are brought and their outcome.

Some women will have an occult anal sphincter injury which will be isolated to the internal and/or external anal sphincter and would not be clinically detectable. These injuries are, however, rare but have a worse prognosis for future continence problems.[3, 4]

3. Risk Factors

In most situations, it is not possible to predict or prevent these types of tears[5]

The RCOG Guidelines identify the risk factors for third and fourth degree tears as including:

- birth weight over 4kg;
- persistent occipitoposterior position;
- nulliparity;
- induction of labour;
- epidural analgesia;
- second stage longer than 1 hour;
- midline episiotomy; and
- forceps delivery.

This is supported by the findings of a research study[6] in Holland which reviewed all 284,783 vaginal deliveries in 1994 and 1995 in the country. High fetal birth weight, long duration of the second stage of delivery and primiparity were associated with an elevated risk of anal sphincter damage. Mediolateral episiotomy was also suggested to protect strongly against damage to the anal sphincter during delivery. Of all assisted vaginal deliveries, the use of forceps increased the risk of damage further.

4. Cohort

83 questionnaires were returned by NHSLA Panel solicitors, which represents approximately 19% of the total number of claims received during the review period. Given the low level of completed questionnaires, the findings of this study should be treated with some caution.

From the data provided, the cost of the cohort of 83 claims reviewed in terms of damages and all legal costs paid and reserved totalled £17.5 million.

5. Timing of cohort of claims

The number of claims by calendar year is relatively stable. Claimants generally have 3 years from the date of negligence or the date of knowledge (if that is later) in order to bring a claim and so it would be expected that there would be fewer claims received in the period immediately prior to the review. The randomised nature of the study means that many panel solicitors would have concluded files from 2004 to 2007 more recently and so this era of claims formed the majority of those which were considered as part of the detailed analysis. Figure 24 shows the number of perineal trauma claims by year of incident and the number of claims for which questionnaires were completed. As these claims involve injury to the mother, most should be brought within three years of the date of incident, meaning that the years prior to 2007 ought to be complete. Although it is too soon to be sure, on this basis, the data suggest that the number of these claims may be beginning to fall.

Figure 24 – Number of claims for perineal trauma by year of incident and for which questionnaires were completed

Year	All claims	Number of claims for which a questionnaire was completed
2000	59	8
2001	64	7
2002	60	7
2003	58	6
2004	61	10
2005	52	16
2006	43	13
2007	28	12
2008	15	3
2009	1	1
Total	**441**	**83**

There was an even split of deliveries being managed by midwives (39 in number) as compared with those which were managed by doctors (44 in number).

It was therefore felt that breaking down the analysis of the claims by who managed the delivery would produce learning outcomes for both midwifery and medical teams.

6. Allegations of negligence

The claims which were reviewed involved the following criticisms of the standard of care being made:

- failure to consider a caesarean section
- failure to perform or extend the episiotomy
- failure to diagnose the true extent and grade of the injury, including failure to perform a rectal examination
- the adequacy of the repair
- failure to perform a repair

From a legal perspective, it is not surprising to note the first allegation on the basis that a caesarean section would have avoided the tear in its entirety. Causing a tear during a vaginal delivery is not per se evidence of substandard or negligent management, and this makes the ability to succeed in a claim evidentially more difficult. A number of the claims included the first allegation but it was ultimately not pursued or of relevance in relation to the resolution of the claim.

The claims which are brought for perineal trauma focus on the events which take place immediately following delivery by way of examination and repair, rather than on the delivery itself.

7. Identification of injury

Best practice points highlighted by the RCOG Guidelines state:

All women having a vaginal delivery with evidence of genital tract trauma should be examined systematically to assess the severity of damage prior to suturing.

All women having an operative vaginal delivery or who have experienced perineal injury should be examined by an experienced practitioner trained in the recognition and management of perineal tears[6]

In midwifery-managed deliveries, a tear was identified in 37 out of the 39 claims. The two other claims involved the failure to diagnose a third degree tear at all.

In doctor-managed deliveries, a tear was identified in all 44 claims.

The analysis shows that those managing deliveries are undertaking appropriate examinations to identify damage. This supports the RCOG's finding that training has led to an increase in the detection of such injuries. However, the next question to be asked must be whether the correct grade of damage is being recognised and diagnosed and thus an appropriate repair made.

8. Identification of the severity of injury

The definitions of perineal and anal sphincter injuries in Figure 25 have been adopted by the RCOG and the International Consultation on Incontinence[7]:

Figure 25 – Definitions of perineal and anal sphincter injuries

Tear	Definition
First degree	Injury to perineal skin only.
Second degree	Injury to perineum involving perineal muscles but not involving the anal sphincter.
Third degree	Injury to perineum involving the anal sphincter complex: 3a: Less than 50% of EAS thickness torn. 3b: More than 50% of EAS thickness torn. 3c: Both EAS and IAS torn.
Fourth degree	Injury to perineum involving the anal sphincter complex (EAS and IAS) and anal epithelium.

One of the questions featured in the questionnaire was the extent to which the grade of the perineal or anal sphincter injury was correctly assessed.

Allegations of negligence in 23 of the midwife-managed claims (59%) and 29 of the doctor-managed claims (65%) were made that the grade of the tear had been incorrect and, therefore, negligent.

Figure 26 shows the grade of the tear that was diagnosed and the true grading of the tear as established in the litigation claim.

20 of the 23 claims managed by midwives (87%) involved the under grading of the tear as a first or second degree tear when the tears were actually of third or fourth degree severity.

A very similar percentage applies to the checks carried out by medical staff, being 25 of 29 claims (86%).

Figure 26 – Grade of tear diagnosed and the true grading

Midwife-managed claims		
Grade of tear	**Correct grade of tearing**	**Number of claims**
First degree	Third/fourth degree	10
Second degree	Third degree	5
Second degree	Fourth degree	5
Third degree	Fourth degree	3
Doctor-managed claims		
Grade of tear	**Correct grade of tearing**	**Number of claims**
First degree	Third degree	9
First degree	Fourth degree	2
Second degree	Third degree	10
Second degree	Fourth degree	4
Third degree	Fourth degree	4

The experience of those managing the delivery will be relevant in each of these claims. However, the four claims where a fourth degree tear was under-reported as a second degree tear involved under-reporting on the part of consultant obstetricians.

All of the claims where the delivery was managed by a senior house officer involved allegations of a failure to diagnose and identify the correct grading of tear.

9. Time of delivery

The questionnaire recorded the number of claims in the cohort in which delivery took place outside week days when there would be consultant cover (Monday to Friday 8:00am to 8:00pm) and this information is shown in Figure 27. It is worth observing, however, that the number of hours outside these times is actually greater than the number of hours within them.

Figure 27 – Time when delivery giving rise to claims occurred

Time	Number of claims
Weekday hours	37
Outside weekday hours	46

10. Surgical competence

The RCOG recognise the importance of adequate repairs of such injuries being performed:

Obstetric anal sphincter repair should be performed by appropriately trained practitioners.[8]

Formal training in anal sphincter repair techniques is recommended as an essential component of obstetric training.

In the 83 claims which were reviewed, it was possible to identify who performed the repairs and also who performed the immediate post-repair checks as shown in Figure 28. It is accepted practice for a further review to take place after six weeks as well, although data about who performed this check have not been collected.

Figure 28 – Who performed the repair

Who performed repair	Number performed	Immediate post-repair check
Consultant	13	18
Doctor – Training grades*	52	45
Midwife	11	10
No repair or check	7	10
Total	**83**	**83**

* Specialist Registrar, Registrar and Senior House Officer

Midwives do not routinely undertake third or fourth degree tear repairs. The reason why midwives appear in the figure above is because a number of the claims involve an under diagnosis of the grade of the tear (set out in Figure 26).

A large proportion of the claims involved allegations of negligence being brought about the adequacy of the repair and it can be seen that the majority of these were dealt with at registrar level and below (from the medical side).

There were also criticisms made as to whether a post-repair check was carried out and who performed this. Issues arose as to whether the fact that a post-repair check had been carried out had been documented in the medical records, including who performed that check. It is interesting to note the low number of repairs checked by a consultant in the claims where the questionnaire was completed.

The majority of the repairs are carried out by training grade doctors but a 2009 survey[9] revealed that approximately one-third of trainees had not attended a training course or given routine counselling to women about the long-terms effects of the injury.

11. Consequences of such claims

The long-term symptoms which the mothers who brought claims developed and continued to suffer with were broadly similar, including:-

- incontinence of faeces and/or flatus
- vaginal discharge
- rectovaginal fistula requiring repair
- irritable bowel syndrome
- colostomy
- psychiatric damage

12. Case study

Case Study 4

The delivery was being managed by a senior registrar, under the supervision of the consultant obstetrician. It was completed using Keilland's Forceps after three tractions. The medical records were detailed. A second degree tear was sutured and a first degree tear was also noted. No third degree tear was noted nor an extension to the episiotomy. This was said to be a straightforward delivery.

The claimant developed disabling faecal incontinence as a result of a third degree tear. She was unable to work. Her claim was valued in the region of £500,000.

An endo-anal ultrasound scan confirmed that the tear in the external anal sphincter was not present at the anal verge and was "occult". This confirmed the findings of the specialist registrar and the tear was not clinically detectable.

With good quality notes and independent radiology, the claim was withdrawn and the Trust's legal costs met.

13. Discussion

Bearing in mind the overall number of maternity claims that the NHSLA receives, only a small number relate to perineal damage. However, there are some consistent messages which arise from the claims made which can influence and improve clinical practice.

Training remains a crucial issue in diagnosing the existence and severity of tears following delivery. Whilst there are known risk factors, it cannot be predicted which women will tear. From a legal perspective, ensuring a thorough examination is carried out where indicated, the extent of which is documented, will help to reduce the number of claims. All women should be advised to attend for a postnatal check at 6-8 weeks and should be asked about their "stitches" and perineum. Not all women need examination if they are symptom free but what is important is that all women are advised to report any adverse symptoms including any faecal incontinence and those that have had 3rd and 4th degree tears should be reviewed by a consultant after 6-12 weeks.

Consent was not an issue in any of the cohort of claims reinforcing the importance of women receiving information on perineal care and for the risks to be discussed antenatally and included in antenatal education. And, where perineal injury has occurred, women should be provided with an appropriate debrief by a senior clinician or midwife to ensure they fully understand the situation.

The cases brought demonstrate the important of every women having a rectal examination following delivery, which should be documented in accordance with the protocol in the maternity service.

With some tears being truly "occult", the detection failures which occur will never be truly eradicated but this paper confirms the relevant factors which will ensure that best practice is adopted by all.

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d. Uterine Rupture

Contents

1. Introduction

Review of the NHSLA's claims data from 1st April 2000 to 31st March 2010 identified 85 claims of uterine rupture. In 19 claims the rupture was linked to vaginal birth after caesarean section (VBAC). Increasing rates of caesarean section have led to an increased proportion of the obstetric population who have a history of prior caesarean section delivery.[1] The total estimated value of the claims arising from the identified 85 claims, including damages and costs, was £103,264,627.

The initial signs and symptoms of uterine rupture are typically non specific, so diagnosis is difficult and intervention can be delayed. Previous caesarean section is the main risk factor for uterine rupture. As the rate of caesarean section increases worldwide, (with the NHS Institute for Innovation and Improvement describing this as a "global concern"[2]) there is an increasing number of mothers with previous caesarean section, with consequent higher risk of uterine rupture, although the absolute risk of uterine rupture is still considered to be low. The CNST Maternity Clinical Risk Management Standards 2011/12[3] includes a criterion 2.10: *Vaginal Birth after Caesarean Section*, which at Level 2 requires the implementation of an individual management plan for labour. Can data from claims inform an analysis of risk factors? To endeavour to answer this question, the panel of solicitors acting for the NHSLA were asked to respond to a detailed questionnaire, formulated with assistance from key stakeholders, including the RCOG and CQC. The questionnaire is reproduced at Appendix 24. The completed questionnaires have been analysed and full details of the findings related to uterine rupture are published in this report.

2. Incidence

"Uterine rupture in pregnancy is a rare and often catastrophic complication with a high incidence of fetal and maternal morbidity. Several factors are known to increase the risk of uterine rupture, but, even in high-risk subgroups, the overall incidence of uterine rupture is low. From 1976-2009, 20 peer-reviewed publications that described the incidence of uterine rupture reported 1,864 cases among 2,863,330 pregnant women, yielding an overall uterine rupture rate of 1 in 1,536 pregnancies (0.07%)".[4] However, notwithstanding these figures and the relatively low number of claims notified to the NHSLA, uterine rupture has also been reported as one of the most common causes of medical litigation in the developed world.[5]

3. The cohort

Questionnaires were returned by panel solicitors relating to 45 births spanning the period April 2000 to July 2009 (one earlier birth included from 1992). The cohort included 27 open claims, 17 closed claims and 1 other. The sex of the baby was female in 24 claims, male in 20 claims and unknown in 1 case. Those returning questionnaires were asked whether rupture occurred during VBAC and surprisingly, given the uncommon occurrence of spontaneous rupture, the cohort of claims included only 24 where it could be confirmed from the information available that rupture occurred during VBAC. It is also worthy of note

that the 45 questionnaires identified 24 cases with VBAC, whereas the review of claims on the database alone identified only 19. The explanation may well lie in the quality of the data on the database or in the reliability of some of the questionnaire responses, or a combination of both. The return rate of 53% (45 questionnaires returned relating to 85 identified claims categorised as uterine rupture) is in all probability explained by archiving practices at the individual panel solicitors and an inability easily to identify the 85 claims, which could not be specified by name due to data protection, leading to difficulties in examining the impact of selection bias.

4. Value

The 85 claims brought between 1st April 2000 and 31st March 2010 identified by the NHSLA had a total estimated value for damages of £103,264,627. The open claims within the ruptured uterus cohort of 45 births had an average damages valuation of £2.5 million, with the average reserve for claimants' and defendants' costs being £176,000 and £73,000 respectively.

5. Rupture or dehiscence?

Uterine rupture during pregnancy is an infrequent obstetric complication which can result in life-threatening maternal and fetal compromise: a UKOSS Study[6] found that "The estimated incidence of uterine rupture was 0.2 per 1,000 maternities overall; 2.1 and 0.3 per 1,000 maternities in women with a previous caesarean delivery planning a vaginal or elective caesarean delivery, respectively." By contrast, uterine scar dehiscence less frequently results in major maternal or fetal complications. By definition, Uterine scar dehiscence constitutes separation of a pre-existing scar that does not disrupt the overlying visceral peritoneum, whilst uterine rupture is defined as a full-thickness separation of the uterine wall and the overlying serosa. Uterine rupture is associated with:

1. clinically significant uterine bleeding;
2. fetal distress;
3. expulsion or protrusion of the fetus, placenta, or both into the abdominal cavity; and
4. the need for prompt caesarean delivery and uterine repair or hysterectomy.

The questionnaires sought to elicit whether the 45 claims related to rupture or dehiscence and the following information was gleaned. The numbers shown in Figure 29 tend to suggest that a claim is more likely where there has been a rupture, in all probability due to poor perinatal outcome following rupture, leading to "rupture" as opposed to "dehiscence" being over represented in the cohort claims.

Figure 29 – Cause of uterine rupture claims

Cause	Number of claims
Rupture	40
Dehiscence	3
Unknown	2
Total	**45**

6. The Allegations

The panel were asked to summarise the principal allegations of negligence. In 47% of the claims the allegations of negligent care included an allegation that recognition of rupture or impending rupture was delayed. The RCOG[7] has advised that women should be advised to have continuous electronic fetal monitoring following the onset of uterine contractions for the duration of the labour. An abnormal cardiotocograph (CTG) is the most consistent finding in uterine rupture and is present in 55-87% of these events.[8] A failure to offer appropriate maternal counselling regarding modes of delivery was alleged in 24% of claims. Allegations relating to augmentation and/or induction of labour occurred in 27% of claims. Breach of duty (the care fell below a standard that would be acceptable to a responsible body of medical opinion) was admitted in 25 out of the 45 claims. Causation (damage resulted from the breach of duty) was admitted in 22 out of the 45 claims.

7. Maternal counselling

Communicating the health risks and benefits of repeat caesarean or VBAC has been the focus of previous study including that published in the December 2006 edition of *BJOG: An International Journal of Obstetrics and Gynaecology*[9] which looked at the reasons for the type of delivery women want after a previous caesarean section. The study surveyed 21 women from 2 city hospitals in Bristol and Dundee. Uncertainty in decision making, information provision and decision-making roles were examined by researchers, as these were considered to be the main factors behind women opting for a repeat caesarean section or VBAC. Women who chose to have a caesarean section did so because they were afraid of vaginal birth or were convinced that a vaginal birth was not for them, or wanted to have control over the birth. Women choosing VBAC did so because they were influenced by the shorter recovery time after birth, wanted the experience of a natural delivery, or feared having to go through another caesarean section. The information these women received about caesarean sections was mostly about procedural issues rather than the health risks, alternatives and benefits of the different methods of delivery. Many women felt that it would be helpful to receive information after the first caesarean section.

Commenting on the study, Professor Phil Steer, Editor-in-Chief of BJOG said, “This study is unique as it places the obstetrician at the centre of expert information provision for women

who are unsure about whether to have a repeat caesarean or VBAC. The 'consumerist' approach towards decision making means that women are encouraged to make their own decisions instead of relying solely on their doctor's recommendations. Obstetricians need to adopt more flexibility by tailoring the information they provide to women. The research shows that they need to talk about safety issues alongside information about procedures and statistics."

The RCOG has presented the best evidence available to facilitate antenatal counselling in women with prior caesarean birth and to inform the intrapartum management of women undergoing planned VBAC in its *Green-top Guidance* (No 45, February 2007).[10] This guidance advocates the following approach to counselling in the antenatal period:

"Women with a prior history of one uncomplicated lower-segment transverse caesarean section, in an otherwise uncomplicated pregnancy at term, with no contraindication to vaginal birth, should be able to discuss the option of planned VBAC and the alternative of a repeat caesarean section (ERCS).

The antenatal counselling of women with a prior caesarean birth should be documented in the notes.

There should be provision of a patient information leaflet with the consultation.

A final decision for mode of birth should be agreed between the woman and her obstetrician before the expected/planned delivery date (ideally by 36 weeks of gestation).

A plan for the event of labour starting prior to the scheduled date should be documented.

Women considering their options for birth after a single previous caesarean should be informed that, overall, the chances of successful planned VBAC are 72–76%."

The questionnaire therefore examined the extent to which there was a documented discussion of the relative risks and benefits of VBAC and elective repeat caesarean, although it must be recognised that the cohort of claims in part predates this *RCOG Green-top* guidance. In 19 of the 24 claims (79%) where rupture was associated with VBAC, there was a discussion on the risks and benefits of VBAC and elective repeat caesarean. The questionnaires also considered whether there had been consultant obstetric or consultant midwife involvement in discussions concerning the mode of delivery, and established that this was present in 49% of the claims. The discussions regarding mode of delivery had taken place in a VBAC clinic in 22% of the claims. An approved guideline was in place in 18 out of the 45 claims, not in place in 6 claims and unknown in 21. In 44% of the claims the questionnaire indicated that a consultant obstetrician had been present on the labour ward or in the obstetric theatre. A question was posed about the provision of a potential information leaflet, which resulted in the answers shown in Figure 30.

Figure 30 – Provision of information leaflet

Leaflet provided	Number of Claims
No	4
Yes	3
Unknown	38
Total	**45**

The questionnaires also enquired into when a decision had been made concerning mode of delivery. In 11 out of the 45 claims no information was available concerning when the decision had been made. As shown in Figure 31, the remaining 34 claims demonstrated the decision regarding the mode of delivery being made in a time bracket of 10 plus weeks (earliest point) to during the first stage of labour (latest point). For practical reasons, the data collected did not indicate whether the decision regarding the mode of delivery was changed during the pregnancy and, if this was the case, the reason.

Figure 31 – Time of decision regarding mode of delivery

Gestation	When a decision was made about mode of delivery
10+	1
12	1
16	1
20	1
32	2
33	1
36	4
37	3
37+	1
37+6	1
38	1
38+4	1
39	5
39+	1
40+4	2
40+5	1
40+8	1
41+1	3
During 1st Stage	3
Total	**34**

8. Risk Factors

Miss Mellissa Kaczmarczyk of the Department of Epidemiology at Emory University, Atlanta, responsible for one of the largest population-based studies to examine the risk factors for uterine rupture, has categorised previous caesarean, induction of labour and high maternal age as factors amongst the most likely to increase the risk of uterine rupture. This is, of course, of great interest given the increasing incidence of all these factors in pregnant women. Others have explored the effect of high maternal BMI on the incidence of uterine rupture and inter-delivery interval. The questionnaire, inter alia, examined in addition: categorisation of the pregnancy as high risk, augmentation, monitoring, pain relief and day/hour of delivery.

8.1. Induction or Augmentation

The questionnaire posed the question whether labour was induced or augmented as it was considered helpful to establish whether syntocinon or prostaglandin were used and when the rupture occurred. Unfortunately, as shown in Figure 32, in a number of cases the responses to this question were unclear. In summary, of the 45 claims, labour was induced or augmented in 25, not induced or augmented in 14, and the position unknown in 6.

Figure 32 – Was labour induced or augmented?

Was labour induced or augmented?	Number of claims
Yes	13
No	14
Augmentation	7
Induced	5
Not known	6
Total	**45**

Case Study 5

The claimant's mother opted for VBAC. There was an interval of 16 months between the previous caesarean and this delivery. Mode of delivery was discussed at 16 weeks with the consultant and a maternal preference for vaginal delivery was noted. The Claimant attended hospital at 41 weeks gestation, having noticed occasional tightening, but she was not in labour.

Prostin E2 3mg was inserted and IV Syntocinon was commenced 24 hours later, with increases in the rate of infusion three times in the next three hours up to 36 lml/hour. Ultimately a forceps delivery was performed, following a delay in the second stage, in the presence of fetal bradycardia. Blood and mucus needed to be removed from the claimant's trachea before intubation and successful re-establishment of the circulation. A gaping hole was discovered in the lower segment of the uterus when the Claimant's mother was taken to theatre post delivery, when the placenta did not deliver. The claimant has cerebral palsy.

The principal allegations were (1) that in breach of the Trust's own guidelines, medical induction was carried out notwithstanding that these guidelines stipulate that there should be no such induction in women with a previous caesarean section scar and (2) that the Claimant's mother was not advised ante-natally, or following her admission to hospital, of the increased risk of uterine rupture associated with induction of labour.

Liability was admitted. The Trust's guidelines on use of prostaglandins for induction in a VBAC case were inconsistent with RCOG Guidelines and it was accepted that there had been a failure to consult the claimant's mother about the increased risk of uterine rupture with induction of labour in a VBAC case.

The claim resolved on the basis of an order for Periodic Payments with a conventional lump sum value of £6.1 million

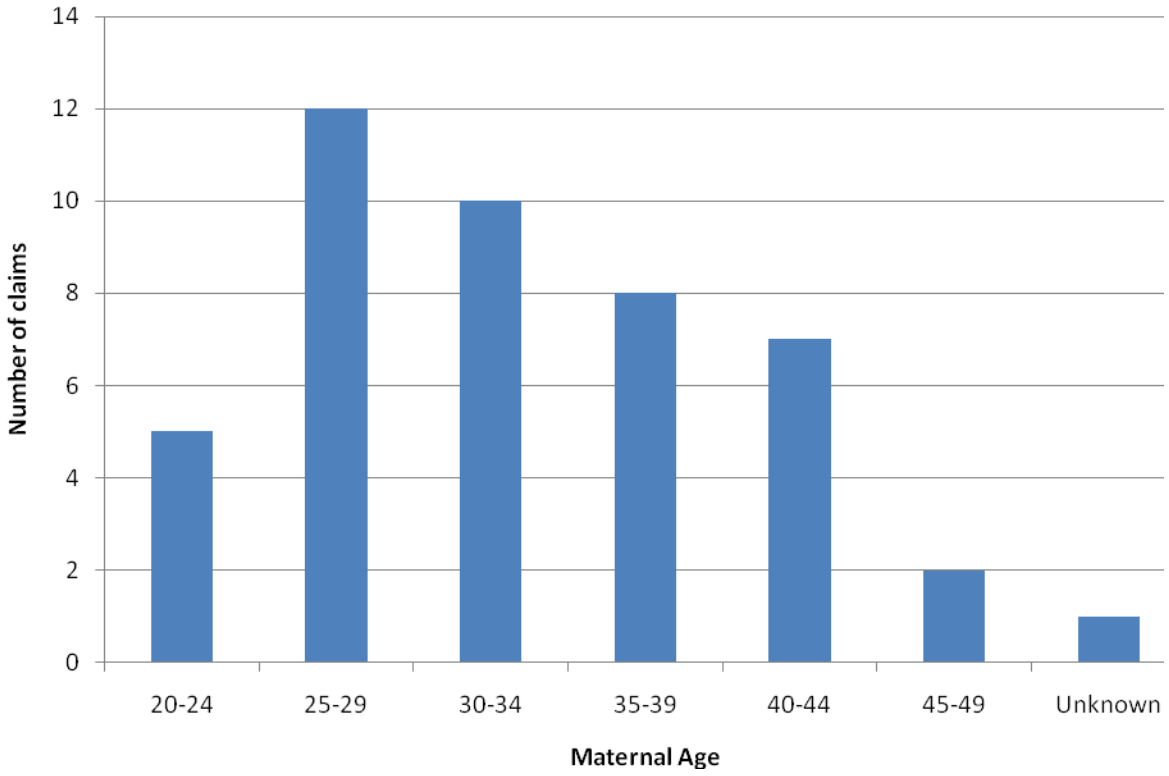
8.2. Maternal Age

Shipp et al showed that increasing maternal age has a detrimental effect on the rate of uterine rupture. In a multiple logistic regression analysis that was designed to control for confounding factors, the overall rate of uterine rupture in 3,015 women with 1 previous caesarean delivery was 1.1%. The rate of uterine rupture in women older than 30 years

(1.4%) versus younger women (0.5%) differed significantly (OR, 3.2; 95% CI, 1.2-8.4).[11] Gordon Smith and others[12] have explored the effect of delaying childbirth on primary caesarean section rates and the conclusion of the study was that advancing maternal age is associated with higher rates of caesarean section, with a possible mechanism for this association being impaired uterine function. Impaired myometrial function with advancing maternal age may also explain the increased rate of uterine rupture for older women.

Figure 33 demonstrates the age of the mothers whose deliveries were the subject of the cohort claims (average age 38).

Figure 33 – Maternal Age in the cohort of claims



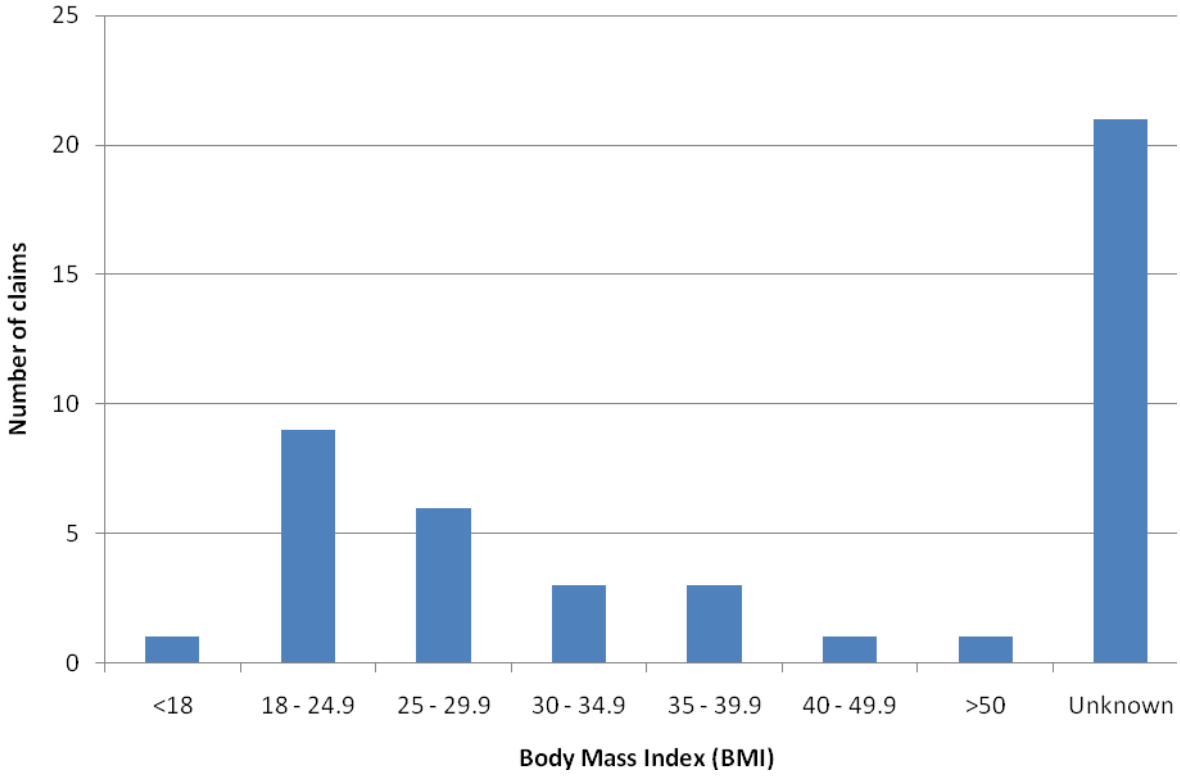
8.3. Body Mass Index (BMI)

Excessive weight gain and obesity have an increasing relevance in obstetrics. The World Health Organisation (WHO) now accepts a BMI of 25 or higher as abnormal; the overweight category is classified as obese when the BMI is 30 or more. Obesity has long been known to complicate pregnancy and is associated with increased risk for pregnancy induced hypertension, preeclampsia and gestational diabetes, as well as anaesthesia related risks for those women who have surgery. Among these women the incidence of the caesarean delivery increases, while VBAC success decreases.[13]

The cohort of claims in the uterine rupture study demonstrated an average BMI for the women involved of 37.95 with the lowest BMI being 17.9 and the highest reaching 58. 60.8

% of the women whose deliveries were considered had a BMI over 25. However within the study 48% had an unknown BMI. The data are shown in Figure 34.

Figure 34 – Body Mass Index in the cohort of claims



8.4. Fetal Macrosomia

High birth weight (the highest in the study was 4.81kg (10lb 6oz) has been reported to play a significant role in increasing the incidence of uterine rupture. Fetal macrosomia is reported to be difficult to predict and both clinical and ultrasonographic estimates of fetal weight are prone to error.[14]

Zelop et al reported that the rate of uterine rupture for women delivering neonates weighing >4,000g was 1.6% versus 1% for newborns ≤4,000g, but that the difference was not statistically significant.[15] More recently, Jastrow et al showed that birth weight was directly correlated with the rate of uterine rupture, with uterine rupture rates of 0.9%, 1.8%, and 2.6% for birth weights of < 3,500g, 3,500-3,999g, and ≥4,000g, respectively.[16] However the analysis of the data from the claims reported via the study demonstrated that whilst 19 out of 45 mothers had a gestation over 40 weeks, the average weight of the babies delivered was 3360g with a range of 2300g to 4810g. The *RCOG Green-top Guideline,*[17] advise a "cautious approach" when considering planned VBAC in women with fetal macrosomia, as there is uncertainty in the safety and efficacy of planned VBAC in such situations.

8.5. Inter-delivery interval

It has previously been speculated that a prolonged inter-pregnancy interval may allow time for the previous caesarean delivery scar to reach its maximal tensile strength before the scar undergoes the mechanical stress and strain of a subsequent intrauterine pregnancy. An analysis of claims in the cohort demonstrated that the average length of time between the previous caesarean section and the most recent was 3 years 7 months. The study also confirmed that the longest amount of time since the previous caesarean section was 11 years 5 months and the shortest amount of time since the previous caesarean section was 11 months, although in one case a woman experienced uterine rupture in her first pregnancy. Three observational studies of limited size[18 19 20] have shown a two to three-fold increased risk of uterine scar rupture for women with a short inter-delivery interval (below 12-24 months) from their previous caesarean section.

8.6. Categorisation of the pregnancy as high risk

In answer to a question concerning whether the pregnancy had been categorised as high risk, the responses in Figure 35 were ascertained. Although there are concerns about the reliability of some of the data obtained via the questionnaires, it is noteworthy that cases involving VBAC were not necessarily categorised as high risk.

Figure 35 – Categorisation of the pregnancy as high risk

Categorisation	Number of claims
No	18
Yes	18
Unknown	9
Total	**45**

8.7. Monitoring

The answers to the questionnaires established that continuous electronic fetal monitoring was present in 28 out of the 45 claims (62%), a surprisingly low figure given that an abnormal CTG is the most consistent finding in uterine rupture and is present in 55-87% of these events.[21]

8.8. Day/Hour of Delivery

The questionnaire examined whether the delivery had occurred Monday to Friday, 8:00am to 8:00pm. The answers in Figure 36 were provided.

Figure 36 – Time of delivery

Week day 8:00am to 8:00pm	Number of claims
No	18
Yes	24
Unknown	3
Total	**45**

These results suggest that a supposition that uterine rupture would be more likely to go undetected outside the hours of 8:00am to 8:00pm, Monday to Friday, would not be well founded.

8.9. Pain Relief

The questionnaires identified 60 incidences of pain relief being administered across the cohort of 45 claims.

9. Conclusion

Despite a low reported incident rate of uterine rupture of 1 in 1,536 pregnancies (0.07%)[22], this often catastrophic complication results in the NHSLA receiving maternity claims of significant value. The 85 claims identified from a review of the NHSLA database, with an incident date between 1st April 200 and 31st March 2010, had an estimated value in excess of £100million.

Whilst the cohort of claims received in response to questionnaires sent to panel solicitors was fewer, even allowing for the impact of self selection, it is clear that the themes that emerge are often consistent with those emerging from larger studies. In particular, this is seen from the allegations which focused on delayed recognition of rupture due to absence of monitoring and inadequate maternal counselling regarding modes of delivery.

It is worthy of note that in those cases where rupture was not associated with VBAC the allegations were diverse: the Claimant's womb was perforated during an endoscopic retrograde cholangiopancreatography, the uterus was inadequately sutured following caesarean section, there was a failure to control a post partum haemorrhage and excessive traction of the umbilical cord, leading to rupture. With increased focus on maternal choice following the 2011 amendments to NICE guidance on caesarean section (CG132)[22], it should also be highlighted that in one of the questionnaires the focus of the allegations was a refusal to deliver by lower segment caesarean section notwithstanding that this had been requested.

Overall, the result is to underscore the importance of best practice guidance from the RCOG[23]. And, for incidents which occur following the publication of *Green-top* Guideline (No 45, February 2007)[24], the evidential burden on a Trust seeking to justify a departure from such guidance will be significant. Against this background it is perhaps unsurprising that a failure in the standard of care was admitted in over 50% of the claims in the study cohort.

Given that the study demonstrated that in over a quarter of the claims there were concerns about the adequacy of information provided to women considering modes of delivery, it is worth highlighting that the 2011 NICE guidance (CG132)[25] states that when advising about the mode of birth after a previous caesarean section, specific heed should be paid to: maternal preferences and priorities; the risks and benefits of repeat caesarean section and the risks and benefits of planned vaginal birth after caesarean section, including the risk of unplanned caesarean section [new in 2011]. A desire to ensure that the needs of individual women are met sits behind the CNST Maternity Clinical Risk Management Standards criterion 2.10 on VBAC, and it is to be hoped that the analysis emerging from this study is helpful to those professionals working to provide safer maternity care.

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8. Discussion

Risk management initiatives by the NHSLA, the RCOG, the RCM and the NPSA[11], as well as others involved in patient safety, have resulted in a sizeable body of work aimed at improving safety in maternity care. While the true extent of error in maternity units cannot be assessed, an analysis of instances of harm that have resulted in litigation does provide valuable information to allow lessons to be learned and changes made as necessary.

In 2000 the Department of Health report *An Organisation With A Memory* highlighted how "data from litigation claims represent a potentially rich source of learning from failure"[12] and how a substantial proportion of money paid out in clinical negligence settlements by the NHS relates to obstetric problems resulting in brain damaged babies with serious permanent disabilities. Whilst recognising that this is not always due to clinical error, the report proposed that a concerted effort to learn from the mistakes would prevent some future births of brain damaged babies. One of the key recommendations in the field of obstetrics was that, "by 2005, reduce by 25% the numbers of instances of negligent harm in the field of obstetrics and gynaecology which result in litigation". At the time, obstetric claims accounted for over 50% of the annual NHS litigation bill. According to the data analysed for this project, and in particular the Primary Level Study, there was a 15% reduction from the 692 claims with an incident date in the financial year 2000/01, to the 588 claims with an incident date in 2005/06. However, the total value of these claims in the same financial years rose by 44%, from £315 million in 2000/01 to £455 million in 2005/06. While it is unlikely that there will be many more claims with an incident date falling into the financial year 2000/01, it is certainly possible that far more claims could still be notified for the financial years 2005/06 and onwards. Although we do not know exactly how many more claims may be notified, if this study were repeated in five years it is likely, based on the NHSLA's experience of when claims are reported, that there will be an increase in the numbers in each year set out in the table at Figure 5.

The results from the Primary Level Study as set out at Figure 6 support the conclusion that, not surprisingly, the most common and expensive maternity claims relate to shortcomings in the management of labour and CTG interpretation, including those which resulted in a baby suffering cerebral palsy. As indicated above, almost 70% of the overall total value of £3.1 billion relates to these three categories of claim. With 40%, (£1.2 billion), attributed to cerebral palsy alone, this category may warrant a further separate study although the authors believe it is likely to highlight similar issues to those raised in the CTG study.

With a likely rise in the number of maternity claims between 2005 and 2010 identified in Figure 5 and a likely increase in ongoing care costs and other needs to help a severely disabled child for the remainder of his/her life, the overall cost to the NHS, through both compensation and additional treatment costs, will almost certainly increase. This financial cost to the NHS, along with the costs that cannot be quantified, can only be reduced through improved risk management. The Secondary Level Study showed that areas to consider from a risk management perspective based on the findings in this project include:

Improved Reporting and Review

Various papers have referred to safety reporting systems in healthcare using and developing reporting systems similar to those in aviation and the nuclear power industry.[13] It has been argued that an improvement in the reporting culture within healthcare would allow better analysis of adverse events and near misses, with lessons being learnt from the mistakes of others and those events which did not result in harm. Initiatives within the NHS have encouraged reporting but, as one commentator has observed, incident reporting is one of a number of differences between healthcare and other industries.[14] While in many industries there may be a few hundred reports a year even at a national level, in contrast a single healthcare organisation may receive thousands of reports. This can limit the possibility of feeding back lessons from these reports.

What is required is an engagement with the risk management process at all levels, from staff working in maternity units through to trust boards, which ensures that there is identification and analysis of the risks within their organisation and furthermore that adequate resources and systems are in place to control the risk and learn from incidents which may or may not have resulted in harm. Regular review of claims, complaints and incident reports will allow organisations to look for any patterns of error which would not be apparent on analysing a single case. The House of Commons Health Committee recognised that there are measures with the potential to improve the approach of boards to safety and quality.[15] Clinical Dashboards such as the 'maternity dashboard' have been reported to be a useful tools to monitor certain mandatory requirements in maternity services including midwives to birth ratios, weekly prospective obstetric consultant presence on the labour ward and percentages of staff who have undergone mandatory skills and drills training, based on the organisation's own training requirements analysis.[16]

Learning and Training

In two of the categories of claims in the Secondary Level Study the allegations of negligence often centred on interpretation of a result, namely a CTG or an antenatal scan. As such, individual human error could result in an adverse event. One issue which this highlighted was the need for further training in these areas, including the use of technology to assist in the training and development of staff. Various initiatives, such as using e-learning, are already being implemented but the ongoing training of maternity staff, through dedicated programmes which are flexible enough to ensure attendance/completion, is vital.

Supervision and Support

Ensuring that staff are aware of when supervision is required and how to access a more senior opinion also arose as a learning point from the four categories of claims in the Secondary Level Study. In all four areas, as may be expected, junior staff were often involved in the management of the woman and her baby. For example, in the majority of CTG interpretation claims, the care provided was either by a midwife acting alone, or by a midwife and a junior doctor. The availability of more experienced senior medical staff to

assist in difficult decisions may help to develop a system whereby error on the part of less experienced staff dealing with difficult situations can be identified before any harm occurs to the patient. Junior doctors and midwives must be supported in the development of their decision-making processes, and be confident enough to ask for assistance where necessary. Effective multi-disciplinary team working is also essential to the provision of safe care, as is mutual professional respect, so that midwives support doctors and doctors support midwives. The majority of claims within the Secondary Level Study were not identified as high risk cases where senior staff were involved from the outset, so knowing when they should be called is paramount.

Protocols and Guidelines

Appropriate care pathways for the management of women in maternity units can minimise risk. The development of local scanning protocols following publication of the RCOG guidelines on routine ultrasound scanning, and the NICE guidance on fetal monitoring, are examples of how national guidelines can help to improve practice at a local level. In litigation claims, the Court is often asked to consider whether the staff followed the unit's own protocol/guidance or national guidelines for the management of a particular condition or set of circumstances. Organisations must therefore ensure not only that their guidelines and protocols are up-to-date and accessible when needed, but also that staff are familiar with the detail of the protocol or guideline and the need to follow it as appropriate. Again, information technology and initiatives such as e-learning can assist in the dissemination and updating of protocols and guidelines.

Learning Lessons from Claims

The claims management process can inform safe maternity care in a number of ways, for instance by providing a more thorough investigation of an incident than would otherwise be possible and having the benefit of external expert input and opinion.

To facilitate the analysis of maternity claims for learning purposes on an ongoing basis, the risk management coding used by the NHSLA needs to be improved. The risk management reports on claims initiative should continue, with changes to increase the usefulness of the reports and to help analysis, and the approach to follow-up strengthened.[17]

There is a potential to carry out an in-depth study of another category of the claims identified in this project. If this is to be done, the NHSLA should consult with and involve healthcare professionals to determine the category chosen and scope of the study. In due course, consideration should be given to updating the Primary Level Study to identify any emerging trends. Also, in the longer term, one category that could be revisited is claims involving CTG interpretation, to identify whether the introduction of the Fetal Heart Rate Monitoring (EFM)[18] learning resource has had an impact on claims.

As shown in Appendix 20, there is already a strong correlation between the findings in this report and the CNST Maternity Standards.[19] Nevertheless, the NHSLA will be reviewing the findings to determine whether any changes should be made to future versions of the

Standards as a result of the project. As a minimum, the key findings should be incorporated into the Standards manual to emphasise their relevance to improving safety.

Current evidence indicates that the cost of clinical negligence claims is likely to continue to rise in future years due to a number of external factors, e.g. inflation. In addition to minimising the human cost of providing unsafe care, this is an important reason for NHS boards to fully engage with and support risk management initiatives to improve safety within their own maternity services and thereby minimise claims, as any increase in the cost of claims will be reflected in higher CNST contributions. Implementing the suggested actions in the risk management reports on claims, where appropriate, and being able to demonstrate compliance with the higher levels of the CNST maternity standards are both ways in which the safety of women and their babies can be improved.

9. Conclusion

This study has shown that claims arising from maternity units continue to be the single most costly type of litigation claims managed by the NHSLA. With increasing future care costs, the size of these awards is only likely to increase. The most effective way to reduce the ongoing financial cost to the NHS, and the human cost to patients and staff alike, is to continue to improve risk management in maternity care.

The findings of this project indicate that resources should be focused on preventing incidents associated with the management of labour, which would also include those cases which centre on interpretation of a CTG trace and the timing of a caesarean section. These issues are often seen in legal claims for babies suffering cerebral palsy, and although cerebral palsy was not considered in the Secondary Level Study, the learning points are likely to be similar. Recommendations for improving safety in maternity care, such as compulsory attendance at regular training sessions, especially for CTG interpretation, good communication between midwives, doctors and women, up-to-date guidelines for managing routine care and protocols to guide staff dealing with emergencies remain as relevant now as at any time in the past.[20] Unfortunately, many of the same errors are still being repeated.

Whilst litigation represents the tip of the iceberg when considering incidents of error, an analysis of claims does allow valuable lessons to be learned when considered alongside information gleaned from incidents, complaints and other sources.

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11. Appendices

1-19	Information Sheets
20	Links to CNST Maternity and NHSLA Acute Risk Management Standards
21-24	Secondary Level Study – Questionnaires
25	Glossary
26	Acknowledgements

Information Sheets

(All data correct as at 1st April 2010)

Introduction

These Information Sheets are intended to be used separately to assist with learning and training. They provide details of the number and total value of claims in each of the categories identified in the Primary Level Study; guidance, including reference sources, available to help manage the associated risks; and details to consider whether management of the risk is addressed in the CNST Maternity Standards.

A number of the pie charts in the Information Sheets have large sections described as "Unspecified" or "Other". As explained in the main report, the NHSLA claims database was not designed to provide an analysis of the clinical situation from which claims arise. However, steps are now being taken by the NHSLA to improve the database so as to better record risk management information on claims.

List

1. Anaesthetic Issues
2. Antenatal Care
3. Antenatal Investigations
4. Bladder
5. Caesarean Section
6. Cerebral Palsy
7. CTG Interpretation
8. Drug Error
9. Management of Labour
10. Maternal Death
11. Midwifery Care
12. Operative Vaginal Delivery
13. Perineal Trauma
14. Postpartum Haemorrhage
15. Psychological Harm
16. Retained Swabs
17. Shoulder Dystocia
18. Stillbirth
19. Uterine Rupture

Appendix: 1

Maternity Claims - Information sheet
Anaesthetic Issues

Claims

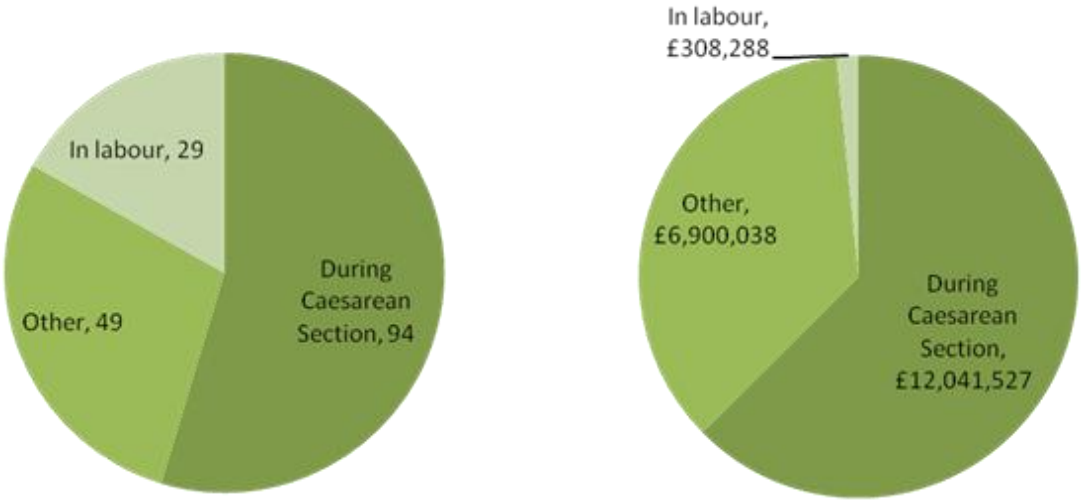
A review of the claims on the NHS Litigation Authority (NHSLA) database with an incident date between 1st April 2000 and 31st March 2010 identified 172 maternity claims involving anaesthetic issues, with an estimated total value of £19 million.

Incident Date*	Total Number	Total Value
2000/2001	17	£846,570
2001/2002	31	£957,793
2002/2003	25	£8,741,821
2003/2004	27	£1,079,220
2004/2005	19	£224,532
2005/2006	12	£404,513
2006/2007	20	£6,033,082
2007/2008	10	£786,612
2008/2009	9	£110,710
2009/2010	2	£65,000
Grand Total	**172**	**£19,249,853**

Total number and value of claims involving anaesthetic issues by financial year

* Due to the time delay between an incident occurring and a claim being made, it is very likely that claims with an incident date towards the end of the review period have yet to be issued.

These claims included adverse incidents that had occurred in labour and during caesarean section.



Total number and value of claims involving anaesthetic issues by sub categories

Guidance

Whilst there is national guidance for maternity services in relation to the anaesthetic care provided within a maternity service, most guidance looks at the provision of services (RCOG 2007[1]) (RCOA 2011[2]) rather than the clinical care provided to women by anaesthetists

The Association of Anaesthetists of Great Britain and Ireland (AAGBI) and Obstetric Anaesthetists' Association (OAA) provide further guidance on the provision of anaesthetic services on the labour ward (AAGBI/OAA 2005[3]) which includes guidance on the use of guidelines and appropriate training for the staff providing the service. The AAGBI/OAA also has clinical guidelines, although these are only available to members.

CNST Maternity Standards

Since the revision of the CNST Maternity Standards in 2009, a criterion has been included that requires maternity services to have an approved document that contains certain minimum requirements relating to consultant anaesthetist staffing on the labour ward. Assessment at the higher levels of the 2011/12 CNST Maternity Standards[4] requires the maternity service to demonstrate implementation and monitoring of several minimum requirements in the criterion. Additionally, it is expected that anaesthetists are included in the training provided within the maternity services. It is also expected that anaesthetists are included within the Training Needs Analysis (TNA) for the maternity service and, at higher levels of assessment, evidence of implementation of the training as described in the TNA and monitoring of attendance is required at Levels 2 and 3 respectively.

References

1. Royal College of Anaesthetists, Royal College of Midwives, Royal College of Obstetricians and Gynaecologists, Royal College of Paediatrics and Child Health. (2007). *Safer Childbirth: Minimum Standards for the Organisation and Delivery of Care in Labour*. London: RCOG Press. Available at: www.rcog.org.uk

2. The Royal College of Anaesthetists (2011). *Providing equity of critical and maternal care for the critically ill pregnant or recently pregnant woman*. London: RCOA. Available at: www.rcoa.ac.uk/docs/Prov_Eq_Mat_and_CritCare.pdf

3. The Association of Anaesthetists of Great Britain and Ireland, and the Obstetric Anaesthetists' Association. (2005). *OAA/AAGBI Guidelines for Obstetric Anaesthetic Services (Revised edition)*. London: AAGBI/OAA. Available at: www.aagbi.org.uk and www.oaa-anaes.ac.uk

4. NHS Litigation Authority. (2011). *CNST Maternity Clinical Risk Management Standards*. London: NHSLA. Available at: www.nhsla.com

Appendix: 2

Maternity Claims - Information sheet
Antenatal Care

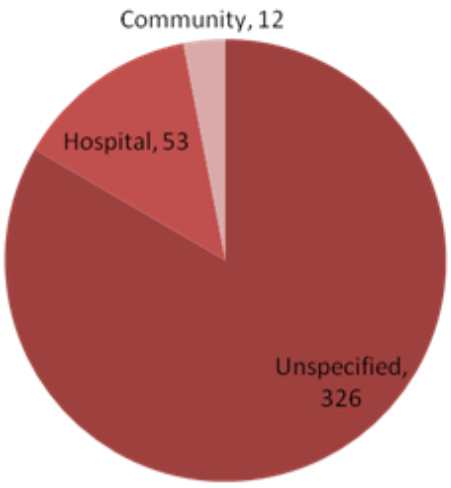
Claims

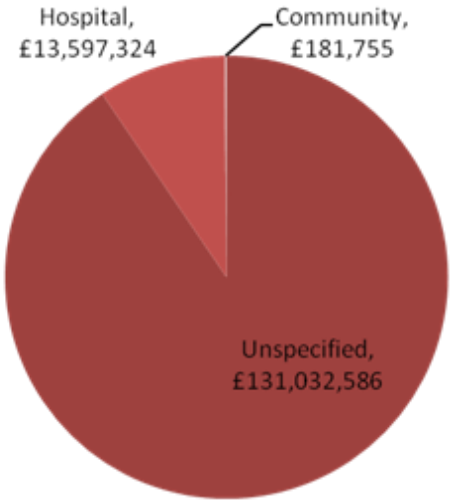
Review of the NHS Litigation Authority (NHSLA) claims database identified 391 claims with an incident date between 1st April 2000 and 31st March 2010 where negligent antenatal care was included within the description of the allegation. For most of these claims (326) it was not possible to say definitively where or by whom the antenatal care had been provided, but in 53 claims it appeared to be hospital care and for the remaining 12 claims care appeared to have been provided in the community. The estimated total value of these claims is £145million.

Incident Date*	Total Number	Total Value
2000/2001	61	£1,263,123
2001/2002	46	£8,930,530
2002/2003	59	£34,355,314
2003/2004	43	£7,141,931
2004/2005	56	£22,289,349
2005/2006	46	£29,124,260
2006/2007	36	£18,021,734
2007/2008	28	£13,561,858
2008/2009	13	£9,910,000
2009/2010	3	£213,565
Grand Total	**391**	**£144,811,665**

Total number and value of claims involving antenatal care issues by financial year

* Due to the time delay between an incident occurring and a claim being made, it is very likely that claims with an incident date towards the end of the review period have yet to be issued.





Total number and value of claims involving antenatal care issues by sub categories

Guidance

The current National Institute of Health and Clinical Excellence (NICE) guidance *Antenatal care*[1] (NICE 2008) provides guidance on best practice for the baseline clinical care of all pregnant women, and comprehensive information on the antenatal care of healthy women with uncomplicated singleton pregnancies. This guideline replaced the original NICE guidance on this subject published in 2003.

As in the previous report *Why Mothers Die*[2] (CEMACH 2004), within the top ten recommendations in *Saving Mothers' Lives*[3] (CEMACH 2007) there are a number that relate to the antenatal period. In the 2011 report on *Saving Mothers' Lives*[4] (BJOG 2011) there continues to be a number of recommendations for the care of women in the antenatal period.

CNST Maternity Standards

The CNST Maternity Standards[5] contain criteria on antenatal care. Some are related to communication e.g. booking appointments and patient information and discussion. There is also a criterion that requires maternity services to have approved documentation for the process of Clinical Risk Assessment (Antenatal) that is implemented (Level 2) and monitored (Level 3).

References

1. National Institute for Health and Clinical Excellence. (2008). *Antenatal care: Routine care for the healthy pregnant woman*. London: NICE. Available at: www.nice.org.uk

2. Confidential Enquiry into Maternity and Child Health. (2004). *Why Mothers Die 2000-2002*. London: RCOG Press. Available at: www.rcog.org.uk

3. Confidential Enquiry into Maternity and Child Health. (2007). *Saving Mothers' Lives: Reviewing maternal deaths to make motherhood safer - 2003-2005*. London: CEMACH. Available at: http://cemach.interface-test.com/Home.aspx

4. Confidential Enquiry into Maternity and Child Health. (2011). *Saving Mothers' Lives: Reviewing maternal deaths to make motherhood safer: 2006-2008*. London: BJOG. Available at www.bjog.org

5. NHS Litigation Authority. (2011). *CNST Maternity Clinical Risk Management Standards*. London: NHSLA. Available at: www.nhsla.com

Appendix: 3

Maternity Claims - Information sheet
Antenatal investigations

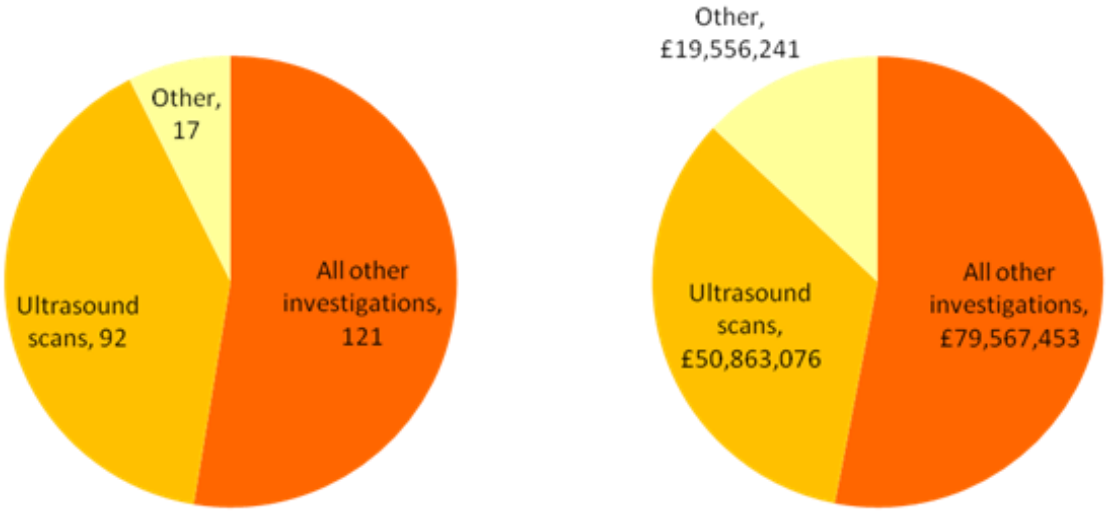
Claims

Review of the NHS Litigation Authority (NHSLA) claims database found a total of 230 claims with an incident date between 1st April 2000 and 31st March 2010. This total includes all claims involving ultrasound scans (92), other antenatal investigations (121) and a small number (17) where this information was not specified on the database. The estimated total value of these claims was £150million.

Incident Date*	Total Number	Total Value
2000/2001	42	£16,993,948
2001/2002	25	£4,981,969
2002/2003	33	£25,645,552
2003/2004	36	£24,797,441
2004/2005	22	£21,051,078
2005/2006	28	£20,941,207
2006/2007	18	£13,849,679
2007/2008	15	£14,118,837
2008/2009	8	£284,558
2009/2010	3	£7,322,500
Grand Total	**230**	**£149,986,770**

* Due to the time delay between an incident occurring and a claim being made, it is very likely that claims with an incident date towards the end of the review period have yet to be issued.

Total number and value of claims involving antenatal investigations issues by financial year



Total number and value of claims involving antenatal investigations issues by sub categories

Guidance

There are a number of publications that give guidance on antenatal investigations that should be carried out for pregnant women. The National Institute of Health and Clinical Excellence (NICE) guidance *Antenatal care: Routine care for the healthy pregnant woman*[1] (NICE 2008) includes guidance on the screening tests that should be offered for the detection of fetal abnormalities as well as maternal screening for infections.

Both the RCOG (RCOG 2000)[2] and the UK National Screening Committee provides guidance on all screening tests that should be offered in the antenatal period.[3]

CNST Maternity Standards

The 2011/12 CNST Maternity Standards[3] include a criterion on the Maternal Antenatal Screening Tests. This requires maternity services to have in place approved documentation for the process of ensuring all appropriate maternal screening tests are offered, undertaken and reported on, during the antenatal period. At the higher assessment levels, maternity services are required to demonstrate implementation (Level 2) and monitoring (Level 3) of selected minimum requirements in the criterion.

References

1. National Institute for Health and Clinical Excellence. (2008). *Antenatal care: Routine care for the healthy pregnant woman*. London: NICE. Available at: www.nice.org.uk

2. Routine Ultrasound Screening in Pregnancy: Protocol, Standards and Training Supplement to Ultrasound Screening for Fetal Abnormalities. London: RCOG Available at www.rcog.org.uk

3. UK National Screening Committee Available at: http://www.screening.nhs.uk

4. NHS Litigation Authority. (2011). *CNST Maternity Clinical Risk Management Standards*. London: NHSLA. Available at: www.nhsla.com

Appendix: 4

Maternity Claims - Information sheet
Bladder

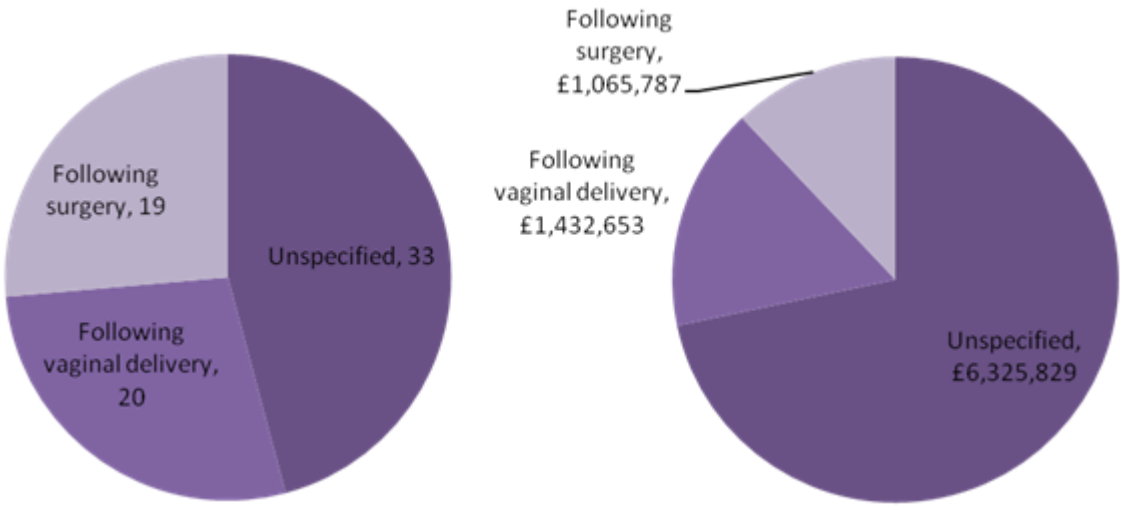
Claims

Review of the claims on the NHS Litigation Authority (NHSLA) database with an incident date between 1st April 2000 and 31st March 2010 identified 72 claims that related to the care of the bladder. These exclude any claims where the information in the NHSLA claims database indicated that the claim was related to an injury which occurred during surgery. During this period the estimated total value of the claims is almost £9million.

Incident Date*	Total Number	Total Value
2000/2001	6	£360,305
2001/2002	6	£4,270,625
2002/2003	8	£487,849
2003/2004	6	£385,542
2004/2005	8	£545,723
2005/2006	16	£1,197,980
2006/2007	8	£503,993
2007/2008	10	£767,252
2008/2009	4	£305,000
2009/2010	0	£0
Grand Total	**72**	**£8,824,269**

Total number and value of claims involving the bladder by financial year

* Due to the time delay between an incident occurring and a claim being made, it is very likely that claims with an incident date towards the end of the review period have yet to be issued



.Total number and value of claims involving the bladder by sub categories

Guidance

The National Institute of Health and Clinical Excellence (NICE) guidance *Routine Postnatal Care*[1] (NICE 2006) provides brief guidance to maternity services on the care that should be provided to women following delivery in relation to the care of the bladder. The RCOG provides guidance on Operative Vaginal Delivery[2] (RCOG 2011) which includes issues related to the bladder. There is little other national guidance beyond this.

CNST Maternity Standards

The 2011/12 CNST Maternity Standards[3] include a criterion on the management of the bladder following delivery. In addition, the criterion on operative vaginal delivery includes a minimum requirement on care of the bladder during these procedures. These criteria were introduced when the revised standards were released in April 2009. The criteria require maternity services to have in place an approved document that contains certain minimum requirements. At the higher level assessments, maternity services are required to demonstrate implementation and monitoring of selected minimum requirements in the criteria.

References

1. National Institute for Health and Clinical Excellence. (2006). *Routine postnatal care of women and their babies*. London: NICE. Available at: www.nice.org.uk

2. Royal College of Obstetricians and Gynaecologists. (2011). *Operative Vaginal Delivery*. London: RCOG. Available at: www.rcog.org.uk

3. NHS Litigation Authority. (2011). *CNST Maternity Clinical Risk Management Standards*. London: NHSLA. Available at: www.nhsla.com

Appendix: 5

Maternity Claims - Information sheet
Caesarean Section

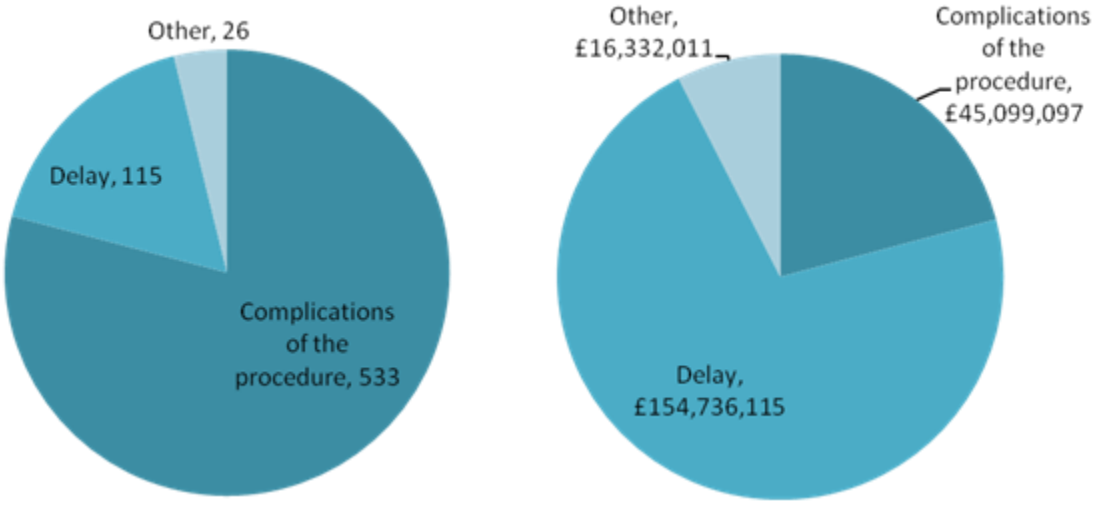
Claims

Review of the NHS Litigation Authority (NHSLA) claims database identified 674 claims with an incident date between 1st April 2000 and 31st March 2010; these included alleged delay in undertaking the procedure as well as claims where a complication of the procedure had occurred. The estimated total value of the claims identified was £216million.

Incident Date*	Total Number	Total Value
2000/2001	89	£20,956,050
2001/2002	81	£23,482,218
2002/2003	101	£30,160,536
2003/2004	103	£37,372,664
2004/2005	80	£36,807,184
2005/2006	70	£21,622,078
2006/2007	71	£17,301,008
2007/2008	47	£18,106,539
2008/2009	24	£9,910,190
2009/2010	8	£448,755
Grand Total	**674**	**£216,167,223**

Total number and value of claims involving caesarean section by financial year

* Due to the time delay between an incident occurring and a claim being made, it is very likely that claims with an incident date towards the end of the review period have yet to be issued.



Total number and value of claims involving caesarean section by sub categories

Guidance

The National Institute of Health and Clinical Excellence (NICE) guidance *Caesarean Section*[1] (NICE 2011) includes a number of recommendations for caesarean section, including some for the surgical procedure. NICE also recommends the classification of caesarean section into four grades of urgency based on the NCEPOD classification system. These gradings do not include a time for the decision-to-delivery interval although most units will have in place a 30 minute recommendation for those graded as Grade 1, with other grades having a locally agreed timeframe. In May 2010 the RCOG published in May 2010 *Classification of Urgency of Caesarean Section – a continuum of risk*[2] which continues to suggest 30 minutes for a Grade 1 caesarean section but encourages the review of all cases for the risk to the mother and fetus.

CNST Maternity Standards

The NHSLA standards have included a criterion on caesarean section since before the introduction of the CNST Maternity Standards[3] in June 2003. Following the revision of the Standards in April 2009 a criterion has been in place that requires maternity services to have an approved document that contains certain minimum requirements in relation to caesarean section. At the higher assessment levels, maternity services are required to demonstrate implementation and monitoring of several minimum requirements in the criterion.

References

1. National Institute for Health and Clinical Excellence. (2011). *Caesarean Section*. London: NICE. Available at: www.nice.org.uk

2. Royal College of Obstetricians and Gynaecologists. (2010). Classification of Urgency of Caesarean Section – a continuum of risk London: RCOG. Available at: www.rcog.org.uk

3. NHS Litigation Authority. (2011). *CNST Maternity Clinical Risk Management Standards*. London: NHSLA. Available at: www.nhsla.com

Appendix: 6

Maternity Claims - Information sheet
Cerebral Palsy

Claims

Review of the NHS Litigation Authority (NHSLA) claims database showed there were a total of 542 claims with an incident date between 1st April 2000 and 31st March 2010 where the principle or only information available was that the case involved cerebral palsy. The estimated total value of the claims in this category is £1.3billion.

Incident Date*	Total Number	Total Value
2000/2001	100	£164,552,993
2001/2002	76	£125,452,852
2002/2003	72	£170,168,827
2003/2004	70	£141,739,008
2004/2005	70	£189,315,906
2005/2006	59	£172,688,834
2006/2007	55	£168,022,905
2007/2008	21	£68,715,000
2008/2009	19	£62,925,000
2009/2010	0	£0
Grand Total	**542**	**£1,263,581,324**

Total number and value of claims involving cerebral palsy by financial year

* Due to the time delay between an incident occurring and a claim being made, it is very likely that claims with an incident date towards the end of the review period have yet to be issued.

Due to the limited information available on the database, it was not possible to analyse the cerebral palsy claims by sub category.

Guidance

There has been national guidance for maternity services for many years on both antenatal and intrapartum care which aims to ensure that women receive high quality care and that the incidence of morbidity and mortality is as low as possible. The National Institute for Health and Clinical Excellence (NICE) has produced guidance for both antenatal care[1] (NICE 2008) and intrapartum care[2] (NICE 2007) which has been widely implemented by maternity services.

There has also been national guidance for maternity services for a number of years on cardiotocograph (CTG) interpretation. *Intrapartum Care*[2] (NICE 2007) includes recommendations on the use of continuous electronic fetal monitoring, with interpretation and record keeping. This guidance is aimed at identifying hypoxia before it is sufficient to lead to damaging acidosis and long term neurological adverse outcome for the baby.

Training for staff who interpret CTGs has been the subject of various recommendations in recent years. *Safer Childbirth*[3] (RCOG 2007) recommends multidisciplinary training for all who are involved in the care of women, but makes no comment on the content of the training.

Additionally there is guidance on staffing levels for the various staff groups who provide care in the intrapartum period, which is aimed at ensuring staffing levels are sufficient to provide the appropriate level of care for all women in labour[3] (RCOG 2007)

CNST Maternity Standards

The CNST Maternity Standards[4] have always looked at the use of cardiotocography. Prior to the revision of the Standards, this was by requesting that maternity services had a suitable guideline in place. Since the introduction of the revised standards in 2009, the standards have contained criteria on both intermittent auscultation and continuous electronic fetal monitoring. Both criteria require maternity services to have specific minimum requirements in their approved guidance (based on national guidance) and at the higher assessment levels to demonstrate these are being implemented (Level 2) and monitored (Level 3). Additionally, the Standards now also contain a criterion on fetal blood sampling.

References

1. National Institute for Health and Clinical Excellence. (2008). *Antenatal care: Routine care for the healthy pregnant woman*. London: NICE. Available at: www.nice.org.uk

2. National Institute for Health and Clinical Excellence. (2007). *Intrapartum care: Care of healthy women and their babies during childbirth*. London: NICE. Available at: www.nice.org.uk

3. *Royal College of Anaesthetists, Royal College of Midwives, Royal College of Obstetricians and Gynaecologists, Royal Col*lege of Paediatrics and Child Health. (2007). *Safer Childbirth: Minimum Standards for the Organisation and Delivery of Care in Labour*. London: RCOG Press. Available at: www.rcog.org.uk

4. NHS Litigation Authority. (2011). *CNST Maternity Clinical Risk Management Standards*. London: NHSLA. Available at: www.nhsla.com

Appendix: 7

Maternity Claims - Information sheet
CTG Interpretation

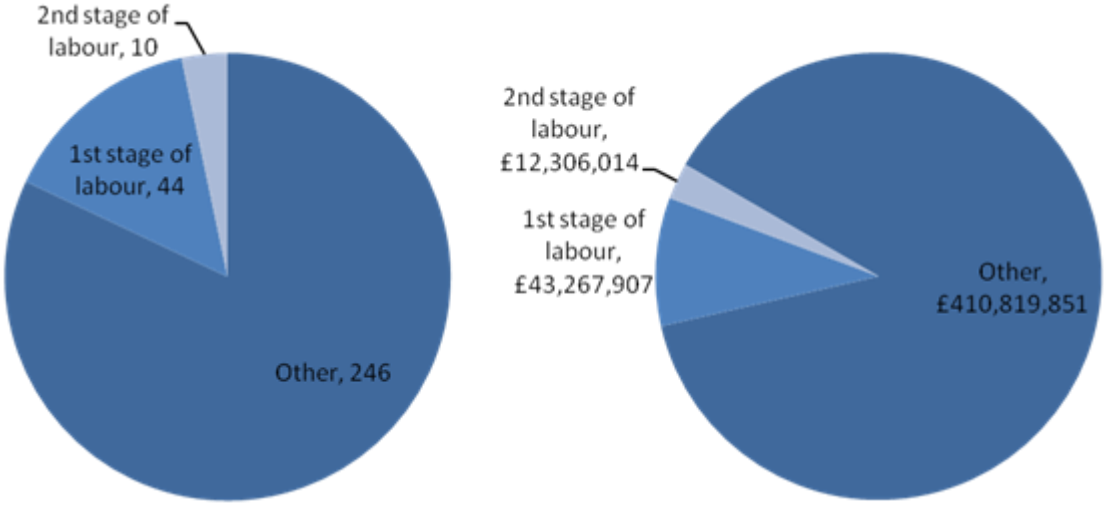
Claims

Review of the NHS Litigation Authority (NHSLA) claims database identified 300 claims involving CTG Interpretation, during both the first and second stages of labour, with an incident date between 1st April 2000 and 31st March 2010. In addition, allegations regarding CTG interpretation were made in claims categorised as Management of Labour in the study and those resulting in an outcome of Cerebral Palsy. The estimated total value of the claims identified within the CTG Interpretation category was £466million.

Incident Date*	Total Number	Total Value
2000/2001	33	£29,131,590
2001/2002	29	£30,319,697
2002/2003	42	£90,785,679
2003/2004	46	£72,183,507
2004/2005	39	£49,000,848
2005/2006	42	£72,849,588
2006/2007	30	£44,244,889
2007/2008	23	£43,499,219
2008/2009	10	£21,815,553
2009/2010	6	£12,563,200
Grand Total	**300**	**£466,393,771**

Total number and value of claims involving CTG interpretation issues by financial year

* Due to the time delay between an incident occurring and a claim being made, it is very unlikely that claims with an incident date towards the end of the review period have yet to be issued.



Total number and value of claims involving CTG interpretation issues by sub categories

Guidance

There has been national guidance for maternity services for a number of years on CTG interpretation. The current National Institute of Health and Clinical Excellence (NICE) guidance *Intrapartum Care*[1] (NICE 2007) includes recommendations on the use of continuous electronic fetal monitoring, including interpretation and record keeping.

Training for staff who interpret CTGs has been the subject of various recommendations for many years as well as more recently. *Safer Childbirth*[2] (RCOG 2007) recommends multidisciplinary training for all who are involved in the care of women, but makes no comment on the content of the training. In recent years PROMPT[3] (PRactical Obstetric Multi-Professional Training) training endorsed jointly by the RCOG and RCM has been utilised by a number of maternity services to ensure staff are trained in this topic. Most recently the RCOG and RCM have launched an on-line training resource Fetal Heart Rate Monitoring (eFM) in partnership with e-Learning for Healthcare, which reflects NICE guidance.[4]

CNST Maternity Standards

The NHSLA Maternity Standards[5] have included CTG Interpretation since before the introduction of the revised Standards in April 2009. Since then there has been a criterion that requires maternity services to have an approved document that contains certain minimum requirements in relation to CTG interpretation. At the higher assessment levels, maternity services are required to demonstrate implementation (Level 2) and monitoring (Level 3) of several minimum requirements in the criterion. The requirement for maternity services to include CTG interpretation training in their Training Needs Analysis is also included in the CNST Maternity Standards and at the higher levels evidence of implementation and monitoring of this training is required.

References

1. National Institute for Health and Clinical Excellence. (2007). *Intrapartum care: Care of healthy women and their babies during childbirth*. London: NICE. Available at: www.nice.org.uk
2. Royal College of Anaesthetists, Royal College of Midwives, Royal College of Obstetricians and Gynaecologists, Royal College of Paediatrics and Child Health. (2007). *Safer Childbirth: Minimum Standards for the Organisation and Delivery of Care in Labour*. London: RCOG Press. Available at: www.rcog.org.uk
3. Draycott, T. Winter, C. Crofts, J. & Barnsfield, S. (2008) *Practical Obstetric MultiProfessional Training (PROMPT)*. Bristol: PROMPT Foundation. Available at: http://www.prompt-course.org
4. Royal College of Obstetricians and Gynaecologists and Royal College of Midwives. EfM e-learning resource. 2011. Available at http://www.e-lfh.org.uk/projects/efm/index.html
5. NHS Litigation Authority. (2011). *CNST Maternity Clinical Risk Management Standards*. London: NHSLA. Available at: www.nhsla.com

Appendix: 8

Maternity Claims - Information sheet
Drug Error

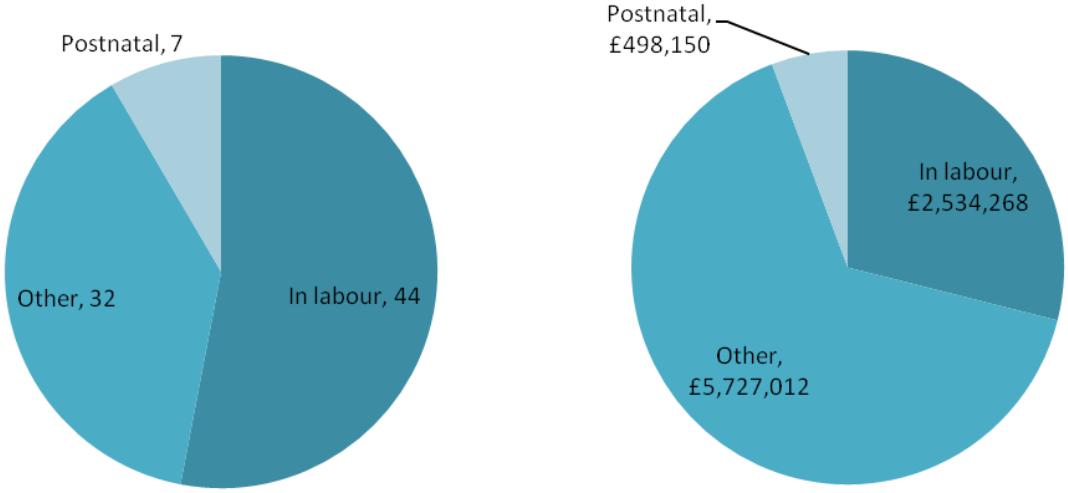
Claims

Review of the NHS Litigation Authority (NHSLA) claims database found that between 1st April 2000 and 31st March 2010 there were a total of 83 maternity claims where the main allegation involved a drug error. The largest number of these (44) occurred in labour, with seven during the postnatal period. The information on the remaining 32 claims was not sufficient to indicate when the alleged drug error occurred. The estimated total value of the claims is around £9million. The information on the NHSLA database indicates that the drugs involved in the errors are often those commonly used in midwifery and obstetric practise i.e. Pethidine, Syntometrine, Syntocinon and antibiotics.

Incident Date*	Total Number	Total Value
2000/2001	8	£347,105
2001/2002	13	£120,999
2002/2003	12	£524,532
2003/2004	12	£263,756
2004/2005	12	£630,534
2005/2006	3	£1,150,000
2006/2007	11	£5,316,823
2007/2008	9	£323,682
2008/2009	3	£82,000
2009/2010	0	£0
Grand Total	**83**	**£8,759,430**

Total number and value of claims involving drug error issues by financial year

* Due to the time delay between an incident occurring and a claim being made, it is very likely that claims with an incident date towards the end of the review period have yet to be issued.



Total number and value of claims involving drug error issues by sub categories

Guidance

There is considerable guidance available for health care professionals on the use and administration of medication in their practice. For midwives the Nursing and Midwifery Council's *Standards for Medicines Management*[1] (NMC 2010) provide the minimum standards by which practice should be conducted and a benchmark against which practice is measured. For medical staff, the General Medical Council has detailed guidance on prescribing[2] (GMC 2008).

CNST Maternity Standards

There are no criteria within the CNST Maternity Standards[3] (NHSLA 2011) that require maternity services to have guidance for staff on dealing with drugs. Following their revision and re-launch in 2005, the NHSLA Risk Management Standards for Acute Trusts[4] (which also apply to maternity services) included a criterion on medicines management which looked at the prescribing and administration of medicines. However, the 2011/12 version of the NHSLA Acute Standards[4] (NHSLA 2011), whilst still looking at medicines management, does not look directly at prescribing or administration.

References

1. Nursing and Midwifery Council. (2007). *Standards for Medicines Management*. London. Available at: www.nmc-uk.org

2. General Medical Council (2008) *Good Practice in Prescribing.* London. Available at: www.gmc-uk.org

3. NHS Litigation Authority. (2011). *CNST Maternity Clinical Risk Management Standards*. London: NHSLA. Available at: www.nhsla.com

4. NHS Litigation Authority. (2011). *NHSLA Risk Management Standards for NHS Trusts providing Acute, community, or Mental Health & Learning Disability Services and Independent Sector Providers of NHS Care*. London: NHSLA. Available at: www.nhsla.com

Appendix: 9

Maternity Claims - Information sheet
Management of Labour

Claims

Review of the NHS Litigation Authority (NHSLA) claims database identified 715 claims involving the management of labour with an incident date between 1st April 2000 and 31st March 2010. These claims are those where the information on the NHSLA database described a number of events during labour that had led to allegations of negligent care rather than just one isolated event. For some claims, it was possible to determine from the information on the database whether the negligent care took place during the 1st or 2nd stage of labour, but for more than 50% of claims this was not specified. The estimated total value of the management of labour claims was £424million.

Incident Date*	Total Number	Total Value
2000/2001	101	£31,906,931
2001/2002	90	£49,001,472
2002/2003	83	£32,541,907
2003/2004	85	£42,748,983
2004/2005	87	£46,843,411
2005/2006	85	£81,031,677
2006/2007	78	£52,931,451
2007/2008	56	£44,234,259
2008/2009	41	£29,463,061
2009/2010	9	£13,336,500
Grand Total	**715**	**£424,039,651**

Total number and value of claims involving issues during management of labour by financial year

* Due to the time delay between an incident occurring and a claim being made, it is very likely that claims with an incident date towards the end of the review period have yet to be issued.

Total number and value of claims involving issues during management of labour by sub categories

Guidance

There are a number of publications guiding maternity services on the care of women in labour. The National Institute of Health and Clinical Excellence (NICE) guidance *Intrapartum care*[1] (NICE, 2007) gives advice on the care of healthy women who are giving birth between 37-42 weeks (known as 'term'); it excludes a number of other groups of women who do not meet these criteria.

As stated in the Claims section at the beginning of this Information Sheet, the claims included in this category are those where a number of events appear to have led to the allegation of negligent care. Individual information sheets are available on the other categories.

CNST Maternity Standards

The 2011/12 CNST Maternity Standards[2] include a criterion on the care of women in labour. This criterion requires maternity services to have in place an approved document that contains certain minimum requirements on observations, guidance on duration of all stages of labour and referral to obstetric care. At assessment at the higher levels maternity services are required to demonstrate implementation and monitoring of selected minimum requirements in the criterion.

References

1. National Institute for Health and Clinical Excellence. (2007). *Intrapartum care: Care of healthy women and their babies during childbirth*. London: NICE. Available at: www.nice.org.uk

2. NHS Litigation Authority. (2011). *CNST Maternity Clinical Risk Management Standards*. London: NHSLA. Available at: www.nhsla.com

Appendix: 10

Maternity Claims - Information sheet
Maternal Death

Claims

Review of the NHS Litigation Authority (NHSLA) claims database found a total of 38 claims for maternal deaths with an incident date between 1st April 2000 and 31st March 2010. The timing of these deaths was unspecified in 36 claims, with two specified as occurring in the antenatal period. The estimated total value of the claims was £20million.

Incident Date*	Total Number	Total Value
2000/2001	6	£6,836,237
2001/2002	2	£0
2002/2003	7	£5,399,264
2003/2004	3	£450,220
2004/2005	9	£3,833,185
2005/2006	5	£1,020,000
2006/2007	4	£1,800,000
2007/2008	2	£915,000
2008/2009	0	£0
2009/2010	0	£0
Grand Total	**38**	**£20,253,906**

Total number and value of claims for maternal death by financial year

* Due to the time delay between an incident occurring and a claim being made, it is very likely that claims with an incident date towards the end of the review period have yet to be issued.

Guidance

For a number of years there has been national guidance for maternity services on both antenatal and intrapartum care which aims to minimise the risk of maternal and fetal loss occurring both antenatally and during labour. The National Institute for Health and Clinical Excellence (NICE) has produced guidance for Antenatal care[1] (NICE 2008) and Intrapartum care[2] (NICE 2007) which has been widely implemented by maternity services.

Additionally, the United Kingdom has a well established process for enquiry into all maternal deaths that occur. The results of the enquiries are reported on every three years and always include recommendations for the improvement of care. The last two enquiries[3 & 4] have organised the recommendations into the top ten and included additional guidance to support maternity services in the prioritisation of the recommendations (CEMACH 2007 and CMACE 2011).

CNST Maternity Standards

The CNST Maternity Standards[5] do not contain any criteria that directly refer to maternal death. However, since the revision of the Standards in 2009 they have contained two standards that focus predominantly on clinical care: Standard 2 *Clinical Care* and Standard 3 *High Risk Conditions*. The criteria in these standards and other criteria that refer to the care of the women are all based on guidance which is aimed at reducing the incidence of maternal death. The top ten recommendations of CEMACH (2007) are reflected in a number of the criteria.

References

1. National Institute for Health and Clinical Excellence. (2008). *Antenatal care: Routine care for the healthy pregnant woman*. London: NICE. Available at: www.nice.org.uk

2. National Institute for Health and Clinical Excellence. (2007). *Intrapartum care: Care of healthy women and their babies during childbirth*. London: NICE. Available at: www.nice.org.uk

3. Confidential Enquiries into Maternal and Child Health (2007). *Saving Mothers' Lives Reviewing maternal deaths to make motherhood safer – 2003 to 2005.* London: CEMACH. Available at: www.hqip.org.uk

4. Confidential Enquiries into Maternal Deaths in the United Kingdom. (2011). *Saving Mothers' Lives: reviewing maternal deaths to make motherhood safer: 2006 – 2008.* London: wiley-Blackwell. Available at http://onlinelibrary.wiley.com

5. NHS Litigation Authority. (2011). *CNST Maternity Clinical Risk Management Standards*. London: NHSLA. Available at: www.nhsla.com

Appendix: 11

Maternity Claims - Information sheet
Midwifery Care

Claims

Review of the NHS Litigation Authority (NHSLA) claims database showed that there were a total of 35 claims with an incident date between 1st April 2000 and 31st March 2010 where the main allegation involved issues with midwifery care. Most of these claims (28) related to pressure area care. The number of these claims has remained small but constant over the years reviewed, but due to the time delay between an incident occurring and a claim being made, it is very likely that claims with an incident date towards the end of the review period have yet to be issued.

The estimated total value of the claims identified is just over £500,000 with almost 80% relating to pressure area care.

Incident Date	Total Number	Total Value
2000/2001	1	£0
2001/2002	6	£79,975
2002/2003	4	£53,462
2003/2004	4	£63,001
2004/2005	1	£15,135
2005/2006	4	£40,698
2006/2007	4	£650
2007/2008	5	£89,031
2008/2009	6	£169,750
2009/2010		
Grand Total	**35**	**£511,700**

Total number and value of claims involving midwifery care issues by financial year

Total number and value of claims involving midwifery care issues by sub categories

Guidance

Whilst there is considerable guidance on the care of women in labour this guidance does not in general look at the "nursing care" that should be provided. The National Institute of Health and Clinical Excellence (NICE) guidance *Intrapartum Care*[1] (NICE 2007) gives guidance on care throughout labour. However this guidance is generally about communication, support, hygiene and where appropriate, referral when emergencies occur, and not about nursing care.

As noted above, allegations related to pressure areas were the largest in number. This allegation was most often connected with the use of epidural analgesia. NICE *Intrapartum Care*[1] includes in its chapter on regional analgesia a recommendation that women should be encouraged to move and adopt an upright position but no more explicit guidance on pressure area care during regional analgesia is provided.

CNST Maternity Standards

There are no criteria within either the 2011/12 NHSLA Risk Management Standards for Acute Trusts[2] (NHSLA 2011) or CNST Maternity Standards (NHSLA 2011) that require maternity services to have guidance in place for the "nursing care" of women in labour.

References

1. National Institute for Health and Clinical Excellence. (2007). *Intrapartum care: Care of healthy women and their babies during childbirth*. London: NICE. Available at: www.nice.org.uk

2. NHS Litigation Authority (2011) *Risk Management Standards for Acute Trusts, Primary Care Trusts and Independent Sector Providers of NHS Care.* London: NHSLA. Available at: www.nhsla.com

3. NHS Litigation Authority. (2011). *CNST Maternity Clinical Risk Management Standards*. London: NHSLA. Available at: www.nhsla.com

Appendix: 12

Maternity Claims - Information sheet
Operative Vaginal Delivery

Claims

Review of the claims on the NHS Litigation Authority (NHSLA) database with an incident date between 1st April 2000 and 31st March 2010 identified 160 claims involving operative vaginal delivery: 88 of these relate to Forceps deliveries; 42 to Ventouse deliveries; and in 30 claims the instrument was not stated. The estimated total value of the claims was £94million.

Incident Date*	Total Number	Total Value
2000/2001	21	£12,418,345
2001/2002	18	£19,949,232
2002/2003	21	£8,097,140
2003/2004	15	£771,284
2004/2005	28	£21,352,246
2005/2006	22	£5,655,255
2006/2007	14	£13,215,527
2007/2008	15	£9,001,939
2008/2009	4	£2,936,255
2009/2010	2	£262,000
Grand Total	**160**	**£93,659,223**

Total number and value of claims involving operative vaginal delivery

* Due to the time delay between an incident occurring and a claim being made, it is very likely that claims with an incident date towards the end of the review period have yet to be issued.

Total number and value of claims involving operative vaginal delivery

Guidance

The RCOG has guidance for obstetricians on Operative Vaginal Delivery which includes information for those who conduct both Forceps and Ventouse deliveries (RCOG 2011)[1]. Guidance on obtaining consent for these procedures[2] is also provided by the RCOG, (RCOG 2010).

The National Institute of Health and Clinical Excellence (NICE) guidance *Intrapartum care*[3] (NICE 2007) includes a number of recommendations for operative vaginal deliveries.

Both of these documents include reference to the staff undertaking the procedures, who should be appropriately trained and, where appropriate, have their competency assessed.

CNST Maternity Standards

The 2011/12 CNST Maternity Standards[4] include a criterion on Operative Vaginal Delivery, which was included in the standards in April 2009. This criterion requires maternity services to have in place an approved document that contains certain minimum requirements. At the higher levels of assessment, maternity services are required to demonstrate implementation and monitoring of selected minimum requirements in the criterion.

References

1. Royal College of Obstetricians and Gynaecologists. (2011). *Operative Vaginal Delivery*. London: RCOG. Available at: www.rcog.org.uk

2. Royal College of Obstetricians and Gynaecologists. (2010). *Consent Advice No 11 Operative Vaginal Delivery.* London: RCOG. Available at: *www.rcog.org.uk*

3. National Institute for Health and Clinical Excellence. (2007). *Intrapartum care: Care of healthy women and their babies during childbirth*. London: NICE. Available at: www.nice.org.uk

4. NHS Litigation Authority. (2011). *CNST Maternity Clinical Risk Management Standards*. London: NHSLA. Available at: www.nhsla.com

Appendix: 13

Maternity Claims - Information sheet
Perineal Trauma

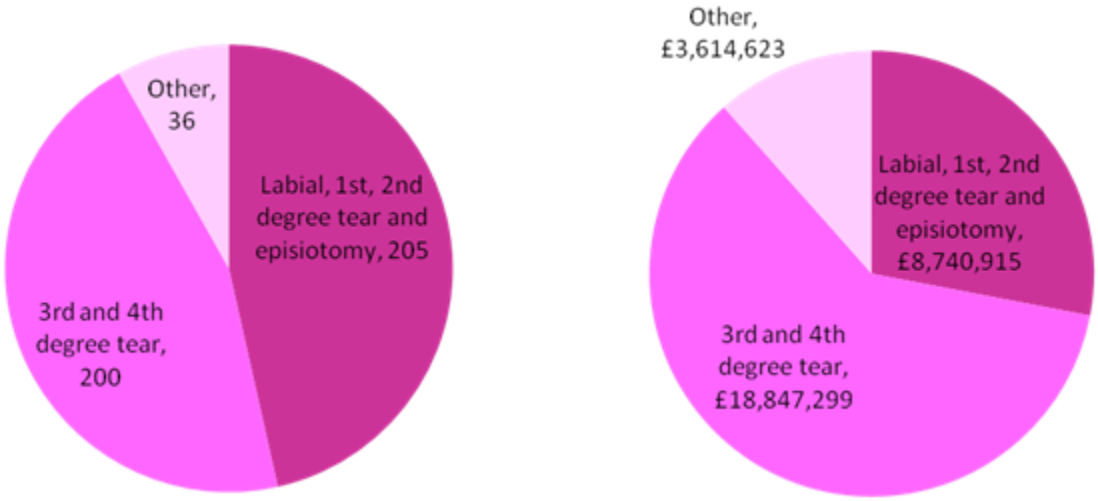
Claims

Review of the NHS Litigation Authority (NHSLA) claims data identified 441 claims with an incident date between 1st April 2000 and 31st March 2010 relating to perineal trauma. 205 claims involved labial, 1st or 2nd degree tears or episiotomies whist 200 involved 3rd or 4th degree tears, in the remaining 36 claims it was not possible to establish this information. The estimated total value of the claims identified is around £31million.

Incident Date*	Total Number	Total Value
2000/2001	59	£3,801,330
2001/2002	64	£2,866,619
2002/2003	60	£2,628,727
2003/2004	58	£3,531,886
2004/2005	61	£6,084,096
2005/2006	52	£3,705,554
2006/2007	43	£4,160,900
2007/2008	28	£2,691,697
2008/2009	15	£1,716,027
2009/2010	1	£16,000
Grand Total	**441**	**£31,202,836**

Total number and value of claims involving perineal trauma by financial year

* Due to the time delay between an incident occurring and a claim being made, it is very likely that claims with an incident date towards the end of the review period have yet to be issued.



Total number and value of claims involving perineal trauma by sub categories

Guidance

The National Institute of Health and Clinical Excellence (NICE) guidance *Intrapartum care*[1] includes recommendations on the basic principles for perineal repair which includes guidance on assessment and repair of perineal trauma (NICE 2007).

The RCOG has guidance for obstetricians on the repair of 3rd and 4th degree tears[2]. (RCOG 2007) The RCOG guideline recommends that those undertaking anal sphincter repairs should be appropriately trained. Additionally, it makes recommendations for formal training to be included within obstetric training. Note should also be taken of the NPSA Rapid Response Report[3] issued in May 2010 requiring NHS organisations to have set processes in place when using swabs during vaginal delivery or perineal repair.

CNST Maternity Standards

The 2011/12 CNST Maternity Standards[4] include a criterion on perineal trauma which requires maternity services to have in place an approved document which includes details on particular points. Implementation of this document needs to be demonstrated at Level 2 assessments and monitoring of the implementation at Level 3 assessments.

References

1. National Institute for Health and Clinical Excellence. (2007). *Intrapartum care: Care of healthy women and their babies during childbirth*. London: NICE. Available at: www.nice.org.uk

2. Royal College of Obstetricians and Gynaecologists. (2007). *The Management of Third- And Fourth-Degree Perineal Tears*. London: RCOG. Available at: www.rcog.org.uk

3. National Patient Safety Agency (2010) Never *Events Framework Update for 2010/11.* London: NPSA. Available at www.nrls.npsa.nhs.uk

4. NHS Litigation Authority. (2011). *CNST Maternity Clinical Risk Management Standards*. London: NHSLA. Available at: www.nhsla.com

Appendix: 14

Maternity Claims - Information sheet
Postpartum Haemorrhage

Claims

Review of the NHS Litigation Authority (NHSLA) claims database identified 111 claims for postpartum haemorrhage with an incident date between 1st April 2000 and 31st March 2010. These claims included 82 where there appeared to be a clear link to retained products, 25 where the haemorrhage appeared to be primary, and four where the exact cause was not clearly recorded. The estimated total value of the claims identified was £3million.

Incident Date*	Total Number	Total Value
2000/2001	10	£118,348
2001/2002	15	£144,489
2002/2003	24	£416,464
2003/2004	14	£573,188
2004/2005	14	£626,417
2005/2006	15	£631,354
2006/2007	8	£201,461
2007/2008	6	£235,000
2008/2009	5	£78,111
2009/2010	0	£0
Grand Total	**111**	**£3,024,833**

Total number and value of claims involving postpartum haemorrhage by financial year

* Due to the time delay between an incident occurring and a claim being made, it is very likely that claims with an incident date towards the end of the review period have yet to be issued.

Total number and value of claims involving postpartum haemorrhage by sub categories

Guidance

Guidance on the care of women who have a postpartum haemorrhage, either at the time of birth (primary) or later (secondary), is produced by RCOG in its publication *Prevention and Management of Post Partum Haemorrhage*[1] (RCOG, 2009). The NICE guidance *Intrapartum care*[2] (NICE, 2007) also includes brief guidance on the care of women who experience a haemorrhage immediately after the birth.

Saving Mothers' Lives[3] (CEMACH 2007) identified haemorrhage as one of the top five causes of direct deaths with 14 deaths from 2003 to 2005. However, this has reduced to 9 in the latest report[4] (CMACE, 2011).

CNST Maternity Standards

The 2011/12 CNST Maternity Standards[5] include a criterion on haemorrhage which was introduced when the revised standards were released in April 2009, and limited to postpartum haemorrhage in 2010. The criterion requires maternity services to have in place an approved document that contains certain minimum requirements. At the higher levels of assessment, maternity services are required to demonstrate implementation and monitoring of several minimum requirements in the criterion. An alternative criterion is used for those maternity services that solely provide midwifery led care.

References

1. Royal College of Obstetricians and Gynaecologists. (2009). *Prevention and management of post partum haemorrhage*. London: RCOG. Available at: www.rcog.org.uk

2. National Institute for Health and Clinical Excellence. (2007). *Intrapartum care: Care of healthy women and their babies during childbirth*. London: NICE. Available at: www.nice.org.uk

3. Confidential Enquiry into Maternity and Child Health. (2007). *Saving Mothers' Lives: Reviewing maternal deaths to make motherhood safer - 2003-2005*. London: CEMACH. Available at: http://cemach.interface-test.com/Home.aspx

4. Confidential Enquiries into Maternal Deaths in the United Kingdom. (2011). Saving Mothers' Lives: Reviewing maternal deaths to make motherhood safer: 2006-2008. London. Wiley-Blackwell. Available at http://onlinelibrary.wiley.com/doi/10.1111/j.1471-0528.2010.02847.x/pdf

5. NHS Litigation Authority. (2011). *CNST Maternity Clinical Risk Management Standards*. London: NHSLA. Available at: www.nhsla.com

Appendix: 15

Maternity Claims - Information sheet
Psychological Harm

Claims

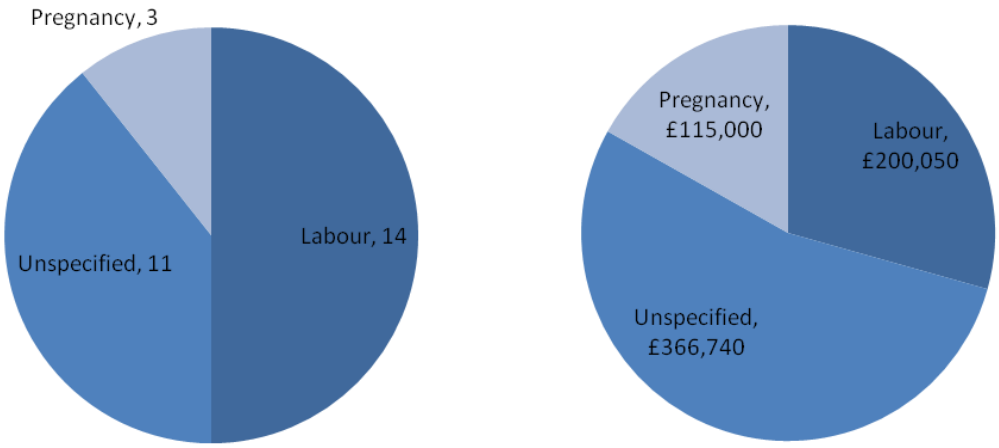
Review of the NHS Litigation Authority (NHSLA) claims database indicated that in the period between 1st April 2000 and 31st March 2010 there were 28 incidents related to maternity care resulting in claims where the sole allegation was that psychological harm had occurred. (Psychological harm may also be an additional allegation in other categories of claims reviewed.) Of the 28 claims, harm had occurred during labour in 14, in the antenatal period in 3, and for 11 claims this information was not specified. Whilst the information of the claims database was limited, for most claims it indicated that the psychological harm was linked to a fetal loss.

The estimated total value of the claims identified was £681,791. At the time the review was carried out, there were no claims for incidents in the final two years of the period.

Incident Date*	Total Number	Total Value
2000/2001	5	£47,383
2001/2002	3	£45,561
2002/2003	4	£145,759
2003/2004	3	£29,138
2004/2005	3	£45,825
2005/2006	6	£241,453
2006/2007	3	£126,673
2007/2008	1	£0
2008/2009	0	£0
2009/2010	0	£0
Grand Total	**28**	**£681,791**

Total number and value of claims involving psychological harm by financial year

* Due to the time delay between an incident occurring and a claim being made, it is very likely that claims with an incident date towards the end of the review period have yet to be issued.



Total number and value of claims involving psychological harm by sub categories

Guidance

The National Institute of Health and Clinical Excellence (NICE) guidance *Intrapartum Care*[1] (NICE 2007) gives guidance on care throughout labour and, whilst the document gives no explicit guidance on psychological care, it makes recommendations about care which studies have suggested may improve the psychological outcome for women.

CNST Maternity Standards

There are no criteria within either 2011/12 NHSLA Risk Management Standards for Acute Trusts[2] (NHSLA 2011) or the 2011/12 CNST Maternity Standards[3] (NHSLA 2011) that require maternity services to have guidance in place for care to prevent psychological harm. However, the CNST Maternity Standards (2011) include a criterion that looks at the support provided to the parent(s) where there has been a poor outcome for the baby. The aim of this criterion is to reduce the psychological harm experienced by the parents when there has been a poor outcome for the baby, either suspected or actual.

References

1. National Institute for Health and Clinical Excellence. (2007). *Intrapartum care: Care of healthy women and their babies during childbirth*. London: NICE. Available at: www.nice.org.uk

2. NHS Litigation Authority. (2011). NHSLA Risk Management Standards for NHS Trusts providing Acute, Community, or Mental Health & Learning Disability Services and Independent Sector Providers of NHS Care Available at: www.nhsla.com

3. NHS Litigation Authority. (2011). *CNST Maternity Clinical Risk Management Standards*. London: NHSLA. Available at: www.nhsla.com

Appendix: 16

Maternity Claims - Information sheet
Retained Swabs

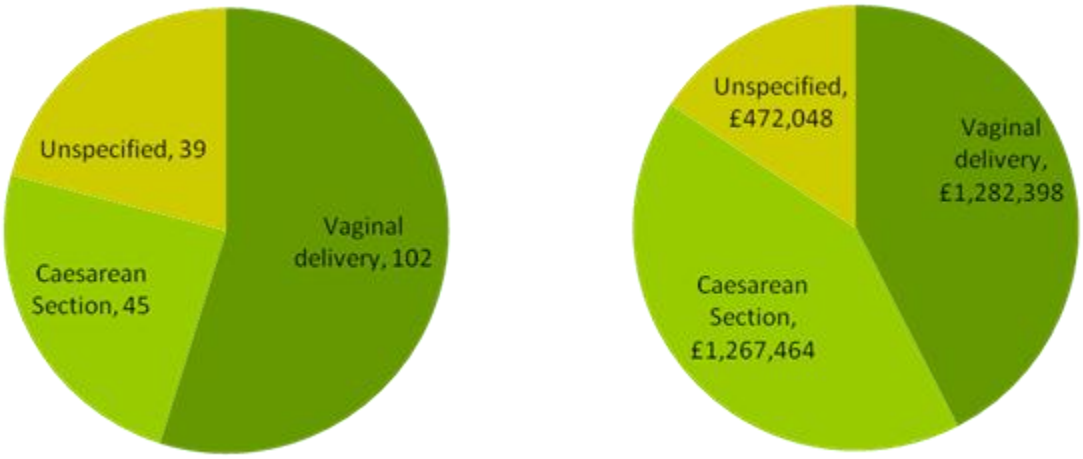
Claims

Review of the NHS Litigation Authority (NHSLA) claims database has identified 186 claims for retained swabs with an incident date between 1st April 2000 and 31st March 2010. These claims occurred following both operative and vaginal deliveries, but for some claims it was not possible to determine the timing of the retention of the swab from the information on the database. The estimated total value of these claims was £3million.

Incident Date*	Total Number	Total Value
2000/2001	14	£255,573
2001/2002	21	£245,274
2002/2003	23	£253,408
2003/2004	27	£507,873
2004/2005	22	£440,551
2005/2006	13	£222,160
2006/2007	20	£257,375
2007/2008	22	£495,922
2008/2009	21	£274,430
2009/2010	3	£69,345
Grand Total	**186**	**£3,021,910**

Total number and value of claims involving retained swaps by financial year

* Due to the time delay between an incident occurring and a claim being made, it is very likely that claims with an incident date towards the end of the review period have yet to be issued.



Total number and value of claims involving retained swaps by sub categories

Guidance

The NPSA included retained instruments following surgery in its Never Events list[1] in 2009, and this requirement was strengthened in March 2010[2] to include swabs retained following surgery. In addition, the NPSA produced a Rapid Response Report[3] in May 2010 requiring NHS organisations to have set processes in place when using swabs during vaginal delivery or perineal repair.

The National Institute of Health and Clinical Excellence (NICE) guidance *Intrapartum care*[4] (NICE 2007) includes recommendations on the basic principles for perineal repair which include needle and swab counts pre- and post-procedure.

CNST Maternity Standards

There are no criteria within either the 2011/12 NHSLA Risk Management Standards for Acute Trusts[5] or within the CNST Maternity Standards[6] that require maternity services to have written guidance for staff on dealing with swabs during these clinical situations.

References

1. National Patient Safety Agency. (2009). *Never Events Framework 2009/10.* London: NPSA. Available at www.nrls.npsa.nhs.uk

2. National Patient Safety Agency (2010) *Never Events Framework Update for 2010/11.* London: NPSA. Available at www.nrls.npsa.nhs.uk

3. National Patient Safety Agency (2010) *Rapid Response Report RRR012 Reducing the risk of retained swabs after vaginal birth and perineal suturing*. London: NPSA. Available at www.nrls.npsa.nhs.uk/alerts

4. National Institute for Health and Clinical Excellence. (2007). *Intrapartum care: Care of healthy women and their babies during childbirth*. London: NICE. Available at: www.nice.org.uk

5. NHS Litigation Authority. (2011). NHSLA Risk Management Standards for NHS Trusts providing Acute, Community, or Mental Health & Learning Disability Services and Independent Sector Providers of NHS Care. Available at: www.nhsla.com

6. NHS Litigation Authority. (2011). *CNST Maternity Clinical Risk Management Standards*. London: NHSLA. Available at: www.nhsla.com

Maternity Claims - Information sheet
Shoulder Dystocia

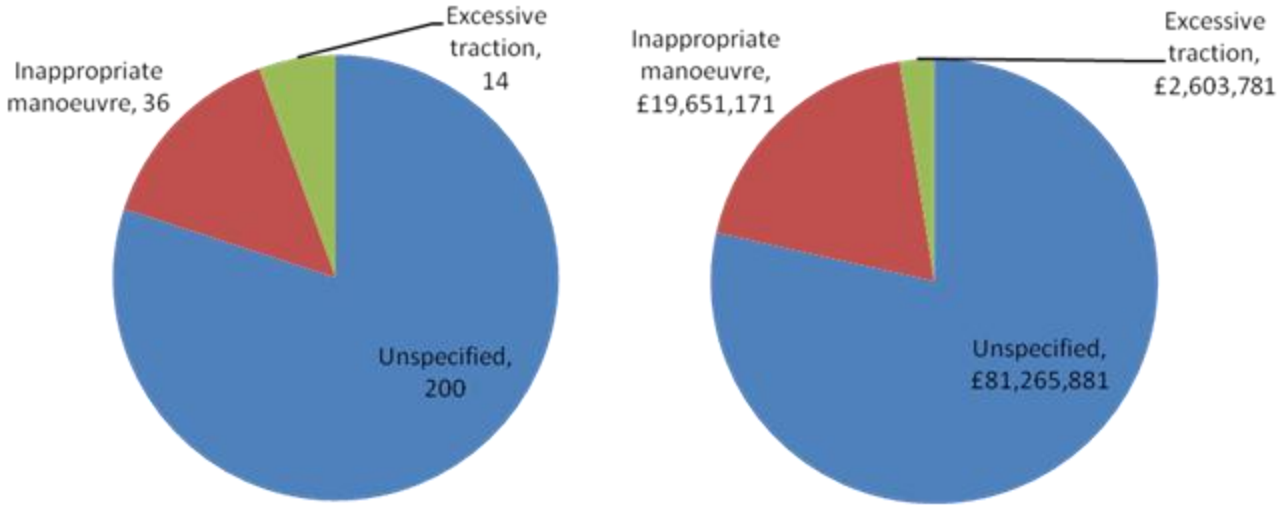
Claims

Review of the NHS Litigation Authority (NHSLA) claims database found 250 claims between 1st April 2000 and 31st March 2010 for shoulder dystocia. While 14 claims alleged excessive traction and 36 inappropriate manoeuvres, the information available did not clearly indicate if the remaining 200 claims fell into one of these two groups. The estimated total value of the claims was over £100million.

Incident Date*	Total Number	Total Value
2000/2001	55	£7,688,680
2001/2002	38	£17,125,484
2002/2003	28	£8,577,812
2003/2004	38	£14,528,994
2004/2005	31	£7,643,976
2005/2006	25	£25,477,422
2006/2007	21	£14,334,690
2007/2008	6	£5,773,275
2008/2009	7	£2,370,500
2009/2010	1	£0
Grand Total	**250**	**£103,520,832**

Total number and value of claims involving shoulder dystocia by financial year

* Due to the time delay between an incident occurring and a claim being made, it is very likely that claims with an incident date towards the end of the review period have yet to be issued.



Total number and value of claims involving shoulder dystocia by sub categories

Guidance

The RCOG has guidance in its Green Top series for Shoulder Dystocia[1] (RCOG 2012) which includes a pro forma for the recording of the event and the manoeuvres used during this obstetric emergency.

The 5th CESDI report[2] in 1998 included within it a recommendation that those involved in care should receive training, and such training has since been introduced. *Safer Childbirth*[3] (RCOG 2007) included shoulder dystocia within its list of recommended multiprofessional training topics. This topic is also included within PROMPT training[4] which a number of maternity services use to train staff (PROMPT 2010).

CNST Maternity Standards

The 2011/12 CNST Maternity Standards[5] (NHSLA 2010) include a criterion on shoulder dystocia which requires maternity services to have in place an approved document which includes details on particular points regarding the management of shoulder dystocia. Implementation of this document needs to be demonstrated at Level 2 assessments and monitoring of the implementation at Level 3.

References

1. Royal College of Obstetricians and Gynaecologists. (2012). *Shoulder Dystocia.* London: RCOG. Available at: www.rcog.org.uk
2. Confidential Enquiry into Stillbirths and Deaths in Infancy. (1998). *5th Annual Report*. London: Maternal and Child Health Research Consortium. Available at: http://cemach.interface-test.com/Home.aspx
3. Royal College of Anaesthetists, Royal College of Midwives, Royal College of Obstetricians and Gynaecologists, Royal College of Paediatrics and Child Health. (2007). *Safer Childbirth: Minimum Standards for the Organisation and Delivery of Care in Labour*. London: RCOG Press. Available at: www.rcog.org.uk
4. Draycott, T. Winter, C. Crofts, J. & Barnsfield, S. (2008) *Practical Obstetric MultiProfessional Training (PROMPT)*. Bristol: PROMPT Foundation. Available at: http://www.prompt-course.org
5. NHS Litigation Authority. (2011). *CNST Maternity Clinical Risk Management Standards* London: NHSLA. Available at: www.nhsla.com

Maternity Claims – Information sheet
Stillbirth

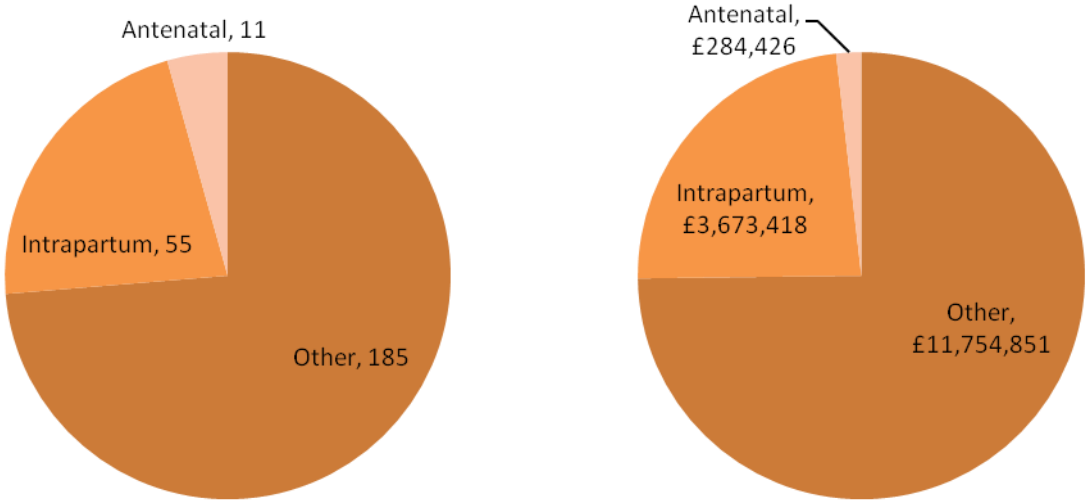
Claims

Review of the claims on the NHS Litigation Authority (NHSLA) claims database with an incident date between 1st April 2000 and 31st March 2010 showed that within the period being reviewed there were a total of 251 stillbirth claims:, 11 occurred in the antenatal period; 55 were intrapartum stillbirths; for the remaining 185, the information on the database did not clearly indicate when fetal death had occurred. The estimated total value of the claims identified is approximately £16million.

Incident Date*	Total Number	Total Value
2000/2001	23	£508,288
2001/2002	24	£472,447
2002/2003	30	£986,040
2003/2004	39	£2,660,730
2004/2005	36	£5,577,550
2005/2006	31	£1,241,785
2006/2007	26	£1,459,423
2007/2008	28	£1,550,939
2008/2009	13	£1,015,492
2009/2010	1	£240,000
Grand Total	**251**	**£15,712,695**

Total number and value of claims involving stillbirth by financial year

* Due to the time delay between an incident occurring and a claim being made, it is very unlikely that claims with an incident date towards the end of the review period have yet to be issued.



Total number and value of claims involving stillbirth by sub categories

Discussion

The rates of stillbirth in England are constantly reviewed and reported on; the UK Office of National Statistics[1] provides annual statistics. Recently, the Lancet (2011) published a series of reports on stillbirth, stating the rate of stillbirth in the United Kingdom to be 3.2 per 1,000 births[2].

In 2009 the NHS Litigation Authority undertook an analysis of 100 stillbirth claims files[3] (NHSLA 2009), some of which are included in the numbers above. As this analysis was undertaken using information available from claims files, it provides a more detailed account of the causes of stillbirth claims than can be established from the database alone. This report is available on the NHSLA website.

Guidance

There has been national guidance for maternity services for a number of years, for both antenatal and intrapartum care, which aims at providing guidance for clinicians on the care of women to minimise the risk of stillbirth occurring either antenatally or during labour. The National Institute for Health and Clinical Excellence (NICE) has produced guidance for both antenatal care[4] (NICE 2008) and intrapartum care[5] (NICE 2007) which has been widely implemented by maternity services.

Additionally, there is guidance on staffing levels for the various staff groups who provide care in the intrapartum period. This guidance is aimed at ensuring staffing levels are sufficient to provide appropriate care for all women in labour[6] (RCOG 2007).

CNST Maternity Standards

The 2011/12 CNST Maternity Standards[7] do not contain any criteria that directly refer to the care of women experiencing a stillbirth, but as described in the NHSLA's study there are a number of criteria which could impact on the outcome. Since the revision of the Standards in 2009 they have contained a criterion that looks at the support provided to parents where there is a poor outcome. Whilst this criterion has no impact on a stillbirth occurring, it aims to reduce the psychological harm experienced by the parents.

References

1. Childhood, Infant and Perinatal Mortality in England and Wales, 2010 The Office of National Statistics Available at: http://www.ons.gov.uk/ons/index.html

2. The Lancet (2011) *Stillbirths An Executive Summary* T*he Lancet Vol 377 N*o 9774 16.4.11 Available at www.thelancet.com

3. NHS Litigation Autho*rity, Study of Stillbirth Claims* ISBN 987-0-9565019-0-5 (2009): London: NHSLA. Available at: www.nhsla.com

4. National Institute for Health and Clinical Excellence. (2008). *Antenatal care: Routine care for the healthy pregnant woman*. London: NICE. Available at: www.nice.org.uk

5. National Institute for Health and Clinical Excellence. (2007). *Intrapartum care: Care of healthy women and their babies during childbirth*. London: NICE. Available at: www.nice.org.uk

6. Royal College of Anaesthetists, Royal College of Midwives, Royal College of Obstetricians and Gynaecologists, Royal College of Paediatrics and Child Health. (2007). *Safer Childbirth: Minimum Standards for the Organisation and Delivery of Care in Labour*. London: RCOG Press. Available at: www.rcog.org.uk

7. NHS Litigation Authority. (2011). *CNST Clinical Risk Management Standards*. London: NHSLA. Available at: www.nhsla.com

Appendix: 19

Maternity Claims - Information sheet
Uterine Rupture

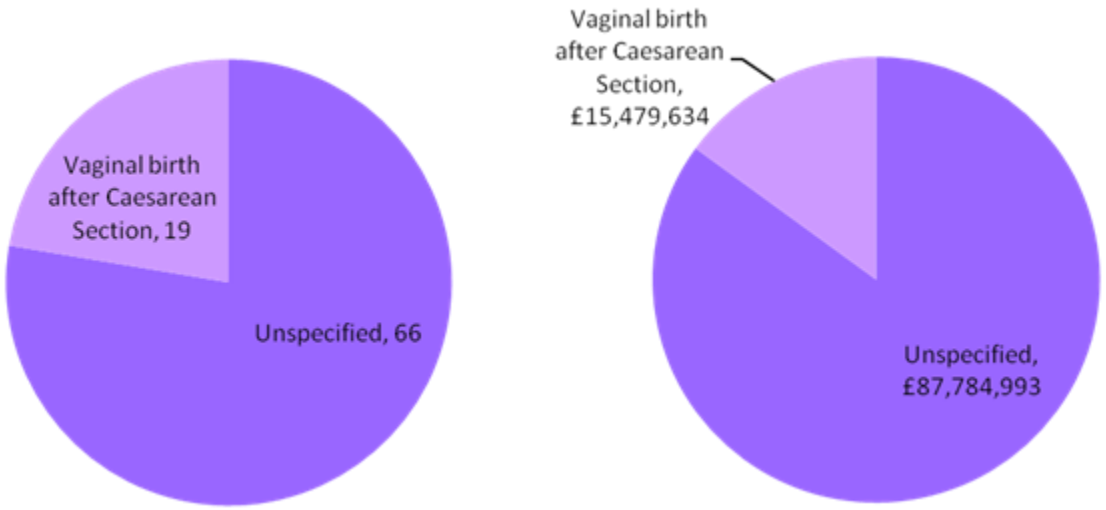
Claims

Review of the NHS Litigation Authority (NHSLA) claims database identified 85 claims for uterine rupture with an incident date between 1st April 2000 and 31st March 2010. In 19 claims it was possible to further identify that the claims were linked to previous caesarean sections. The estimated total value of the claims was more than £100million.

Incident Date*	Total Number	Total Value
2000/2001	13	£15,657,611
2001/2002	11	£7,727,931
2002/2003	16	£15,085,269
2003/2004	8	£15,606,248
2004/2005	16	£39,364,184
2005/2006	9	£8,129,445
2006/2007	7	£1,325,939
2007/2008	2	£95,000
2008/2009	3	£273,000
2009/2010	0	£0
Grand Total	**85**	**£103,264,627**

Total number and value of claims involving uterine rupture by financial year

* Due to the time delay between an incident occurring and a claim being made, it is very likely that claims with an incident date towards the end of the review period have yet to be issued.



Total number and value of claims involving uterine rupture by sub categories

Guidance

The RCOG has guidance for obstetricians on the care of women who are giving birth after a previous caesarean section[1] (RCOG 2007) which includes information on uterine rupture. Additionally, the NICE Caesarean Section guidance[2] (NICE 2011) makes recommendations for the care of this group of women in whom uterine rupture is a risk factor. The NHS Institute for Innovation and Improvement has produced information on reducing caesarean sections and promoting normal birth[3], and as part of this work there are recommendations about vaginal birth after caesarean section. (NHS 2007)

CNST Maternity Standards

The CNST Maternity Standards[4] include a criterion on Vaginal Birth after Caesarean Section (VBAC), which was included in the Standards in April 2009. This criterion requires maternity services to have in place an approved document that contains certain minimum requirements in relation to VBAC. At the higher assessment levels maternity services are required to demonstrate implementation (Level 2) and monitoring (Level 3) of selected minimum requirements in the criterion.

References

1. Royal College of Obstetricians and Gynaecologists. (2007). *Birth after Previous Caesarean Section.* London: RCOG. Available at: www.rcog.org.uk

2. National Institute for Health and Clinical Excellence. (2011). *Caesarean Section*. London: NICE. Available at: www.nice.org.uk

3. NHS Institute for Innovation and Improvement. (2007). *Focus on normal birth and reducing Caesarean section rates*. Coventry: NHS Institute for Innovation and Improvement. Available at: www.institute.nhs.uk

4. NHS Litigation Authority. (2011). *CNST Maternity Clinical Risk Management Standards*. London: NHSLA. Available at: www.nhsla.com

Links to CNST Maternity and NHSLA Acute Risk Management Standards 2011/12

Introduction

The CNST Maternity Standards and assessments were introduced by the NHSLA in 2003 in response to the number and value of maternity claims, with the aim of improving the safety of women and their babies. Since they were introduced, the standards and assessment process have undergone a fundamental review and are updated on an annual basis.

The standards provide a framework within which to focus risk management activities, and encourage and support maternity units in taking a proactive approach to improvement.

There is a close correlation between the categories of maternity claims identified in the project and the risk areas addressed by the Standards which is illustrated in this Appendix. The findings of both the Primary and Secondary Level Studies will be considered in the context of the CNST Maternity Standards and used to inform their future development.

Summary of Links between Primary Level Study and CNST Maternity and NHSLA Acute Standards 2011/12

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
Accident	With birth equipment	Partial	NHSLA Acute Standard 2 – Competent and Capable Workforce	Criterion 2.7: Medical Devices Training
	With other equipment	Partial	NHSLA Acute Standard 2 – Competent and Capable Workforce	Criterion 2.7: Medical Devices Training
Anaesthetic issues	In labour	Yes	CNST Maternity Standard 1 – Organisation CNST Maternity	Criterion1.5: Staffing Levels (Anaesthetists & Assistants) Criterion 1.9: Training Needs Analysis
	During caesarean section	Yes		

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
			Standard 2 – Clinical Care	Criterion 2.6: Caesarean Section
Antenatal Care	Pregnancy	Partial	CNST Maternity Standard 4 – Communications	Criterion 4.1: Booking Appointments Criterion 4.2: Missed Appointments Criterion 4.3: Clinical Risk assessment (Antenatal) Criterion 4.5: Maternal Antenatal Screening Tests
Antenatal investigations	Ultrasound scans	Partial	CNST Maternity Standard 5 – Postnatal & Newborn Care	Criterion 5.1: Referral When A Fetal Abnormality is Detected
	All other investigations	Yes	CNST Maternity Standard 4 – Communication	Criterion 4.5: Maternal Antenatal Screening Tests
Bladder	Following surgery	Yes	CNST Maternity Standard 5 – Postnatal & Newborn Care	Criterion 5.7: Bladder Care
	Following vaginal delivery	Yes		
	Following operative vaginal delivery	Yes	CNST Maternity Standard 3 – High Risk Conditions	Criterion 3.3: Operative Vaginal Delivery

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
Caesarean section	Delay	Yes	CNST maternity Standard 3 – High Risk Conditions	Criterion 2.6: Caesarean Section
	Complications of the procedure	Partial	CNST Maternity Standard 2 – Clinical Care and Standard 5 – Postnatal & Newborn Care	Criterion 2.8: Severely Ill Women Criterion 2.9: High Dependency Criterion 5.10: Recovery
Cerebral Palsy		Yes		The CNST maternity standards do not include a criterion that specifically addresses cerebral palsy. However, a number of criteria and minimum requirements in the standards are relevant to the management of this risk.
CTG Interpretation	1st and 2nd stage of labour	Yes	CNST Maternity Standards 1 – Organisation and 2 – Clinical Care	Criterion 1.9: Training Needs Analysis Criterion 2.2: Intermittent Auscultation Criterion 2.3: Continuous Electronic Fetal Monitoring
Drug Error	In labour	Yes	NHSLA Acute Standard 2 – Competent and Capable	Criterion 2.5: Risk Management Training Criterion 4.5: Medicines Management Criterion 5.2: Incident Reporting

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
			Workforce, Standard 4 – Clinical Care and Standard 5 – Learning from Experience	
	Postnatal	Yes	NHSLA Acute Standard 2 – Competent and Capable Workforce, Standard 4 Clinical Care and Standard 5 – Learning from Experience	Criterion 2.5: Risk Management Training Criterion 4.5: Medicines Management Criterion 5.2: Incident Reporting
Management of Labour	Care provided in the 1st and 2nd stage of labour	Yes	CNST Maternity Standard 2 – Clinical Care	Criterion 2.1: Care of Women in Labour Criterion 4.7: Clinical Risk Assessment (Labour)
Maternal Death		Yes		The CNST maternity standards do not include a criterion that specifically addresses maternal death. However, the top ten recommendations of Saving Mothers' Lives (CEMACH 2007) are included within a number of criteria and minimum requirements throughout the standards.
Midwifery Care	Pressure area care	No	None	

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
Operative Vaginal Delivery	Ventouse and Forceps Deliveries	Yes	CNST Maternity Standard 3 – High Risk Conditions	Criterion 3.3: Operative Vaginal Delivery
Other	Various	N/A		
Perineal Trauma	Labial, 1st and 2nd degree tears and episiotomy	Yes	CNST maternity Standard 3 – High Risk Conditions	Criterion 3.5: Perineal Trauma
	3rd and 4th degree tears	Yes		
Postpartum Haemorrhage	Haemorrhage	Yes	CNST Maternity Standard 3 – High Risk Conditions	Criterion 3.7: Postpartum Haemorrhage
	Retained Products	No		
Psychological		Yes	CNST Maternity Standard 5 – Postnatal & Newborn Care	Criterion 5.8: Support for Parent(s)
Retained Swab	Caesarean section	No	None	
	Vaginal deliver	No	None	
Shoulder Dystocia	Inappropriate manoeuvres	Yes	CNST Maternity Standard 3 –	Criterion 3.6: Shoulder Dystocia

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
	Excessive traction	Yes	High Risk Conditions	
Stillbirth	Antenatal	Partial	CNST Maternity Standard 4 – Communication	Criterion 4.3: Clinical Risk Assessment (Antenatal)
	Intrapartum	Yes	CNST Maternity Standard 2 – Clinical Care and Standard 4 – Communication	Criterion 2.1: Care of Women in Labour Criterion 2.2: Intermittent Auscultation Criterion 2.3: Continuous Electronic Fetal Monitoring Criterion 2.10: Vaginal Birth after Caesarean Section Criterion 4.7: Clinical Risk Assessment (Labour)
Uterine Rupture	Vaginal birth after caesarean	Yes	CNST Maternity Standard 2 – Clinical Care	Criterion 2.10: Vaginal Birth after Caesarean Section
	Unscarred gravid uterus	Yes		Criterion 2.1: Care of Women in Labour

Detail of Links between Primary Level Study and CNST Maternity and NHSLA Acute Standards 2011/12

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
Accident	With birth equipment	Partial	NHSLA Acute Standard 2 – Competent and Capable Workforce	Criterion 2.7: Medical Devices Training expects the organisation to identify which permanent staff are authorised to use equipment and what training they require, including the frequency and how that training will be delivered, in an approved document at Level 1. Level 2 – implementation of the training required by permanent staff authorised to use equipment being delivered in a timely manner with updates at a recommended frequency. Level 3 – monitoring the implementation of the training required by permanent staff authorised to use equipment being delivered in a timely manner, with updates at a recommended frequency.
	With other equipment	Partial		
Anaesthetic issues	In labour	Yes	CNST Maternity Standard 1 – Organisation and Standard 2 – Clinical Care	Criterion1.5: Staffing Levels (Anaesthetists & Assistants) expects the maternity service to identify consultant obstetric anaesthetic and anaesthetic assistant cover, contingency plans for short and long term shortfalls, business plans and annual audits in an approved document at Level 1. Level 2 – implementation of the audit finding, contingency plans for short and long term shortfalls and business plans. Level 3 – monitoring of the implementation of the audit
	During caesarean section	Yes		

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
				findings, contingency plans for short and long term shortfalls and business plans. Criterion 1.9: Training Needs Analysis expects consultant obstetric anaesthetists to be included as one of the staff groups in the approved training needs analysis of a maternity service along with a process to follow-up those who fail to attend and a description of the system for ensuring that audit results, learning from incidents, complaints and claims are considered as part of the ongoing review of training in an approved document at Level 1. Level 2 – implementation of the process for follow-up of those who fail to attend and the system for ensuring that audit results, learning from incidents, complaints and claims are considered as part of the ongoing review of training. Level 3 – monitoring of the implementation of the process for follow-up of those who fail to attend and the system for ensuring that audit results, learning from incidents, complaints and claims are considered as part of the ongoing review of training. Criterion 2.6: Caesarean Section expects the maternity service to have agreed classifications for all caesareans, a timing for Grade 1 caesareans, the reason for performing the Grade 1 caesarean documented by the decision-making clinician, inclusion of the consultant obstetrician and reason for any delay in an approved guideline at Level 1.

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
				Level 2 – implementation of the classification and timing for Grade 1 caesarean and reason for the operation documented by the decision-making clinician. Level 3 – monitoring the implementation of the classification and timing for Grade 1 caesareans and reason for the operation documented by the decision-making clinician.
Antenatal Care	Pregnancy	Partial	CNST Maternity Standard 4 – Communications	<u>Criterion 4.1: Booking Appointments</u> expects the maternity service to have identified the responsibilities of all relevant staff, and to have processes for ensuring: - women have their booking visit and hand held record by twelve weeks of pregnancy - women, who on referral to the maternity service are already twelve or more weeks pregnant, are offered an appointment within two weeks - full medical examinations are performed on migrant women - women whose health records from previous pregnancies should be reviewed are identified and the availability of those records for clinicians to review and for these to be included in an approved guideline at Level 1. Level 2 – implementation of the process for ensuring women have their booking visit and hand held record by twelve weeks of pregnancy and the process for

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
				ensuring women who are already twelve or more weeks pregnant, are offered an appointment within two weeks of the referral. Level 3 – monitoring the implementation of the process for ensuring women have their booking visit and hand held record by twelve weeks of pregnancy and the process for ensuring women who are already twelve or more weeks pregnant, are offered an appointment within two weeks of the referral. Criterion 4.2: Missed Appointments expects the responsibilities of relevant staff groups, the process for ensuring that women who miss any type of antenatal appointment are followed up appropriately, the documentation of the follow-up of these women and process for ensuring that women who miss any type of antenatal appointments are seen to be set out in an approved document at Level 1. Level 2 – implementation of the process for ensuring that women who miss any type of antenatal appointment are followed up appropriately and the documentation of follow-up of these women so that they are seen. Level 3 – monitoring of the implementation of the process for ensuring that women who miss any type of antenatal appointment are followed up appropriately and the documentation of follow-up of these women so that they are seen. Criterion 4.3: Clinical Risk assessment (Antenatal)

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
				expects the maternity service to have the timing of antenatal risk assessments, a minimum list of factors and conditions to be considered, a risk assessment for the place of birth, development of individual management plans for women when risks have been identified, a referral process for women when risks have been identified, a referral process back to midwifery led care and a process for documenting this information in an approved guideline at Level 1. Level 2 – implementation of the referral process for women in whom risks have been identified and documentation of the same. Level 3 – monitoring of the implementation of the referral process for women in whom risks have been identified and documentation of the same. <u>Criterion 4.5: Maternal Antenatal Screening Tests</u> expects the maternity service to have a lead for antenatal screening and systems for ensuring appropriate and timely antenatal investigations are completed along with the process for reviewing results, the timely management of screen positive results and the training expectations for all staff groups in an approved guideline at Level 1. Level 2 – implementation of the process for reviewing results and ensuring women with screen positive results are referred and managed in a timely manner. Level 3 – monitoring the implementation of the process for reviewing results and ensuring women with screen

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
				positive results are referred and managed in a timely manner.
Antenatal investigations	Ultrasound scans	Partial	CNST Maternity Standard 5 – Postnatal & Newborn Care	Criterion 5.1: Referral when a Fetal Abnormality is Detected expects the maternity service to have a process for referring women to tertiary centres, referring to neonatal/specialist services, keeping the woman informed at all times, how the obstetric, neonatal and specialist staff communicate in the antenatal period and document all of this in an approved guideline at Level 1. Level 2 – implementation of the process for referring women to neonatal/specialist services, communication between obstetric, neonatal and specialist staff in the antenatal period and documentation of same. Level 3 – monitoring the implementation of the process for referring women to neonatal/specialist services, communication between obstetric, neonatal and specialist staff in the antenatal period and documentation of same.
	All other investigations	Yes	CNST Maternity Standard 4 – Communication	Criterion 4.5: Maternal Antenatal Screening Tests expects the maternity service to have a lead for antenatal screening and systems for ensuring appropriate and timely antenatal investigations are completed along with the process for reviewing results, the timely management of screen positive results and the training expectations for all staff groups in an approved guideline at Level 1.

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
				Level 2 – implementation of the process for reviewing results and ensuring women with screen positive results are referred and managed in a timely manner. Level 3 – monitoring the implementation of the process for reviewing results and ensuring women with screen positive results are referred and managed in a timely manner.
Bladder	Following surgery	Yes	CNST Maternity Standard 5 – Postnatal & Newborn Care	Criterion 5.7: Bladder Care expects the maternity service to have the recording of the first void including the volume, when indwelling urinary catheters should be used, when to refer to an appropriate clinician for evaluation, instigation of a management plan and the maintenance of a fluid balance chart in an approved guideline at Level 1. Level 2 – implementation of the recording of the first void including volume and when to refer to an appropriate clinician. Level 3 – monitoring of the implementation of the recording of the first void including volume and when to refer to an appropriate clinician.
	Following vaginal delivery	Yes		
	Following operative vaginal delivery	Yes	CNST Maternity Standard 3 – High Risk Conditions	Criterion 3.3: Operative Vaginal Delivery expects the maternity service to have care of the bladder in an approved guideline at Level 1. Level 2 – implementation of the guidance for care of the bladder. Level 3 – monitoring of the implementation of the

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
				guidance for care of the bladder.
Caesarean section	Delay	Yes	CNST maternity Standard 3 – High Risk Conditions	Criterion 2.6: Caesarean Section expects the maternity service to have agreed classifications for all caesareans, a timing for Grade 1 caesareans, the reason for performing the Grade 1 caesarean documented by the decision-making clinician, inclusion of the consultant obstetrician and reason for any delay in an approved guideline at Level 1. Level 2 – implementation of the classification and timing for Grade 1 caesarean and reason for the operation documented by the decision-making clinician. Level 3 – monitoring the implementation of the classification and timing for Grade 1 caesareans and reason for the operation documented by the decision-making clinician.
	Complications of the procedure	Partial	CNST Maternity Standard 2 – Clinical Care and Standard 5 – Postnatal & Newborn Care	Criterion 2.8: Severely Ill Women expects the maternity service to have a description of the responsibilities of relevant staff groups, a process for the use of a modified early warning score system (MEOWS), guidance on when to involve clinicians outside the maternity service, training expectations for all staff groups in relation to the use of the MEOWS and maternal resuscitation in an approved guideline at Level 1. Level 2 – implementation of the process for the use of the MEOWs and the training for all staff groups on the

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
				recognition of severely ill women. Level 3 - monitoring the implementation of the process for the use of the MEOWs and the training for all staff groups on the recognition of severely ill women. Criterion 2.9: High Dependency Care expects the maternity service to have a description of the responsibilities of relevant staff groups, a process for ensuring the availability of medical equipment, guidance on when to involve clinicians outside the maternity service, agreed criteria for transfer to a high dependency unit/intensive care unit and the requirements of each staff group during the transfer in an approved guideline at Level 1. Level 2 - implementation of the guidance on when to involve clinicians outside the maternity service, the agreed criteria for transfer to a high dependency unit/intensive care unit and the requirements of each staff group during the transfer. Level 3 - monitoring the implementation of the guidance on when to involve clinicians outside the maternity service, the agreed criteria for transfer to a high dependency unit/intensive care unit and the requirements of each staff group during the transfer. Criterion 5.10: Recovery expects the maternity service to have defined equipment, transfer criteria, minimum requirements for observations whilst in recovery, agreed discharge and transfer from recovery, documentation of the previous two requirements,

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
				guidelines for care and frequency of observations for 24 hours post recovery and the training expectations for all staff groups in an approved guideline at Level 1. Level 2 – implementation of the minimum requirements for observations whilst in recovery and the agreed discharge and transfer criteria from recovery. Level 3 – monitoring the implementation of the minimum requirements for observations whilst in recovery and the agreed discharge and transfer criteria from recovery.
Cerebral Palsy		Yes		The CNST maternity standards do not include a criterion that specifically addresses cerebral palsy. However, a number of criteria and minimum requirements in the standards are relevant to the management of this risk.
CTG Interpretation	1st and 2nd stage of labour	Yes	CNST Maternity Standards 1 Organisation and 2 – Clinical Care	Criterion 1.9: Training Needs Analysis expects consultant obstetric anaesthetists to be included as one of the staff groups in the approved training needs analysis of a maternity service along with a process to follow-up those who fail to attend and a description of the system for ensuring that audit results, learning from incidents, complaints and claims are considered as part of the ongoing review of training in an approved document at Level 1. Level 2 – implementation of the process for follow-up of those who fail to attend and the system for ensuring that audit results, learning from incidents, complaints

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
				and claims are considered as part of the ongoing review of training. Level 3 – monitoring of the implementation of the process for follow-up of those who fail to attend and the system for ensuring that audit results, learning from incidents, complaints and claims are considered as part of the ongoing review of training. <u>Criterion 2.2: Intermittent Auscultation</u> expects the maternity service to have the process and equipment used for fetal auscultation, recording of the findings and when to transfer to continuous fetal monitoring in an approved guideline at Level 1. Level 2 – implementation of when to auscultate the fetal heart, palpate the maternal pulse, transfer to continuous electronic fetal monitoring and where to record the findings. Level 3 – monitoring of the implementation of when to auscultate the fetal heart, palpate the maternal pulse, transfer to continuous electronic fetal monitoring and where to record the findings. <u>Criterion 2.3: Continuous Electronic Fetal Monitoring</u> expects the maternity service to have the process used for continuous electronic monitoring including the minimum data set for record keeping, hourly systematic review, the actions required should the trace appear suspicious or pathological and the training expectations for all staff groups in an approved

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
				guideline at Level 1. Level 2 – implementation of the minimum dataset for record keeping, hourly systematic review, the actions required should the trace appear suspicious or pathological and the training expectations for all staff groups. Level 3 – monitoring of the implementation of the minimum dataset for record keeping, hourly systematic review, the actions required should the trace appear suspicious or pathological and the training expectations for all staff groups.
Drug Error	In labour	Yes	NHSLA Acute Standard 2 – Competent and Capable Workforce, 4 – Clinical Care and Standard 5 – Learning from Experience	Criterion 2.5: Risk Management Training expects organisations to include medicine management training for all staff groups in the training needs analysis (TNA) at Level 1. Level 2 – medicines management may be selected from the NHSLA minimum dataset for assessment of the implementation of the training as described in the TNA and the follow-up of those who fail to attend. Level 3 – medicines management may be selected from the NHSLA minimum dataset for assessment of the monitoring of the implementation of the training as described in the TNA and the follow-up of those who fail to attend. Criterion 4.5: Medicines Management expects organisations to have processes for the prescribing of medicines, accuracy of prescription charts, monitoring
	Postnatal	Yes		

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
				of side effects, administration of medication (including patient identification), patient self administration and a procedure for safe disposal in an approved document at Level 1. Level 2 – implementation of the process for the accuracy of all prescription charts. Level 3 – monitoring of the implementation of the process for the accuracy of all prescription charts. Criterion 5.2: Incident Reporting expects the organisation to have the duties of all staff in relation to incident reporting , processes for reporting all incidents/near misses and for reporting to external agencies as well as a reference to the whistle blowing/open disclosure policy for raising concerns in an approved document at Level 1. Level 2 – implementation of the processes for reporting all incidents/near misses and for reporting to external agencies. Level 3 – monitoring of the implementation of the processes for reporting all incidents/near misses and for reporting to external agencies.
Management of Labour	Care provided in the 1st and 2nd stage of labour	Yes	CNST Maternity Standards 2 – Clinical Care and 4 – Communication	Criterion 2.1: Care of Women in Labour expects the maternity service to have the observation of women through all three stages of labour in an approved guideline at Level 1. Level 2 – implementation of the observations required

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
				during stage 1 of labour. Level 3 – monitoring of the implementation of the observations required during stage 1 of labour. Criterion 4.7: Clinical Risk Assessment (Labour) expects the process of clinical risk assessment when labour commences, including timing of the assessment, medical conditions (including anaesthetic history), factors from previous pregnancies, lifestyle history, risk assessment for appropriate place of birth, documentation of an individual management plan and process for referral of women when risks are identified, including documentation of all the above where clinically relevant, to be described in an approved document at Level 1. Level 2 – implementation the recording of the timing of the clinical risk assessment in all care settings and documentation of an individual management plan and process for referral of women when risks are identified. Level 3 – monitoring of the implementation of the recording of the timing of the clinical risk assessment in all care settings and documentation of an individual management plan and process for referral of women when risks are identified.
Maternal Death		Yes		The CNST maternity standards do not include a criterion that specifically addresses maternal death. However, the top ten recommendations of Saving Mothers' Lives (CEMACH 2007) are included within a

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
				number of criteria and minimum requirements throughout the standards.
Midwifery Care	Pressure area care	No	None	
Operative Vaginal Delivery	Ventouse and Forceps Deliveries	Yes	CNST Maternity Standard 3 – High Risk Conditions	Criterion 3.3: Operative Vaginal Delivery expects the maternity service to have the process for the management of operative vaginal deliveries, including who can perform the procedure, documentation of the indication for the procedure, informed consent, when to use sequential instruments, when to abandon the procedure, decision to delivery time and bladder care in an approved guideline at Level 1. Level 2 – implementation of who can perform the procedure, documentation of the indication for the procedure, informed consent, when to use sequential instruments, when to abandon the procedure, decision to delivery time and care of the bladder. Level 3 – monitoring of the implementation of who can perform the procedure, documentation of the indication for the procedure, informed consent, when to use sequential instruments, when to abandon the procedure, decision to delivery time and care of the bladder.
Other	Various	N/A		
Perineal Trauma	Labial, 1st and 2nd degree tears and	Yes	CNST maternity Standard 3 –	Criterion 3.5: Perineal Trauma expects the maternity service to have all suturing requirements and training

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
	episiotomy		High Risk Conditions	expectations for all staff groups in an approved guideline at Level 1. Level 2 – implementation of the management of 3rd and 4th degree tears, record keeping for all perineal trauma and training expectations for all staff groups. Level 3 – monitoring of the implementation of the management of 3rd and 4th degree tears, record keeping for all perineal trauma and training expectations for all staff groups.
	3rd and 4th degree tears	Yes		
Postpartum Haemorrhage	Haemorrhage	Yes	CNST Maternity Standard 3 – High Risk Conditions	Criterion 3.7: Postpartum Haemorrhage expects the maternity service to have the management of postpartum haemorrhage including a local definition, lines of communication and the management of postpartum haemorrhage, the requirement to document fluid balance and access to blood (including the portering arrangements) with the arrangements for intraoperative cell salvage, interventional radiology, women who decline blood and blood products and the training expectations of all staff groups in an approved guideline at Level 1. Level 2 – implementation of the lines of communication, management of the haemorrhage, documentation of fluid balance, access to blood and individual management plans for women who decline blood products. Level 3 – monitoring of the implementation of the lines of communication, management of the haemorrhage,

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
				documentation of fluid balance, access to blood and individual management plans for women who decline blood products.
	Retained Products	No		
Psychological		Yes	CNST Maternity Standard 5 – Postnatal & Newborn Care	Criterion 5.8: Support for Parent(s) expects the maternity service to have a process for providing postnatal support to parents where suspected or actual poor neonatal outcome has occurred, the documentation of the communication along with the provision of information in the appropriate language or medium and relevant support groups must be included in an approved guideline at Level 1. Level 2 – implementation of the process for providing support to parents for suspected or actual poor neonatal outcome and documentation of all communication with the parents. Level 3 – monitoring of the implementation of the process for providing support to parents for suspected or actual poor neonatal outcome and documentation of all communication with the parents.
Retained Swab	Caesarean section	No	None	
	Vaginal delivery	No	None	
Shoulder Dystocia	Inappropriate manoeuvres	Yes	CNST Maternity Standard 3 –	Criterion 3.6: Shoulder Dystocia expects the maternity service to have the systematic emergency

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
	Excessive traction	Yes	High Risk Conditions	management of shoulder dystocia, the use of a reporting form with the RCOG minimum dataset on, follow up of the newborn shoulder actual / suspected brachial plexus injury occur or any other injury associated with the birth and the training expectation of all staff groups in an approved guideline at Level 1. Level 2 – implementation of the use of the reporting form which describes the systematic emergency management of shoulder dystocia and the RCOG minimum dataset, follow up of the newborn shoulder actual / suspected brachial plexus injury occur or any other injury associated with the birth. Level 3 – monitoring of the implementation of the use of the reporting form which describes the systematic emergency management of shoulder dystocia and the RCOG minimum dataset, follow up of the newborn should actual / suspected brachial plexus injury occur or any other injury associated with the birth.
Stillbirth	Antenatal	Partial	CNST Maternity Standard 4 – Communication	Criterion 4.3: Clinical Risk Assessment (Antenatal) expects the maternity service to have the timing of antenatal risk assessments, a minimum list of factors and conditions to be considered, a risk assessment for the place of birth, development of individual management plans for women when risks have been identified, a referral process for women when risks have been identified, a referral process back to midwifery led care and a process for documenting this information in an approved guideline at Level 1.

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
				Level 2 – implementation of the referral process for women in whom risks have been identified and documentation of the same. Level 3 – monitoring of the implementation of the referral process for women in whom risks have been identified and documentation of the same.
	Intrapartum	Yes	CNST Maternity Standard 2 – Clinical Care and Standard 4 – Communication	Criterion 2.1: Care of Women in Labour expects the maternity service to have the observation of women through all three stages of labour in an approved guideline at Level 1. Level 2 – implementation of the observations required during stage 1 of labour. Level 3 – monitoring of the implementation of the observations required during stage 1 of labour. Criterion 2.2: Intermittent Auscultation expects the maternity service to have the process and equipment used for fetal auscultation, recording of the findings and when to transfer to continuous fetal monitoring in an approved guideline at Level 1. Level 2 – implementation of when to auscultate the fetal heart, palpate the maternal pulse, transfer to continuous electronic fetal monitoring and where to record the findings. Level 3 – monitoring of the implementation of when to auscultate the fetal heart, palpate the maternal pulse, transfer to continuous electronic fetal monitoring and

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
				where to record the findings. Criterion 2.3: Continuous Electronic Fetal Monitoring expects the maternity service to have the process used for continuous electronic monitoring including the minimum data set for record keeping, hourly systematic review, the actions required should the trace appear suspicious or pathological and the training expectations for all staff groups in an approved guideline at Level 1. Level 2 – implementation of the minimum dataset for record keeping, hourly systematic review, the actions required should the trace appear suspicious or pathological and the training expectations for all staff groups. Level 3 – monitoring of the implementation of the minimum dataset for record keeping, hourly systematic review, the actions required should the trace appear suspicious or pathological and the training expectations for all staff groups. Criterion 2.10: Vaginal Birth after Caesarean Section expects the maternity service to have the management of women in relation to vaginal birth after a caesarean section, including the responsibilities of staff, documentation of the mode of delivery, place of delivery, individual management plan which should also include if labour commences early or late and the documented plan for monitoring of the fetal heart in labour in an approved guideline at Level 1.

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
				Level 2 – implementation of the individual management plan and the documented plan for the monitoring of the fetal heart. Level 3 – monitoring of the implementation of the individual management plan and the documented plan for the monitoring of the fetal heart. <u>Criterion 4.7: Clinical Risk Assessment (Labour)</u> expects the process of clinical risk assessment when labour commences including timing of the assessment, medical conditions (including anaesthetic history), factors from previous pregnancies, lifestyle history, risk assessment for appropriate place of birth, documentation of an individual management plan and process for referral of women when risks are identified, including documentation of all the above where clinically relevant to be described in an approved document at Level 1. Level 2 – implementation of the recording of the timing of the clinical risk assessment in all care settings and documentation of an individual management plan and process for referral of women when risks are identified. Level 3 – monitoring of the implementation of the recording of the timing of the clinical risk assessment in all care settings and documentation of an individual management plan and process for referral of women when risks are identified.

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
Uterine Rupture	Vaginal birth after caesarean	Yes	CNST Maternity Standard 2 – Clinical Care	Criterion 2.10: Vaginal Birth after Caesarean Section expects the maternity service to have the management of women in relation to vaginal birth after a caesarean section, including the responsibilities of staff, documentation of the mode of delivery, place of delivery, individual management plan which should also include if labour commences early or late and the documented plan for monitoring of the fetal heart in labour in an approved guideline at Level 1. Level 2 – implementation of the individual management plan and the documented plan for the monitoring of the fetal heart. Level 3 – monitoring of the implementation of the individual management plan and the documented plan for the monitoring of the fetal heart.
	Unscarred gravid uterus	Yes		Criterion 2.1: Care of Women in Labour expects the maternity service to have the observation of women through all three stages of labour in an approved guideline at Level 1. Level 2 – implementation of the observations required during stage 1 of labour. Level 3 – monitoring of the implementation of the observations required during stage 1 of labour. Criterion 2.2: Intermittent Auscultation expects the maternity service to have the process and equipment used for fetal auscultation, recording of the findings

Category	Clinical Situation	Link	CNST maternity and NHSLA acute standards 2011/12	
				and when to transfer to continuous fetal monitoring in an approved guideline at Level 1. Level 2 – implementation of when to auscultate the fetal heart, palpate the maternal pulse, transfer to continuous electronic fetal monitoring and where to record the findings. Level 3 – monitoring of the implementation of when to auscultate the fetal heart, palpate the maternal pulse, transfer to continuous electronic fetal monitoring and where to record the findings.

Secondary Level Study - Questionnaires

Appendix: 21

MATERNITY DATA CLAIMS PROJECT

Antenatal Investigations – Ultrasound Scanning

Data Recording Sheet

Solicitors Ref ……

Basic Details			
Age of Mother			
Date			
Monday to Friday 8 am to 8 pm	Y/N		
Male or female infant			
Singleton?			
BMI			
Gestation (weeks) at time of negligence			
Birth weight			
Legal Issues			
Breach of Duty Issues - List	Alleged (Y/N)	Admitted (Y/N)	Causative (Y/N)
Was breach of duty admitted/accepted?			
Was causation admitted/accepted?			
Was expert evidence obtained from an: - obstetrician - fetal medicine specialist - sonographer - radiologist - other (please specify)			
Staffing Issues			
i) What was the job title of the person who provided the care in question or undertook the relevant antenatal investigation?			
ii) Was the scan in question undertaken at a local district general hospital or a tertiary centre?			

iii) What was the structure of the unit – i.e. was there a local obstetrician or radiologist with an interest in USS, level of expertise, training etc, who supervised the local screening unit for DGH.	
Medical Issues	
Was this a high risk pregnancy which should have been identified as such during the antenatal period? If so, why?	
Was it identified as such? If so, when?	
If the alleged negligent antenatal investigation involved an ultrasound scan:	
i) At how many weeks was the scan taken?	
ii) Was there an approved protocol in force in the department both for examination of the fetus and referral pattern in case of an anomaly being identified?	
iii) Were scan images saved and if so how? Was there a protocol for saving images?	
iv) What was the reporting policy? How were results documented and communicated?	
v) What was the structural anomaly and was it included in the protocol?	
vi) Would identification of the anomaly have led to referral to a specialist tertiary centre?	
vii) Were there any extenuating factors which may have impacted on the quality of ultrasonic visualization e.g. maternal obesity, previous abdominal surgery or scarring or reduced amniotic fluid.	
viii) Which of the following contributed to the failure to detect the anomaly:	
(a) Human error e.g. misinterpretation of USS	
(b) System failure e.g. out of date protocol; failure to arrange appointment.	
(c) Communication Failure i.e. Anomaly is detected but complications are not appropriately communicated.	
(d) Equipment failure.	

File Status		
Open/Closed		
Financial Cost		
	Current FRS12 (Open Cases)	Payment Made (Closed Cases)
Damages		
Claimant costs		
Defence costs		
Total		

Appendix: 22

MATERNITY DATA CLAIMS PROJECT

CTG Interpretation

Data Recording Sheet

Solicitors Ref ……..…

Basic Details			
Age of Mother			
Date			
Monday to Friday 8 am to 8 pm (double click on box to select check option)	☐ Yes ☐ No		
Male or female infant			
Singleton?			
BMI			
Gestation (weeks) at time of negligence			
Birth weight			
Legal Issues			
Breach of Duty Issues - List	Alleged (Y/N)	Admitted (Y/N)	Causative (Y/N)
Was breach of duty admitted/accepted?			
Was causation admitted/accepted?			
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, what was this?			
Was this during the antenatal period or intra-partum? If intra-partum, at what stage of labour?			
Were any other steps taken to confirm the fetal			

heartbeat? If so, what?	
Were there any approved guidelines or protocols in existence? If so, were these followed?	
Was there a delay in delivery? If so, how long? What was the outcome?	

Staffing Issues

Please select the job titles of the staff alleged to have misinterpreted the CTG:
(double click on box to select check option)

☐ Midwife
☐ SHO
☐ Registrar/SpR
☐ Consultant
☐ Other, please specify -

If Midwife: Was obstetric assistance required? Was obstetric assistance sought? If so, at what level? If not, why not?	
If SHO/Registrar/SpR: Was more senior assistance required? If yes, was it sought? If not, why not?	

File Status (double click on box to select check option)

☐ Open ☐ Closed

Financial Cost

	Current FRS12 (Open Cases)	Payment Made (Closed Cases)
Damages		
Claimant Costs		
Defence Costs		

Appendix: 23

Anal Sphincter Injury Claims Study (third/fourth degree tears)

DATA RECORDING SHEET

PANEL FIRM REFERENCE:……

Basic Details	
Age of Mother	
Date	
Monday to Friday 8.00am to 8.00pm	Y / N
Male or female infant	
Singleton?	
BMI	
Gestation (weeks) at time of negligence	
Birth weight	
Staffing Issues	
Midwife or doctor managing delivery?	
Grade and experience of doctor/midwife managing the delivery?	
Grade of the professional who undertook the repair?	
Grade of the professional who undertook the post-repair check?	
Was there a Consultant present?	
Medical Issues	
Mode of delivery – forceps/ventouse/NVD?	
Epidural?	
Length of second stage of labour?	
Other well-known risk factors present?	
Was a tear identified and, if so, was it correctly graded? (Identifying grades recorded)	
Place of repair e.g. theatre?	
Do the medical records show evidence of a rectal and vaginal examination being performed?	
Was there an issue relating to the failure to notice and repair the tear prior to discharge?	
Was there an issue as to the adequacy of the repair?	

If yes, please set out the technique adopted and the suturing material.		
What symptoms did the patient develop, number of surgical procedures and extent of ongoing symptoms?		
Were any issues raised about the level of information/consent given relating to the repair? Please set these out.		
Was a patient information leaflet given dealing with the repair procedure?	Y/N/Don't Know	
Legal Issues		
Was breach of duty admitted?		
Was there an allegation relating to causing the tear and its extent per se?		
File Status		
Open/Closed		
Financial Cost		
	Current FRS12 (open cases)	Payment Made (closed cases)
Damages Claimant costs Defence costs Total		

Appendix: 24

Ruptured Uterus Claims Study Data Recording Sheet

Ruptured Uterus Claims Study

Data Recording Sheet

Panel Firm Reference …….

Basic Details	
Age of Mother	
Date	
Monday to Friday 8 am to 8 pm	Y/N
Male or female infant	
Singleton?	
BMI	
Gestation (weeks) at time of negligence	
Birth weight	
Legal Issues	
Consent Was a patient information leaflet given dealing with modes of delivery Is there documented discussion of risks and benefits of VBAC and ERCS? If yes – were statistics given and documented? If yes – did the discussion cover - the risk of uterine rupture? - the additional risk of blood transfusion or endometritis with planned VBAC? - the additional risk of birth-related perinatal natal death with VBAC? - the risks of HIE? - the reduction of risk of neonatal respiratory problems with VBAC? - provide other relevant details If labour was induced or augmented – what, if any, warnings were given?	Y/N/Don't Know
Principle allegations of breach (100 characters max)	
Was breach of duty admitted?	

Was causation admitted?	
Staffing Issues	
Is there evidence of Consultant or Consultant Midwife involvement in deciding: (i) mode of delivery (ii) deciding to induce or augment labour Was this in a VBAC clinic? Consultant present in labour ward/obstetric theatre?	Y/N Y/N/Not Relevant Y/N/Don't Know Y/N
Medical Issues	
Was this categorised as a high risk pregnancy?	Y/N/Don't Know
Is this a case of uterine rupture or dehiscence?	Rupture/Dehiscence/Don't Know
Did rupture occur during VBAC? If yes, how many (if any) previous vaginal births had there been? Were any previous successful VBAC?	
Was there an approved guideline in place?	
When was a decision made about mode of delivery?	?/40
How long was it since previous CS (years/months)?	
Is there evidence of review of previous CS to identify indication/type of incision/peri-operative complications?	
Type of pain relief?	
Was continuous electronic fetal monitoring used? If so, at what stage of the labour? What grade of staff reviewed it?	
Was labour induced or augmented? What was the method of induction of labour? Method used for augmentation of labour When did uterine rupture occur?	Y/N ARM/PG Oxytocin/PG(orally) Before labour During labour During delivery (instrumental delivery) Not known
File Status	
Open/Closed	

Financial Cost		
	Current FRS12 (Open Cases)	**Payment Made (Closed Cases)**
Damages Claimant costs Defence costs Total		

Glosssary

BREACH OF DUTY – In clinical negligence claims, the doctor, midwife or nurse will be found to be in breach of duty of care if they failed to act in accordance with a reasonable and responsible body of medical or nursing opinion. This is known as the “Bolam” test and is one of the hurdles which a claimant must overcome to bring a successful claim.

CAUSATION - This is another hurdle which a claimant must overcome. Did the breach of duty of care cause or materially contribute to the damage caused in the particular case?

CLAIMANT - The person who brings a claim, usually the patient in clinical negligence claims.

COSTS – These are incurred by the solicitor of either party. It includes the time spent by the solicitor and any disbursements, for example, the cost of obtaining the GP/hospital records and expert evidence to assist in either bringing or defending the claim. The general rule is that if damages are awarded to the claimant then the defendant will pay the claimant’s legal costs as well.

DAMAGES - This is the value of the claim, as agreed with the parties, or valued by the court, if no agreement is possible. It is the financial compensation the claimant receives for the injuries and losses suffered as a result of the negligent treatment.

DEFENDANT – The party against whom a claim is made, usually an NHS Trust or GP in clinical negligence claims.

LIMITATION – This is the time limit in which a party has to bring a claim from the date of the incident or date of knowledge. The general time-limit to bring a claim is 3 years although this time-period does not commence until the age of 18 years for a child and does not run at all for brain damaged or mentally impaired claimants.

PERIODICAL PAYMENTS – It is now common for the Court to order periodical payments in higher value claims. This is seen as more appropriate than a lump sum settlement because they can be arranged to provide a certain level of income which is guaranteed for the life of the claimant. As well as an annual future payment, a lump sum in relation to other losses will be paid in addition, such as damages for pain and suffering and past losses.

TOTAL VALUE – This is the total financial amount attributed to all known and estimated costs in respect of the claims and includes payments made for damages, claimant and defence legal costs, plus outstanding estimates in respect of damages and all legal costs.

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Project Team

Team members contributed to various aspects of the report using their considerable knowledge of maternity claims and/or risk issues by providing helpful input at each stage as the project progressed, critically reviewing documents, encouraging and supporting colleagues. The primary contribution(s) of Team members were:

Name	Title	Organisation	Primary Role
Alison Bartholomew	Risk Management Director	NHSLA	Project Manager
Emma Corbett	Risk Management Administrator	NHSLA	Data analysis for primary and secondary studies and collation of the report
Esther Kaikai	Risk Manager	NHSLA	Coordinated primary and secondary studies
Chris King	Technical Claims Manager	NHSLA	CTG Questionnaire
Sarah Nicholson	Risk Manager	NHSLA *(to July 2010)*	Preparation of data for primary study
Andrew Craggs	Partner	Hill Dickinson	Questionnaire & Report on Perineal Trauma Claims
Joanna Lloyd	Partner	Bevan Brittan	Questionnaire & Report on Uterine Rupture Claims
Majid Hassan	Partner, Clinical Law	Capsticks	Main Report, Questionnaire & Report on Antenatal Ultrasound Scanning Claims
Anita Dougall	Patient Safety Lead	National Patient Safety Agency *(from July 2011 – February 2012)*	Report on CTG Claims
Lynne Saunders	Senior Assessor, DNV Healthcare & Biorisk UK	Det Norske Veritas *(to December 2010)*	Review and Categorisation of data in the primary study, initial preparation of the Main Report & Information Sheets
	Governance and Risk Management Lead – Maternity	Milton Keynes Hospital NHS Foundation Trust *(January 2011 –*	

		April 2012)	
	Clinical Risk Manager, MaternityServices	West Suffolk NHS Foundation Trust *(May 2012 – date)*	
Tracy Dilger	Senior Assessor, DNV Healthcare & Biorisk UK	Det Norske Veritas *(from January 2011)*	Links to CNST Maternity & NHSLA Acute Standards

Professor Dame Joan Higgins, Chair and Professor Rory Shaw, Non-Executive Director of the NHSLA provided helpful advice and support.

NHSLA Panel Solicitors

All the solicitors on the NHSLA's clinical panel completed part of the detailed review of claim files which formed the basis of the secondary studies described in the report:

Bevan Brittan LLP
Browne Jacobson LLP
Capsticks Solicitors LLP
Clyde & Co LLP
DAC Beachcroft LLP
Hempsons Solicitors
Hill Dickinson LLP
Kennedys Law LLP
Weightmans LLP
Ward Hadaway

Clinicians Advising Project Team

The following clinicians kindly advised the Project Team on the report:

Name	Title	Organisation	Aspect
David Richmond	Vice President	Royal College of Obstetricians & Gynaecologists	Main Report
Jenny Fraser	Independent Midwifery Consultant	-	Report of CTG Claims
Derek Tuffnell	Consultant in Obstetrics	Bradford Teaching Hospitals NHS Foundation Trust	Report of CTG Claims

Professor Lyn Chitty	Consultant in Fetal Medicine	University College London Hospitals NHS Foundation Trust	Report on Antenatal Ultrasound Scanning Claims
Mr Tim Draycott	Consultant Obstetrician	North Bristol NHS Trust	Report on Uterine Rupture
Miss Liz Adams	Consultant Urogynaecologist	Liverpool Women's NHS Foundation Trust	Report on Perineal Trauma

Stakeholders

Towards the end of the primary study, representatives of the following organisations reviewed the findings and contributed to decisions regarding the risk areas to be considered in the secondary study, including advising on the questionnaires:

Care Quality Commission

Centre for Maternal and Child Enquiries

National Institute for Health and Clinical Excellence

National Patient Safety Agency

Royal College of Midwives

Royal College of Obstetricians & Gynaecologists