NHS Resolution

Five years of cerebral palsy claims

A thematic review of NHS Resolution data

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Advise / Resolve / Learn

Contents

Foreword

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Overall the NHS is the safest healthcare system out of 11 western countries (1) and giving birth in England is generally very safe (2). Within England, in 2015, there were 664,777 livebirths and the trend of reducing rates of stillbirths and neonatal deaths continued, with 3.93 stillbirths per 1000 total births and 1.71 neonatal deaths per 1000 live births (3). These improvements occurred despite increasing obesity rates (4), increasing average maternal age (5) and the highest recorded number of live births to women born outside of the UK (27.5%) (5). Unfortunately, avoidable errors within maternity still occur. These can have devastating consequences for the child, family and carers and contributed significantly to the £1.7 billion cost for clinical negligence in 2016/17* (6). Possibly the most devastating and undoubtedly the most expensive, are claims for avoidable cerebral palsy, the number of which has remained relatively static over the last ten years (6).

The ambitions set out by the Secretary of State for Health to reduce the rate of stillbirths, neonatal and maternal deaths and brain injuries that occur during, or soon after, birth by 50% by 2030 (7) and for the NHS to become the "world's largest learning organisation" (8) are powerful drivers to reduce avoidable harm. Important methods for achieving these ambitions are sharing learning when things go wrong and identifying areas for improvement.

NHS Resolution is in a unique position. It holds a wealth of knowledge about every compensation claim made against the NHS in England, which can be used to identify national trends about potential problems associated with NHS care. This information can then be used to inform where the system needs to focus efforts to gain a better understanding of the problems and ultimately stop them from recurring. The learning generated through such activity can be used at both national and local levels to improve care, safety, reduce avoidable harm and decrease future litigation costs.

This thematic review presents a detailed analysis of cerebral palsy claims, identifies the common problems and provides recommendations for improvement to reduce the incidence of avoidable cerebral palsy.

By sharing the learning from these claims and working collaboratively with other organisations within the system to implement the recommendations, we can make maternity care even safer.

Michael Magro BSc(Hons) MBBS MRCOG

Darzi Fellow

*Total payments in respect of clinical schemes (comprising damages to claimants, claimant legal costs and defence legal costs) in 2016/17 were £1,707.2 million. This however, is different from the total provision of £65 billion, which reflects the true cost to the NHS in today's prices of the payments NHS Resolution will have to make in the future.

Aims of the review

This review aims to do the following:

1. Identify the clinical and non-clinical themes from cerebral palsy claims that resulted in a claim for compensation.
2. Disseminate the shared learning and use this as a driver for change and quality improvement.
3. Highlight areas for improvement and evidence of good practice, signpost potential solutions and make recommendations for change.

Executive summary

Purpose:

This thematic review analyses in depth the data held by NHS Resolution on compensation claims for cerebral palsy that occurred between 2012 and 2016. The purpose of this review is to identify the clinical and non-clinical care issues that arose in those claims, share this learning with the wider system to act as a driver for improvement and make recommendations to reduce future harm.

Background:

Negligent care resulting in cerebral palsy (CP) has a devastating and lifelong effect on the child, their family and carers. Compensation claims for CP are a small and highly selected group of incidents involving potential patient harm that may not reflect the entirety of care across the NHS. However, this review uses claims where legal liability has been admitted and in every such claim, by definition, there were errors that could have been prevented. Therefore, each claim contains learning that should be shared.

Methodology:

NHS Resolution's claims management system (CMS) was searched for all obstetric claims with an incident date between 2012 and 2016, where the alleged medical negligence resulted in cerebral palsy or neonatal brain injury.
CMS holds a wealth of information, which can include the original hospital internal investigation report, statements from clinicians and expert reports, amongst other documents. In those claims where legal liability had been admitted, an in-depth review of all the documents was conducted using a thematic analysis methodology.

Results:

The results are split into two parts. The first part analyses the quality of the serious incident investigation reports and the second part analyses the problems identified from the clinical details of each claim.

Part one of the review identified three main areas of concern;

- A lack of family involvement and staff support through the investigation process
- The quality of root cause analysis was generally poor and focused too heavily on individuals
- Due to the poor report quality, the recommendations were unlikely to reduce the incidence of future harm

Part two of the review separates the data into antenatal, intrapartum and neonatal periods, while also identifying recurring themes and areas for improvement. Four areas of clinical practice were common throughout the claims and are discussed in depth;

- Fetal heart rate monitoring
- Breech birth
- Staff competency and training
- Patient autonomy

Key findings:

- There were 50 claims between 2012-2016 suitable for review
- Potential financial liability could be greater than £390 million, which excludes the defence costs and the wider healthcare costs to the NHS
- Evidence of poor quality serious incident investigations at a local level;
  - The patient and family were only involved in 40% of investigations
  - Only 32% had a review that involved an obstetrician, midwife and neonatologist
  - Only 4% had an external reviewer
  - Reports focused too heavily on individual errors
- Errors with fetal heart rate monitoring was the most common theme. However, the underlying causes were often not related to individual misinterpretation but related to systemic and human factors
- Breech births were over-represented within this cohort, compared to the national average
- Inadequate staff training and monitoring of competency identified as an important issue
- Shortcomings in informed consent evident

Although this review analyses a small number of specific claims, the findings resonate with other reports with similar findings (9-11).

Unfortunately, the evidence suggests there has been little improvement in these areas in recent years (9, 12-14).

This review, especially when making recommendations, has taken into account the work currently ongoing within the wider maternity system. This includes, implementation of the recommendations set out in Better Births (15), the forthcoming review of the serious incident framework due in 2018 and the development of local maternity systems (LMS). LMS will have an important role in implementing many of the recommendations within this review and will require national support from the organisations responsible for oversight, safety, training and improvement.

Recommendations:

1

Women and their families offer invaluable insight into the care they received. To ensure this is included in all serious incident (SI) investigations, commissioners should take responsibility by ensuring SIs are not 'closed' unless the woman and her family have been actively involved* throughout the investigation process.

2

The quality of SI investigations has repeatedly been found to be poor with very little or no training for investigators across the NHS. A working party, involving, and possibly led by the Healthcare Safety Investigation Branch (HSIB) should discuss creating a national standardised and accredited training programme for all staff conducting SI investigations. This should focus on improving competency of investigators and reduce variation in how investigations are conducted.

3

In line with the Kirkup and Royal College of Obstetricians and Gynaecologists (RCOG) Each Baby Counts reports, all cases of potential severe brain injury, intrapartum stillbirth and early neonatal death should be subject to an external or independent peer review. However, the most appropriate model requires further national clarification.

4

Adverse events within maternity can have serious negative effects on staff, who are often provided with inadequate support. Trusts' obstetric and midwifery leads, with support from their board level maternity champion, must ensure that improving emotional support for staff throughout an investigation, irrespective of whether it becomes a compensation claim, is a priority.

*Definition of active involvement on page 50

5

Trust boards, alongside their obstetric and midwifery leads, must ensure that all staff undergo annual, locally led, multi-professional training, which includes simulation training for breech birth. This training should focus on integrating clinical skills with enhancing leadership, teamwork, awareness of human factors and communication. Staff should not provide unsupervised care on delivery suite until the competencies have been achieved.

6

Cardiotocograph (CTG) interpretation should not occur in isolation. It should always occur as part of a holistic assessment of fetal and maternal wellbeing. CTG training should incorporate risk stratification, timely escalation of concerns and the detection and treatment of the deteriorating mother and baby.

7

Trusts should monitor the effectiveness of their training by linking it to clinical outcomes. Trust boards should encourage units to publish their local indicators, which can then be subject to benchmarking and external scrutiny.

Background

Cerebral palsy

Cerebral palsy (CP) is the commonest cause of physical disability in early childhood (16), with a rate of approximately 2 per 1,000 live births (17, 18). CP is a permanent neurological disorder caused by non-progressive disturbances or alterations of the developing fetal brain (19), pathological processes while in utero (20-23) or as a complication of prematurity (24) that results in disordered motor function and posture (25). CP ranges in severity but often involves problems with muscle tone, balance, co-ordination, epilepsy, difficulties with communication, feeding and behaviour (19).

There are multiple known risk factors for CP, with prematurity being the single largest risk factor (26). The prevalence of CP increases with decreasing gestational age at delivery (27, 28); however there is some evidence that suggests delivery at 42 weeks also increases the risk (29). Other known risk factors are; poorly treated maternal hypothyroidism, thrombophilia, early onset pre-eclampsia, congenital malformations, multiple pregnancy, fetal growth restriction, birth asphyxia and infections during the antenatal or neonatal period (22, 30-35).

The underlying events that lead to the development of CP can be divided into three categories (25); Firstly, predisposing intrauterine factors; mainly fetal growth restriction, congenital abnormalities, intrauterine infection or inflammation and placental vascular disorders. Secondly, acute peripartum events; chorioamnionitis, placental abruption and birth asphyxia and thirdly, events in the neonatal period; intraventricular haemorrhage, periventricular leukomalacia, sepsis and neonatal stroke. These events can occur in isolation, however recent evidence supports a "two-hit theory" (22, 36, 37) for the development of CP, whereby neonates who suffer a hostile intrauterine environment may be then affected by a second intrapartum or neonatal event.

The majority of cases of CP are not due to medical error. However, in rare and tragic occasions, CP can be as a result of substandard care and this often results in a claim for compensation. In these situations, there is always something to learn.

NHS Resolution

In April 2017, the NHS Litigation Authority (NHS LA) evolved to become NHS Resolution. The NHS LA was originally established in 1995 as a special health authority, providing not-for-profit indemnity cover for compensation claims against the NHS. It continues with this role today in addition to sharing learning with the aim of preventing future harm occurring.

The financial costs of litigation are quantifiable and learning lessons to reduce this burden is essential. However, it is vital to remember that having a child suffer catastrophic avoidable harm is a tragedy for everyone involved and the costs to the child, family and carers are immeasurable.

The human cost of negligence

"Knowing our son has cerebral palsy from medical negligence when my wife looked after him so well while he was still in the womb is very difficult to deal with. He was a healthy boy until 10 minutes before he was born and the events that happened in the hospital still haunt me and my wife every day, reliving the moment that his 'normal' life was taken away from him by people not doing their job correctly will never escape our memories."

Parent of child with cerebral palsy

"I am the father of a wonderful 11-year old girl called Julie. She is an amazing person who makes me proud every day. She enjoys school, has lots of friends and lives life to the full. Julie also has cerebral palsy, epilepsy and severe global developmental delay. She is non-verbal. She cannot dress, feed or wash herself. She doesn't sleep properly and her behaviour can be unpredictable. She will be reliant on one-to-one adult support, 24-hours-a-day, for the rest of her life.

My situation is far from unique. There are thousands of dads across the country who wake up every morning facing the challenge of caring for their severely disabled son or daughter. It's not easy, believe me. The fact that Julie's disabilities were entirely avoidable and were caused by the proven negligence of the people who delivered her, makes it all the more difficult to accept. Julie wasn't meant to be like this; it wasn't meant to be this way. I just can't get that out of my mind. Perhaps I never will."

Parent of child with cerebral palsy

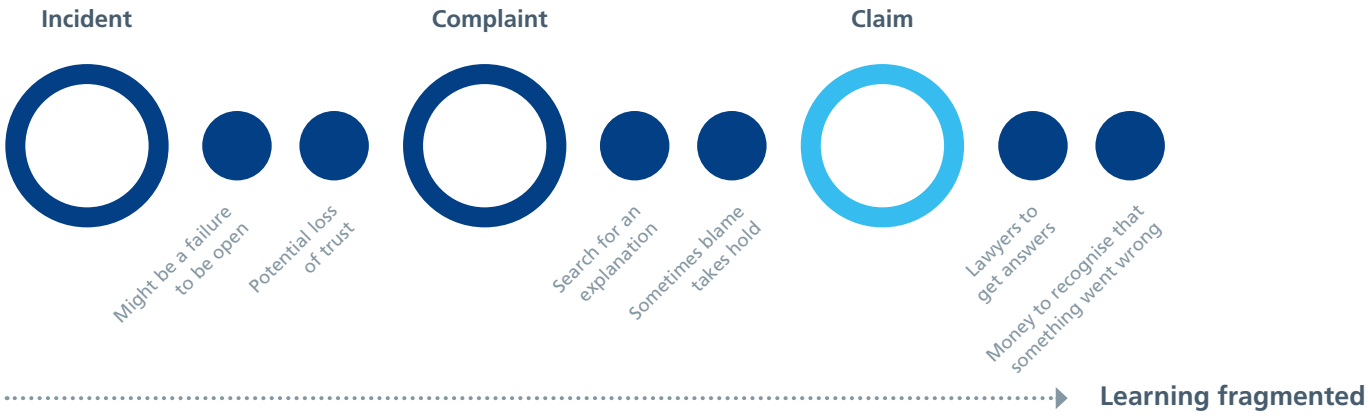
New strategic framework

The primary focus of NHS Resolution is to resolve concerns fairly, but it also has a duty to use its knowledge and influence to prevent future harm.

This evolution in strategy means NHS Resolution is more focused on prevention, learning and early intervention, being able to respond sooner when something goes wrong.

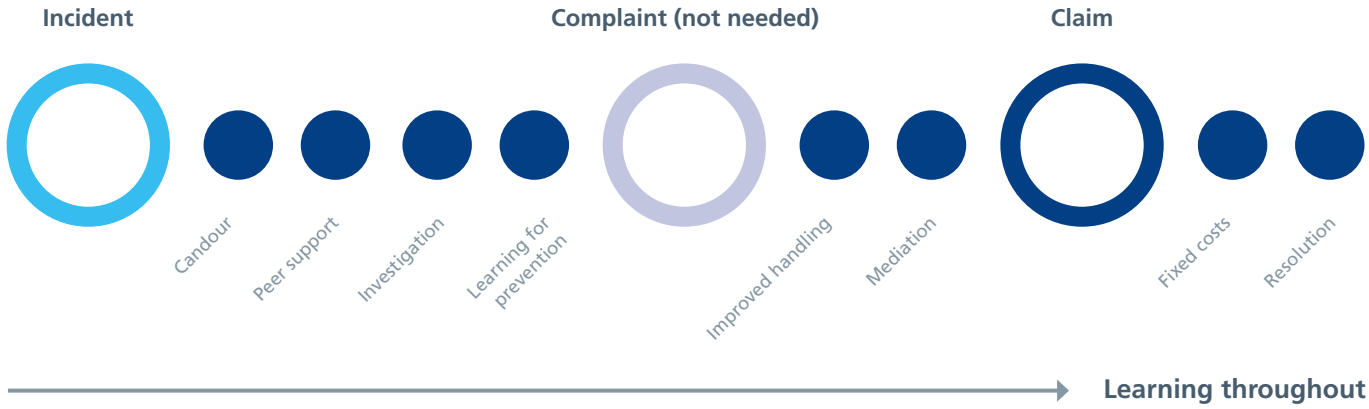
Figure 1 illustrates how an incident may become a claim, the failures that may arise and why learning throughout the process can be disjointed.

Figure 1: The previous model of incident-to-resolution.



The new strategy, demonstrated in figure 2, involves earlier intervention and support with the aim of resolving the incident quickly and fairly, while having a more joined up process for learning along the way.

Figure 2: The new model of incident-to-resolution.



This change in approach is initially focused on incidences of brain injury at birth with the creation of the Early Notification Scheme.

Early Notification Scheme (ENS)

As of 1 April 2017, the NHS Resolution ENS came into effect. This scheme involves a more upstream approach, whereby trusts are required to notify NHS Resolution of all cases of possible severe brain injury* within 30 days of the incident occurring. Previously, trusts were only required to report if the serious incident investigation suggested there had been failings in the care and there was the possibility of a high value claim (>£500,000).

As demonstrated in figure 3, the new approach allows NHS Resolution to provide support and assistance at a very early stage, which then continues throughout.

*Severe brain injury is defined using the RCOG Each Baby Counts (EBC) criteria (10):

Babies born at term (≥37 completed weeks gestation), following labour, with a severe brain injury diagnosed in the first seven days of life, namely babies that have one or more of the following:

- *Grade III hypoxic ischaemic encephalopathy (HIE)*
- *Actively therapeutically cooled*
- *Have all three of the following signs; decreased central tone, comatose, and seizures*

Figure 3: Stage at which the Early Notification Scheme involvement starts after an incident

Trusts are expected to continue to perform local investigations, including parents throughout the process and comply with the statutory duty of candour. Use of the serious incident framework (38) is recommended.

The services the ENS will provide include:

1) Support, advice and practical help on delivering candour in practice at an early stage.
2) Point of incident mediation when the relationship between the trust and family is at risk of breaking down.
3) A peer support network for affected healthcare staff.
4) Help with preservation of records and other evidence and when indicated, starting a preliminary investigation of legal liability.
5) Sharing of local and national trends, publication of annual data on high value maternity claims and publishing best practice in collaboration with the royal colleges and arm's length bodies, including NHS Improvement and the new Healthcare Safety Investigation Branch.

Financial perspective

The NHS Resolution provision, which demonstrates the value in today's prices, of the cost to the NHS of claims arising from harm, up to 31 March 2017, is £65 billion (6). The total payments made for clinical negligence in 2015/16 were £1.7 billion (6) however, this is expected to rise.

Exercising her powers under the Damages Act 1996, the Lord Chancellor announced in February 2017, a change to the personal injury discount rate*, from 2.5% to minus 0.75% (39). This change will increase damages and the biggest increase will be seen in the highest value claims.
For example, a child with CP with a long life expectancy, which settled at £12 million with a 2.5% discount rate, is likely to cost £17,280,000, an additional £5.28 million, with a minus 0.75% discount rate.

It is well known that obstetrics contributes significantly to the financial burden of litigation to the NHS (6, 40). In 2016/17, the numerical volume of claims received by NHS Resolution related to obstetrics and potential neonatal harm, excluding gynaecology, was 10%. However, as demonstrated in figure 5, the monetary value of these claims was 50% of the total value (£4.37 billion) for all specialties (6).

*See link for definition of the personal injury discount rate
https://www.gov.uk/government/news/new-discount-rate-for-personal-injury-claims-announced

Figure 4: The number of clinical negligence claims received in 2016/17 by specialty

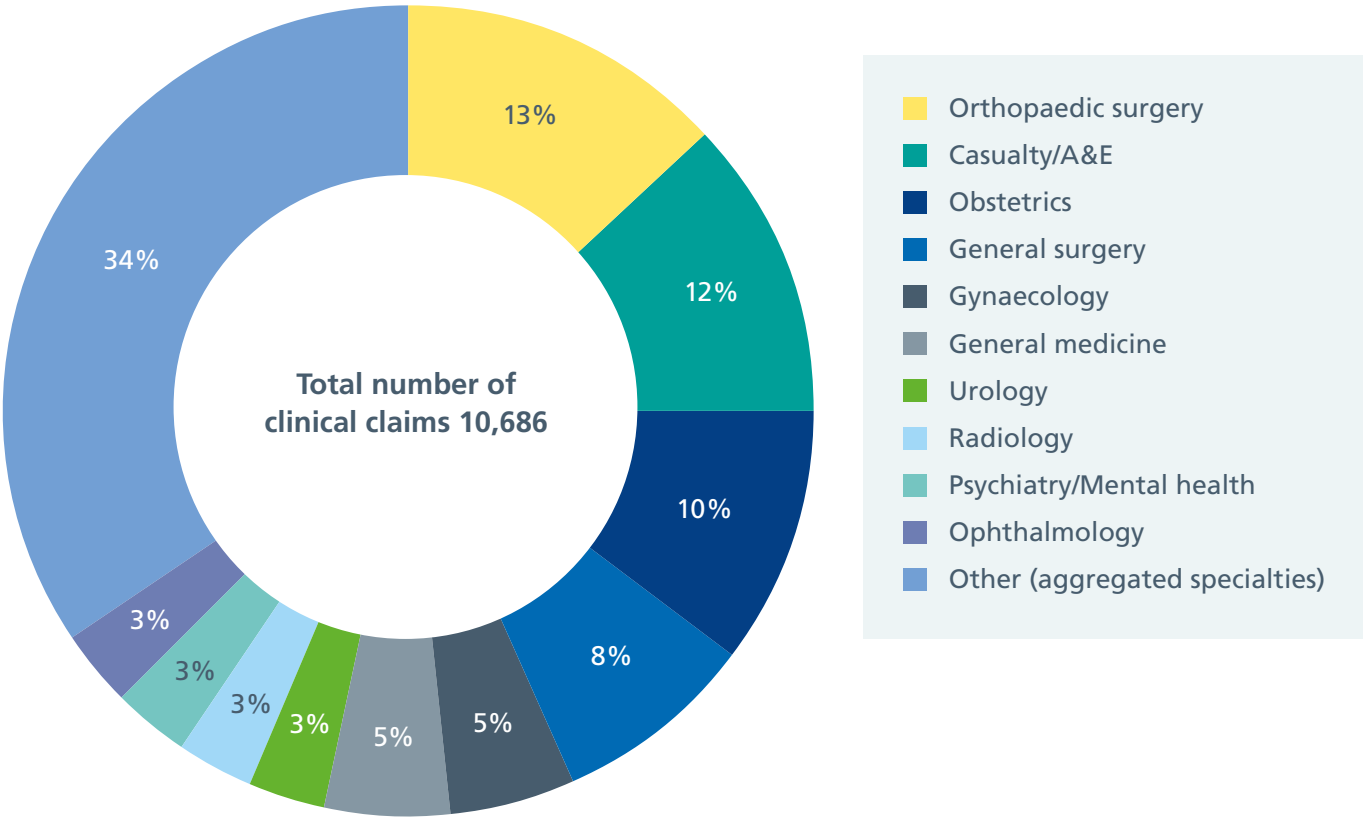
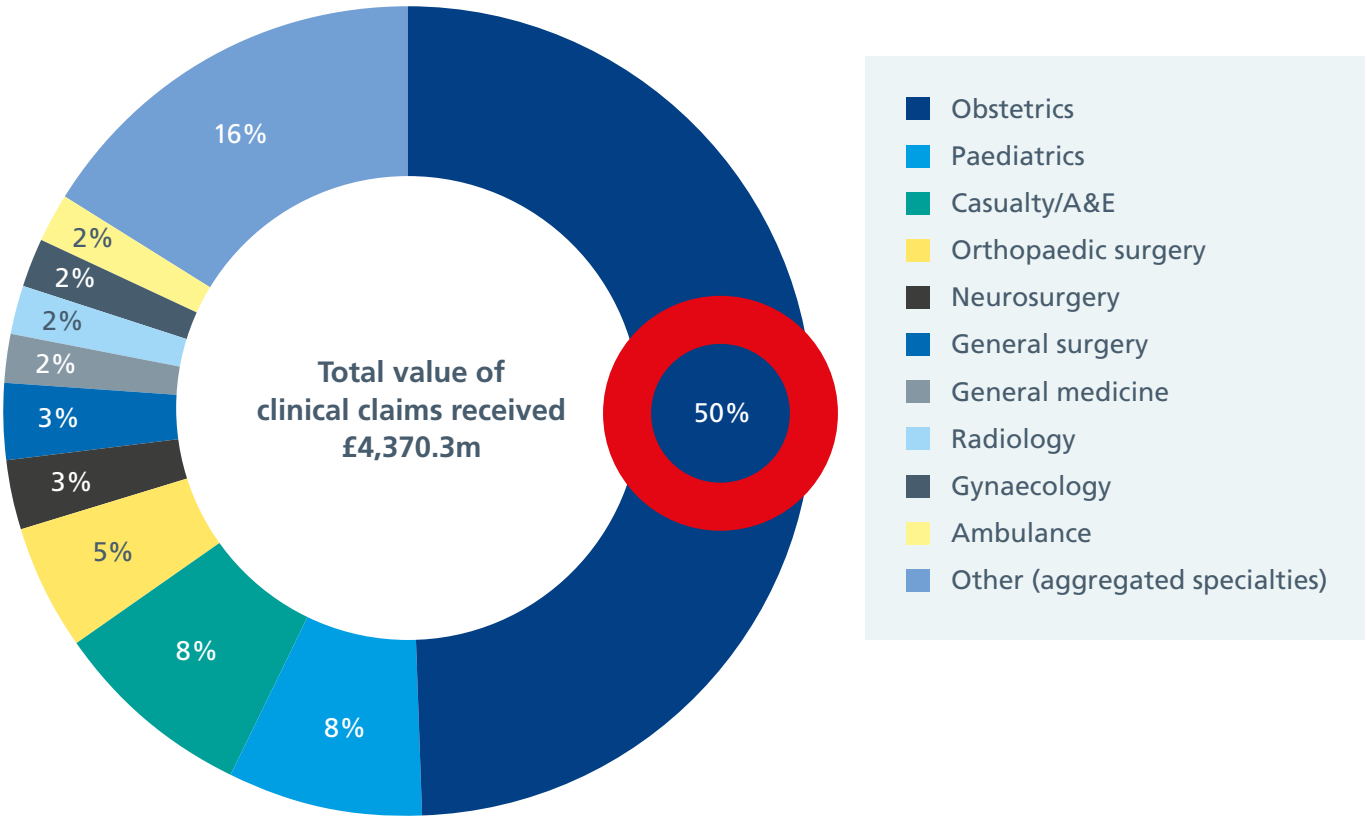


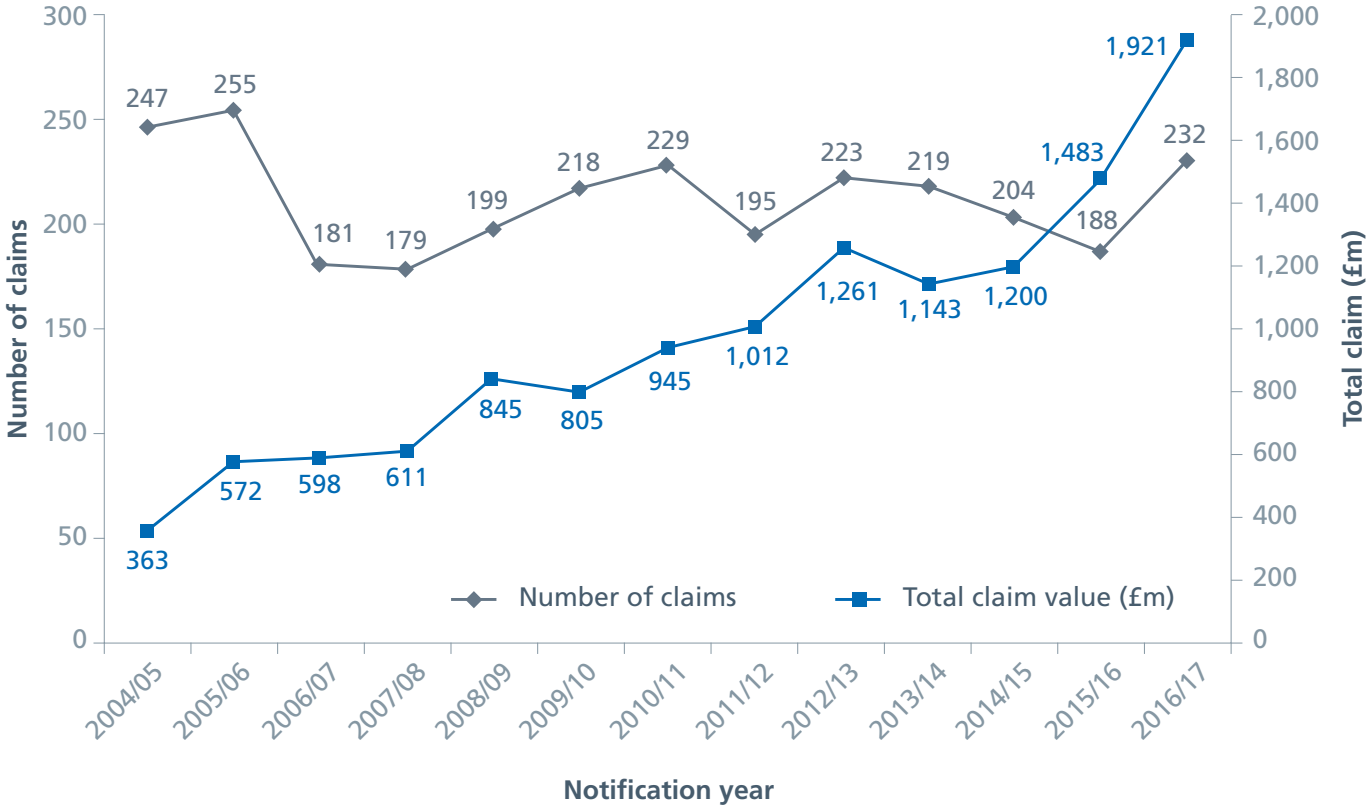
Figure 5: The value of clinical negligence claims received in 2016/17 by specialty



Within obstetrics the most expensive individual claims financially are those for cerebral palsy, which could exceed £20 million per claim. As demonstrated in figure 6, the number of claims for CP dropped between 2005/6 and 2006/7 but has subsequently remained relatively static over the last ten years.

Despite this, the financial cost has risen by 81% since 2004/5, resulting in a total claim value of £1.9 billion in 2016/17 (41). Possible explanations for this rise include; increased life expectancy of children with CP, increased care costs, increased accommodation costs and the courts allowing for greater recoverability of certain heads of loss.

Figure 6: A comparison of the number and total value of claims for cerebral palsy and neonatal brain damage claims over time



Compensation for children with CP will cover damages for pain, suffering and loss of amenity for the injury itself as well as damages for past and future monetary losses. For CP claims, this often includes loss of future earnings, the cost of care and assistance, physiotherapy, hydrotherapy, speech and language therapy, mobility equipment and physical aids, specialist transport, as well as alternative or adaptions to accommodation. The high financial costs represent the lifelong care and assistance that the children often need.

Calculating the average amount paid out for a specific group of CP claims is extremely difficult and therefore the average financial reserve is used in this review, unless the figure is already known. Each claim is dealt with on a case-by-case basis and often the final amount paid out is not known until the child dies. Historically claims were often paid as a lump sum, however it is now more common for most CP claims to be paid via annual periodical payments. These are annual payments for the life of the child, linked to an inflationary index, to ensure all the needs of the individual are always met. Parents have the security of knowing that an annual payment will be made and their child will never run out of funds.

The key to reducing the financial burden on the NHS of the growing costs of claims is "learning from what goes wrong and supporting those who deliver care to make the changes necessary to prevent harm occurring in the first place" (41).

Importantly, these costs are solely those associated with compensation claims and do not include the organisational costs to the NHS, the additional costs of investigating what went wrong (42) or the often unreported personal and psychological costs to staff.

Costs to staff

There is gathering evidence demonstrating the significant effect on staff after an adverse event (43-47) and the lack of support that is often available (44, 48). Staff are the "second victims" (43, 45), after patients and their families, and may experience guilt, fear, anxiety, anger, depression and insomnia (45).

These emotions are often suffered in silence and can lead to post traumatic stress disorder (44, 49) with staff unable to forgive themselves (50) and occasionally resulting in suicide (51). This can also be precipitated by the stress of litigation (52, 53).

A lack of support and supervision has been identified as a key reason why 1 in 5 UK obstetric and gynaecology specialist trainees leave the profession before completing their training (54).

"Reading through the MRI report demonstrating that a baby would have severe brain damage as a result of my actions, or rather, my inaction, I felt as if I'd been winded. Tears flowed as I sat on my own in antenatal clinic, my fingers shaking. I have never wanted more to be able to turn back time. I stumbled through the rest of the day, unable to articulate my distress. Hours became days. The baby and his family occupied pretty much my every waking thought, eating into time at home with my own children. I wandered around in a fog at work, going through the motions, but struggled with any kind of decision making process.

About a month down the line [I was] still struggling to sleep, eat properly or focus on much else. The feeling of guilt was all pervasive; that I deserved to feel awful, that any distress was of my own making, that it was nothing in comparison to what the family were going through.

Every time I started to get back to 'normal', I had to rip the plaster back off - to write my statement, attend the SI review and round table meeting, to discuss the report with my supervisor and at my annual review of competence progression.

The first time I looked after a patient in similar circumstances I felt utter panic rising in my throat. I looked for the first excuse to deliver the baby as soon as possible and finally understood the perspective of being that person that everyone else thinks is over-reacting. I pore over CTGs a lot more now. I get second opinions on things I never would have considered doing. I definitely practice more defensively.

It's a decade since my first job in O&G and yet until very recently I'd never heard the term 'second victim'. It makes me wonder why we wait for tragedy to strike to acknowledge our own fallibility and humanity to each other. We can, and should, do so much more".

Obstetric and Gynaecology specialist trainee who was involved in an adverse event

Methodology

NHS Resolution's claims management system (CMS) and its limitations

CMS is a database which holds details of every claim and contains a significant amount of patient sensitive and legally privileged data. Use of this data is bound by strict information governance processes*.

The primary function of CMS is claims management and the data held within is coded for this purpose. The first limitation is that the clinical data is coded on a macro level, such as specialty, location and a brief description of the incident, such as 'failure to escalate'. For the purposes of learning and identifying clinically relevant data an analysis of the documents stored for each individual claim was required.

Secondly, the quantity of documents and clinically relevant data held within CMS varies on a case-by-case basis. The information held for an individual claim can include letters of claim, letters of response, the original hospital internal investigation report, statements written by clinicians, expert reports, external hospital investigation reports, documents associated with the procedural aspect of the claim and rarely, trial documents such as a court judgment. For claims where an early admission of liability (ie- breach and causation) has been established there will be fewer documents, as the claim will then shift its focus to quantification of the compensation award.

For claims where causation may be unclear and require further investigation there will often be multiple expert reports and sometimes records of joint expert meetings, which provide a deeper source of information. It is important to remember however, that the expert reports are designed to answer whether the care provided breaches the legal standard of clinical negligence. Unlike the SI reports, which are designed to identify why the incident occurred.

Thirdly, CMS does not contain a copy of the healthcare records and therefore the quality of the learning that can be shared is only as good as the data that is provided within the documents stored.

*Information governance

The NHS Resolution guideline CG02 (information governance principles) ensures that archiving, retention and destruction of data, including claim files, complies with the Data Protection Act 1998. All personal data is processed in accordance with this act.

Research ethics committee approval was not required, as this was a retrospective review using routinely collected anonymised data from the NHS Resolution database.

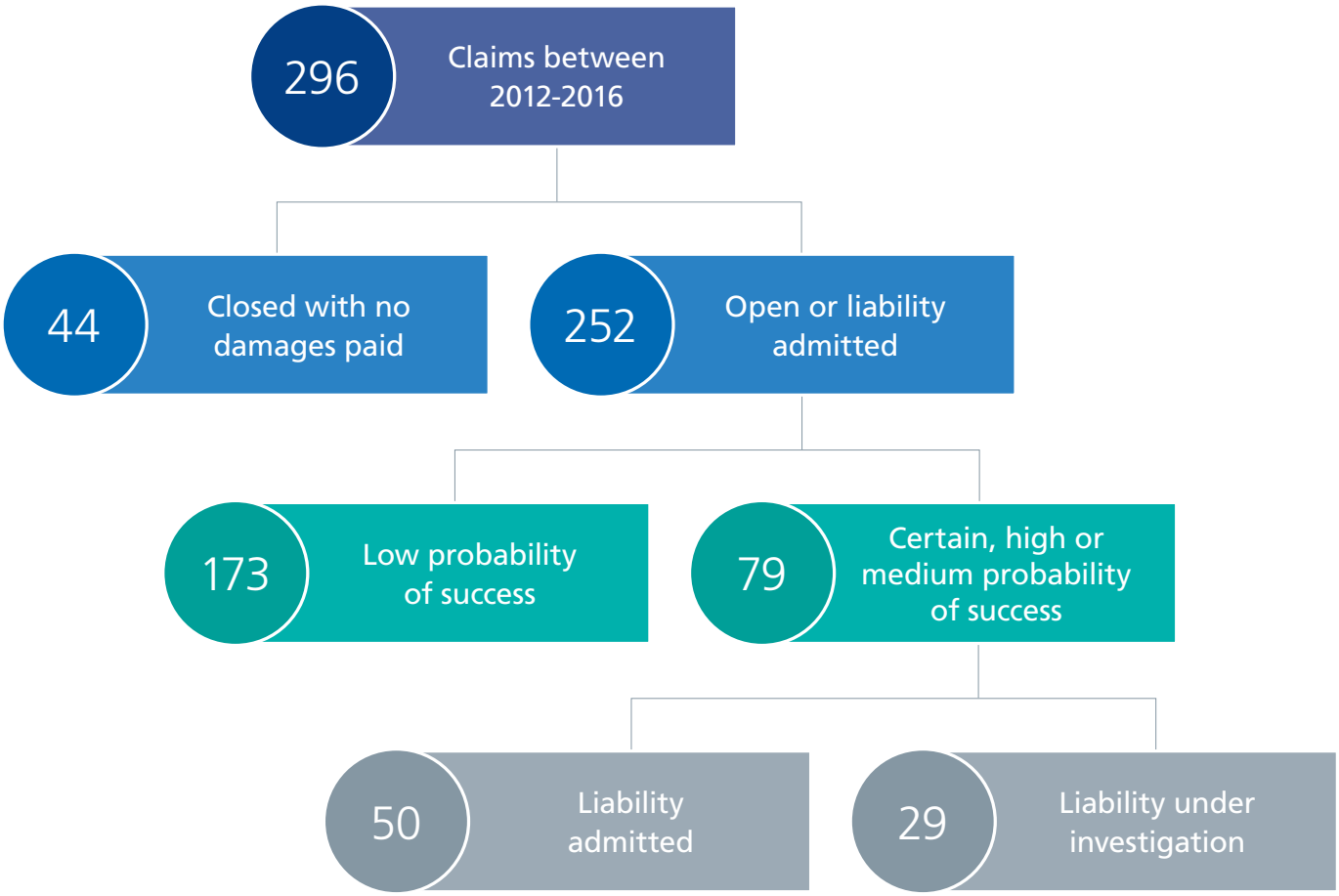
Search criteria

CMS was searched for all obstetric claims where the alleged medical negligence resulted in cerebral palsy or neonatal brain injury. CMS was searched on 31 October 2016 for claims that had an incident date (the date the alleged incident occurred) between the calendar years 2012 and 2016. This search identified 296 claims.

It was identified that only claims where legal liability had been admitted would be suitable for review, as any data produced by NHS Resolution's panel firms could be disclosable to the patient's solicitor as legal privilege could not be claimed. This could potentially jeopardise the claim. Therefore, only those claims that were "open" or where liability had been admitted were searched as demonstrated in figure 7. This excluded 44 claims that were closed with no damages paid.

The remaining 252 claims were further filtered on CMS using a probability of "certain", "high" or "medium", excluding "low", that the claim would succeed, which resulted in 79 claims. This was performed to ensure those claims that would likely fail would not be included in the review. Of those 79 claims, 29 claims were still under investigation for liability and therefore 50 claims were suitable for review.

Figure 7: Breakdown of claims for cerebral palsy and neonatal brain injury between 2012 and 2016



The first limitation to using this search criteria is the small possibility of excluding claims that may provide an opportunity for learning.

A "low" probability score is only given to those claims which are deemed, by NHS Resolution, to be unlikely to succeed and therefore missed claims are possible but extremely unlikely.

The second limitation is that the sample obtained is a highly select, small group. Nevertheless, the claims arose from trusts throughout England and as every claim had legal liability admitted they represent severe avoidable harm that has occurred in the last five years.

Thematic analysis

A data capture tool designed by the author, a senior obstetric and gynaecology registrar, working as a Darzi Fellow at NHS Resolution, was sent to the panel firm solicitors who had originally dealt with the claim to complete. This summarised the following information for ease of reference; claim details, the serious incident investigation report, patient demographics and relevant clinical aspects of the antenatal, intrapartum and neonatal periods that could have contributed to the alleged brain injury or CP. The author also had access to all the documents held within CMS for each claim and conducted a thematic analysis.

Thematic analysis is the most common methodology used for analysing and categorising qualitative data (55). It is an approach for systematically extracting recurring features and patterns into themes (56). Using an inductive approach (57), themes were identified using an open mind, from the data available, rather than trying to fit the data into pre-existing models or frameworks (58). Similar methodology has been used to review other groups of serious incidents (59).

The steps used to identify the themes were firstly, becoming familiar with the data by reading the SI reports and expert witness statements. Coding the data prior to interpretation, identifying patterns within the data and finally, grouping the patterns into themes which explain the data.

To ensure the themes identified were robust they were reviewed independently by a select group of panel firm solicitor partners, with an interest and wealth of experience in dealing with cerebral palsy claims.

Importantly, the data analysed from the SI reports has already been subject to interpretation by those individuals who conducted the reviews. For this reason, supporting evidence from other reports is also referenced to ensure the recommendations of this review are evidence based.

Results

Breakdown of claims

50 claims were identified as being suitable for thematic analysis as demonstrated in figure 7.

The 50 claims were spread between 40 different trusts, with no individual trust having more than two claims.

Table 1 demonstrates the split of claims between nine of the ten solicitor panel firms, with three claims not having a named panel firm but dealt with by NHS Resolution.

Table 1: The panel firm that dealt with the claim

Panel firm	Number
Bevan Brittan	5
Browne Jacobson	1
Capsticks	11
Clyde & Co	2
DAC Beachcroft LLP	9
Hempsons	4
Hill Dickinson	7
Kennedys	6
Weightmans	2
NHS Resolution (in house)	3

The incident date ranged from 15/2/12 to 12/9/15.

Table 2: The number of claims per year:

2012	2013	2014	2015	2016
27	15	6	2	0

Table 3: Year NHS Resolution notified of claim:

2012	2013	2014	2015	2016
5	16	15	12	2

Financial implications

11 claims had settled with damages paid to the claimant or had damages agreed out of court. The average total cost was £111,296 per claim. The remaining 39 claims were still open, with the level of damages to be paid to the claimant being investigated. If the remaining 39 claims are all resolved at the same average, the total financial cost would be £4,451,837. However, the total is likely to be much higher.

A child born with neonatal brain injury that dies soon after birth, as some of these claims were, would likely receive a much smaller settlement than a child with severe CP that requires lifelong care.

If the remaining 39 claims are resolved at the current average financial reserve for a CP claim of £10 million, the total cost to the NHS could be £390,111,296, excluding defence costs.

However, this sum may be higher or lower depending on the child's future prognosis, life expectancy and future needs, which will determine the level of damages, with the possibility of individual claims reaching above £20 million.

Part 1: The quality of the member trusts' serious incident investigation reports

Background to incident investigations

The framework for serious incident (SI) investigations during the period covered in this review spans three documents. In 2010 the National Patient Safety Agency (NPSA) released the 'national framework for reporting and learning from serious incidents requiring investigation' (60).

This was superseded in 2013 by the serious incident framework produced by NHS England (61) and was updated in 2015 (38).

The 2010 framework produced a nationally consistent definition of SIs that required investigation, previously known as serious untoward incidents, that minimised ambiguity and improved consistency;

> ***"An incident* that occurred in relation to NHS-funded services and care resulting in one of the following; 1) unexpected or avoidable death, 2) serious harm (where the outcome results in permanent harm or will shorten life expectancy)" (60)***

The 2015 framework states that there is "no definitive list of events that constitute a serious incident" but they include "acts and or omissions that result in 1) unexpected or avoidable death 2) unexpected or avoidable injury…that has resulted in serious harm" (38).

> ***An incident was defined as "an event or circumstance that could have resulted, or did result in unnecessary damage, loss or harm such as physical or mental injury to a patient" (60)***

The key features shared between the frameworks are: (38, 60)

1) An open, honest and transparent culture with patients and their families involved and supported throughout, including support for staff.
2) The use of root cause analysis (RCA) to identify both active (acts or omissions) and latent (organisational and environmental) failures. Including adequate training of staff in RCA methodology.
3) Learning from the incident and creating actions that will prevent or minimise the risk of recurrence.

Breakdown of claims

The 50 claims analysed in this review, all had liability admitted. They relate to children born with CP or brain injury who would otherwise have been born without a lifelong disability if it were not for medical error or negligence (an act or omission that resulted in serious harm). For this reason, each claim should have triggered an SI report, followed by a robust investigation carried out to the standards outlined in the frameworks, prior to a compensation claim.

A serious incident investigation was performed in all 50 claims, in 42 claims this was performed prior to the compensation claim being brought with eight performed after the claim.

The SI used a RCA methodology in 41 claims. The remaining nine claims used an alternative or no stated methodology.

A formal complaint was made by the mother or family in 21 cases prior to bringing a claim.

From the data available, there was documented evidence of a formal apology from the trust involved in the management of the care in 32 of the 50 claims. NHS Resolution has always advocated that healthcare professionals should offer apologies regardless of any ongoing legal process (62) and since 2014 it has been statutory under the duty of candour (63).

An apology "is critical to preserve the very precious relationship of trust between doctor and patient [which] is most severely tested in the aftermath of an adverse event".

A detailed and honest investigation is a "challenge [that] calls on healthcare at all levels to practice open disclosure, transparency, accountability, reporting and learning. When that happens, healing can occur and public confidence is restored… Inappropriate responses and interactions following an event often prove to be more damaging than the event itself".

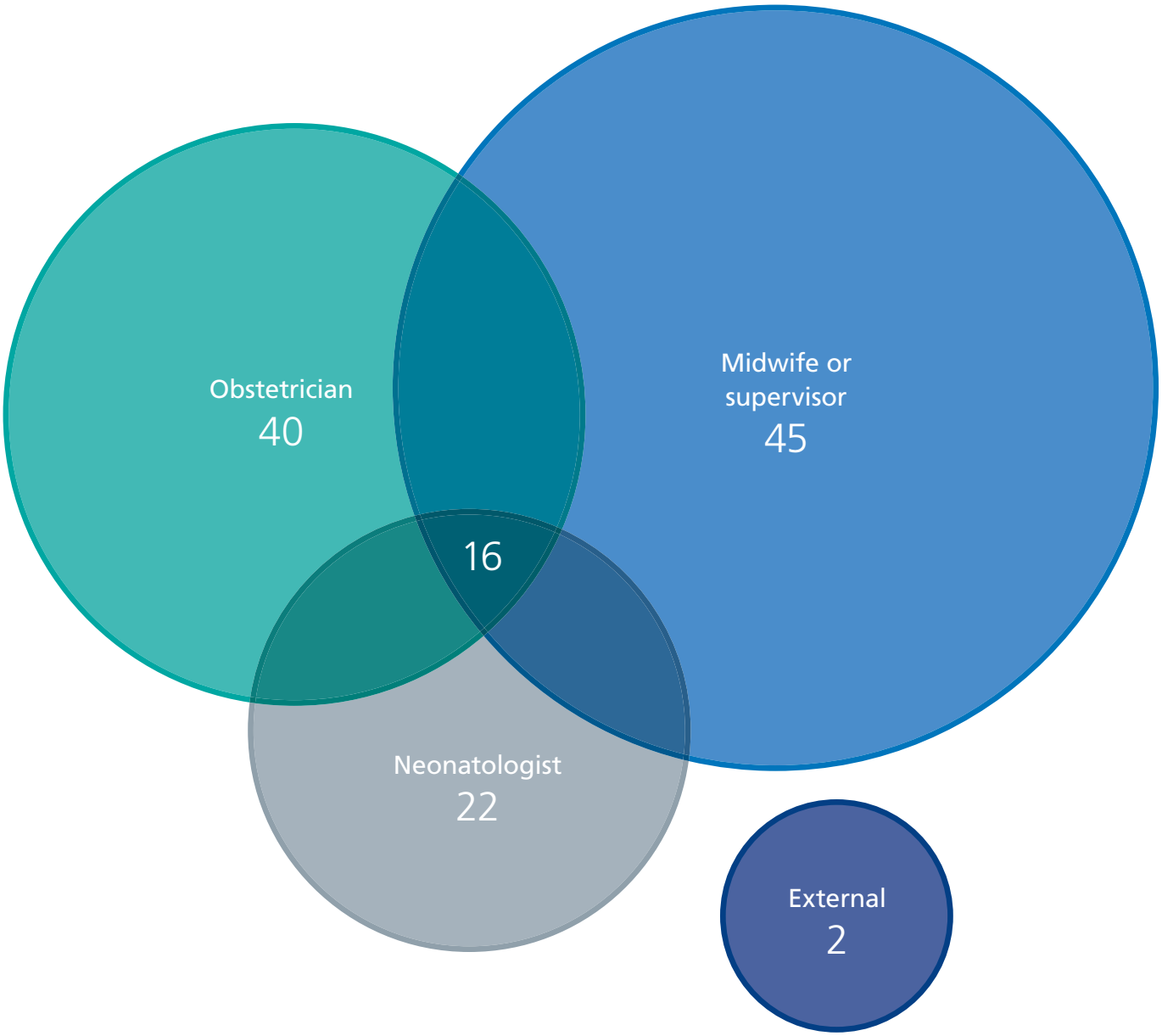
"In order to access truth families are often forced into the arms of litigation which… is adversarial and… is not their preferred environment for achieving that truth"

Parent who has been through the litigation process

The clinical team involved in investigating the SI varied between claims with a consultant obstetrician involved in 40 claims, a midwife or supervisor of midwives in 45 claims and a neonatologist in 22 claims.

In only 16 claims were all three experts involved. In just two claims an external reviewer was involved.

Figure 8: Involvement of the multidisciplinary members in the SI process



Themes identified from SI investigations

The main themes identified in part 1 of this review directly relate to the quality of the SI reports and their failure to adhere to the key features of the frameworks.

The three themes are:

1) A lack of family involvement and staff support.
2) Low quality root cause analysis with a focus on individuals.
3) Recommendations which are unlikely to prevent recurrence due to a lack of focus on systemic changes.

The need for the NHS to learn from incidents was highlighted in the report 'an organisation with a memory' by Liam Donaldson in 2000 (64), yet multiple reports since then have highlighted similar findings of poor family involvement, substandard investigations and a lack of learning.

Within maternity, the RCOG Each Baby Counts (EBC) key messages (10) and 2015 summary report published in 2017 (65), the MBRRACE-UK 2015 Perinatal Confidential Enquiry (11) and the Morecambe Bay investigation (66) and on a national scale the Care Quality Commissions briefing on learning from serious incidents in NHS acute hospitals (9).

The Healthcare Safety Investigation Branch has been created due to the fact that when "investigations are carried out, they are often incomplete and fail to identify the underlying causes of harm, or lead to actions that improve safety" (67).

This review adds further weight to these significant findings and makes recommendations which should be acted upon urgently so that further reports do not find similar conclusions.

Theme 1:

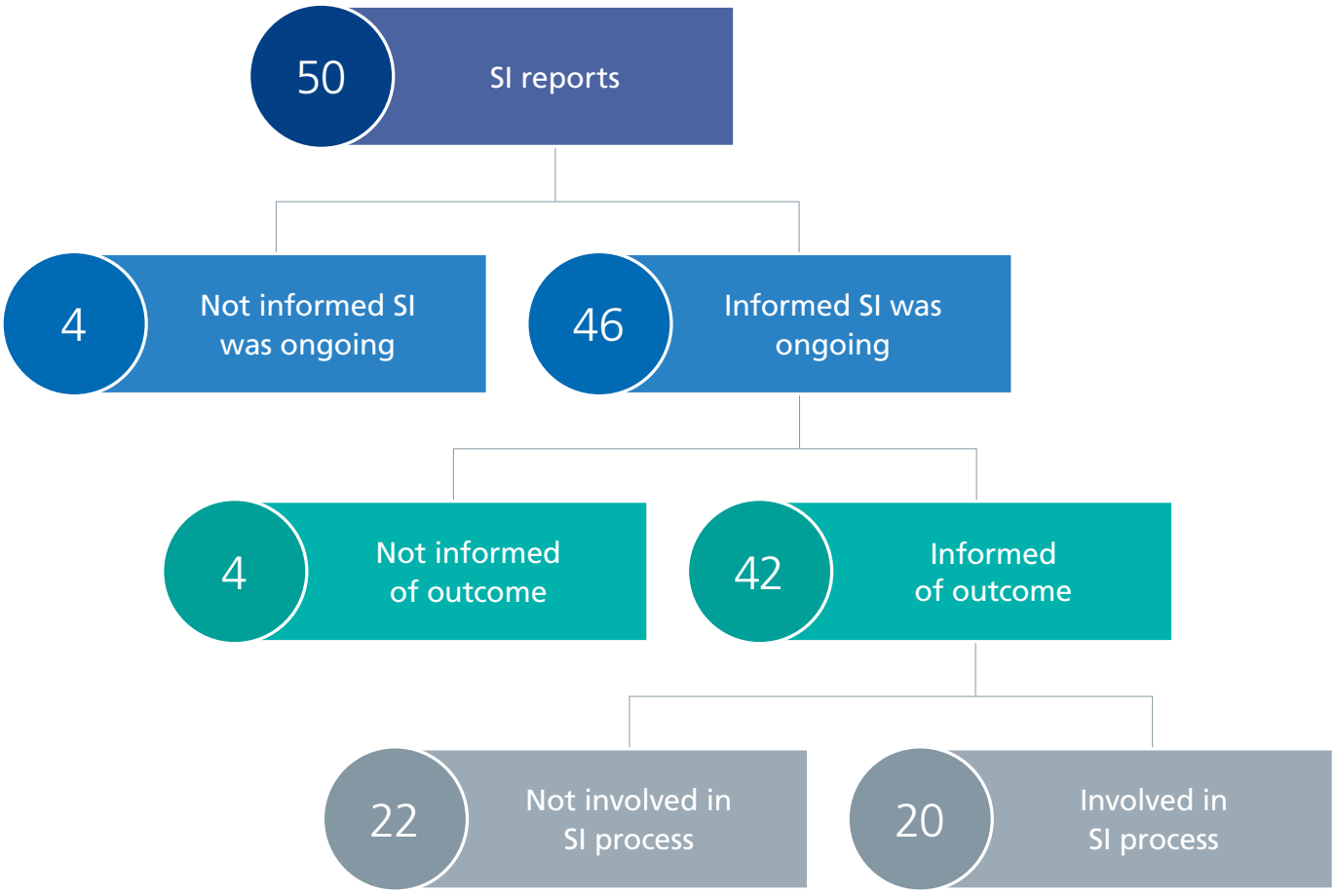
A lack of family involvement and staff support

Family involvement

Information and support should be offered early to patients and their families. The NPSA 'being open' document (68) and since 2014, the Duty of Candour guidance (63) explains how this should be done.

Despite this advice, four families (8%) were not informed an investigation was ongoing and four (8%) were informed it was ongoing but not provided with the report outcome.

Figure 9: Breakdown of patient and family involvement in the SI process

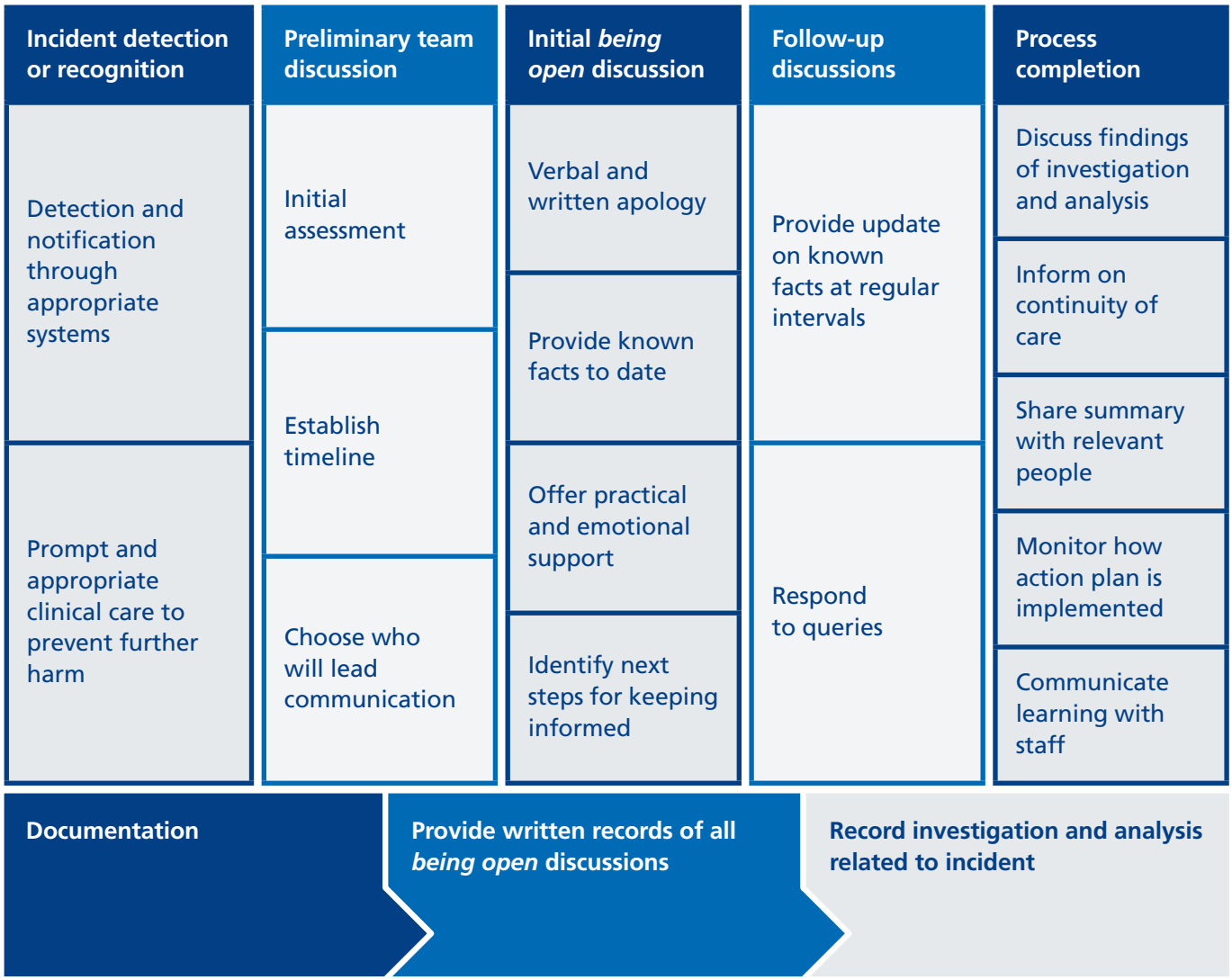


The direct involvement of patients and their families in the SI process was not explicitly stated in the 2010 framework but it was expected that investigators would "recognise patient and carer expectations" (68) prior to conducting the investigation.

The basis for patient, family and carer involvement is set out in figure 10, taken from the NPSA 'Being Open' document (68). It was evident that an apology should be given, that the facts were provided, that support was offered and patients were kept informed throughout.

There was guidance that the investigators should respond to queries, something that could only have occurred if patients were involved and allowed to ask questions.

Figure 10: An overview of the 'being open' process, taken from NPSA Being Open document (68)



The 2013 framework provided greater detail, stating that "providers should… involve patients and families/carers in investigations" (61) and the 2015 framework makes it mandatory that patients, victims, their families and carers should be:

- Made aware in person and in writing, as soon as possible, the rationale for the SI and its purpose
- Have an opportunity to express concerns and questions (acknowledging that the family offer invaluable insights)
- Can inform the terms of reference and can contribute to the investigation process
- Given access to the findings, including interim findings and have an opportunity to respond to those findings

Despite this guidance being available from 2010, only 42 (84%) families were informed that both an investigation was ongoing and informed of the outcome. Only 20 of the 50 families were involved in the SI process (involvement being defined as any of the following; being allowed to comment on the SI contents, participating in the design or writing of the investigation or were involved with a meeting with staff before the report was finalised).

Staff support

One of the expectations of providers of NHS care is to ensure that staff receive support following an SI (60). The primary concern for those individuals investigating the SI should be the needs of those involved, which includes supporting staff throughout the investigation (38).

There was documented evidence that support to staff was offered in 30 claims (60%), whether this offer was taken up is not clear. The support offered was often a discussion of the case with their educational or clinical supervisor, supervisor of midwives or line manager.

Evidence from elsewhere

Evidence of this lack of support is also demonstrated in the 2016 national NHS staff survey where only 45% of responders agreed or strongly agreed that 'my organisation treats staff who are involved in an error, near miss or incident fairly' (69). In 2015, there were 12% who felt their trust punishes people who are involved in errors or near misses (70).

The RCOG EBC project which has been collecting prospective data on local risk management reviews for intrapartum stillbirths, early neonatal deaths and babies born with severe brain injury identified that in 19% of cases parents were not involved or made aware a local review was ongoing and were only invited to contribute in 34% (65). They recommend that "parents should be made aware that a local review is taking place and invite them to participate in accordance to their wishes" (10).

The 2016 CQC *briefing on serious incidents within acute trusts* identified that only "12% included clear evidence that the patient or their family had been involved in the investigation" (9) which, as a result meant the reports lacked the important perspective of the patient and their family (9). It also found that although 78% of staff were offered support this was often a "standard phrase that was repeated in each report… irrespective of the impact on the individual" (9).

The MBRRACE-UK 2015 *perinatal confidential enquiry into stillbirths* found that only 5% of cases had documented evidence that parents' concerns were included in the review and in only 16% of cases did parents receive feedback on the results (11).

Evidence for improved parental involvement and support

Most parents want the opportunity to be involved in the investigation process (71, 72). They are the only individuals present throughout the whole care journey and their input into investigations should be seen as invaluable.

There is evidence that involving parents in the investigation process "promptly, fully and compassionately can help patients and professionals cope better with the after effects" (68) and ensuring the investigation is open and honest, can help prevent such events becoming formal complaints and claims (73). However, identifying how best to do this has not always been clear. This may reflect why the rate of parental involvement is so low.

SANDS, the Stillbirth And Neonatal Death charity are clear that the inclusion of parents in investigations "must be invited early on, genuinely respected as an authoritative account and be facilitated in a manner that is flexible around individual needs" (71).

They also advocate specialist support for parents during the investigation process. This support should take into account parents "inexperience, distress and vulnerability" (71) and provide both emotional and practical help to ensure women and their families are able to fully participate in the investigation process.

The PARENTS I study (Parents' Active Role and ENgagement in Their Stillbirth/perinatal death review) is the first study to formally investigate parental involvement in the perinatal mortality review process (72). The model for parental involvement, recommended in the study, should include; transparency, flexibility combined with specificity, inclusivity and a positive approach (72). This approach will now be piloted in the PARENTS II study and incorporated into a national standardised process (74). The results of these two studies could be incorporated into the wider scope of serious incident investigations.

Theme 2:

Low quality root cause analysis (RCA) with a focus on individuals

Why quality matters

A RCA is a formal, well recognised, evidence based methodology that uses a structured investigation process to uncover the true underlying causes of an incident by understanding what, how and why a system failed (38, 75). Only once these questions have been answered can learning be achieved and an action plan created that will reduce the risk of future occurrence. If the RCA is unsatisfactory, and especially the question of 'why' not answered, there can only be a limited amount of learning and progress towards safer patient care.

A RCA should be logical, fair, open and adopt a just (76), or fair blame, culture (38), as it is often a system failure rather than an error by an individual that is at fault. It is therefore vital that a RCA looks at the wider environmental and organisational factors, often referred to as latent conditions (77), that allowed the error to occur.

Evidence of RCA quality

Overall, 41 claims used a RCA methodology with the remaining nine using alternative or no stated methodology.

From reviewing the SI reports, there appeared to be a focus on individuals, rather than systems and a general lack of detail and depth in the RCA. A description of the problem (what happened) was often well defined, usually with a very clear and detailed timeline of events. The contributing factors (how it happened) mentioned at least one human factor in 39 reports (78%). Table 4 lists the top 8 contributing factors described.

Table 4: Contributing factors mentioned within SI report

Contributing factor	Number of SIs that mention each factor (not mutually exclusive)
Individual skill level	26
Poor communication	22
Guidelines or policy issues	18
Inadequate knowledge of individual	17
Equipment issues	10
Inadequate staffing level	7
Poor teamwork	5
Excess workload pressures	4

The most frequent contributing factor to the failures in care delivery was an individual not having adequate skills. This is explored further in part 2 of the review which focuses on the clinical themes.

It is also interesting to note that poor communication was often described as an individual's lack of communication and the guideline or policy issues were frequently that an individual had not followed a guideline, with no mention of why there was non-compliance, rather than issues with the guidelines themselves.

Looking at the root causes within the reports, it appeared that the question of why the incident happened, or was allowed to happen, is often missing. It is frequently replaced by a description of the incident and a focus on what happened. Table 5 lists some of the root causes taken directly from the SI reports.

Table 5: The root cause(s) as written in the SI reports

Root Causes taken from SI reports
Hypoxic Ischaemic Encephalopathy following a breech delivery
Poor management of a pathological cardiotocograph (CTG)
Failure to make an obstetric emergency call
A premature baby with… a pathological CTG was born in poor condition
Delay in taking cord gasses
Undiagnosed breech with a subsequent vaginal birth
Delay in delivery following an attempted ventouse
The scan was incorrect and the care proceeded as if twin 1 was cephalic
Failure to follow trust guidelines and not start a CTG in a woman with high BP
Concealed placental abruption
Failing to request an obstetric review following transfer from the birth centre.
Deviation from pathway for fetal assessment
Shoulder dystocia due to fetal macrosomia
Deficiency in CTG interpretation

Of the 50 reports three could not identify a single root cause with one report going as far as stating that "this case is an example of excellent multi-disciplinary team working, well-documented management plans and timely reviews", something that was not agreed on by the expert witnesses reviewing the claim.

Table 5 gives a good description of what happened but fails to identify why.

Why was the pathological CTG managed incorrectly? What went wrong with the undiagnosed breech and why did that result in CP? Why was the scan incorrect? Was it inadequate training, a faulty machine, that the operator was distracted? Why did a woman with a concealed abruption have a baby born with CP, remembering that these 50 claims are due to admitted clinical negligence, so what went wrong with her care?

Why was there a deviation from the fetal assessment pathway?

If the serious incident investigation focuses too heavily on individuals and does not identify why the errors occurred they are unable to uncover the system failures. Therefore, finding it impossible to identify any meaningful learning or how to improve the service to avoid the errors recurring.

Evidence from elsewhere

The Kirkup report identified significant systematic and organisational failures which the Morecambe Bay hospitals own SI investigations and RCA process missed, as they were "rudimentary, over protective of staff and failed to identify underlying problems" (66). It is important not to forget the warning from Bill Kirkup that "it is vital the lessons… are learnt and acted upon, not least by other trusts, which must not believe that it couldn't happen here" (66).

The RCOG EBC project identified that 25% of local reviews did not contain sufficient information to allow the care to be classified. Of those reviews that were of sufficient quality, just over 60% of investigations used a RCA methodology, while 21% contained no actions or recommendations and 23% recommended actions focusing solely on individuals (78).

The CQC report demonstrated a worse picture within acute trusts. Only 8% of reports demonstrated evidence that a clearly structured methodology was used, which would identify the key issues, contributing factors, system issues and causal factors that led to the incident (9). Staff were only interviewed in 39%, despite the National Patient Safety Agency (NPSA) recommending it since 2008 (79, 80) and 75% of reports focused on staff acts or omissions and "too many… concluded that the actions of staff were the key causes of the incident (9).

There is widespread evidence that the quality of SI investigations is poor, especially regarding the correct use of RCA methodology. This may relate to a lack of, or inadequate, training, especially in human factors (9).

NHS providers have a duty to provide training for staff involved in SI investigations in RCA methodology but there is a lack of a national standardised training package or methods of assessing RCA quality.

Views of patients and families

The message NHS Resolution has frequently received from claimants, is that they often feel the SI report does not provide the answers they were hoping for. This can result in frustration and some turn to litigation as a last resort, to get the answers they want (15).

"It feels like the priority of the serious incident process is damage limitation rather than learning from mistakes. What makes this even worse is the lack of learning both by the trust and the wider NHS from what happened. The problem with the quality of the report… is that its purpose was not to blame individuals and was to find a root cause [but] it stopped at individual mistakes and not once did it ask why people made these mistakes".

"The frustration from our case is that if a proper root cause had been found, such as training not being given or procedures not being known then it would not just stop similar cases to ours but could reduce serious incidents across the trust".

Parent of child with CP

The problem of effectively implementing RCA methodology

RCA was taken from safety cautious industries such as aviation and nuclear power but has been poorly applied in the healthcare setting (81). If performed correctly, it has a potential value in healthcare but it is not without criticism (82, 83). The evidence suggests that investigators can focus on an "unhealthy quest for the root cause" (83) which may be because the terminology, root cause, implies a single cause, whereas what went wrong is often more complex and multifactorial (82).

There are also concerns that a RCA could be subject to "political hijack" (83) as there is a lack of independence from the organisation where the incident occurred, that timelines create a narrative without taking a wider systems view and that there is a tendency in healthcare to settle for "administrative solutions, such as reminders" (83) rather than address the wider factors.

There is also a concern that investigations are often performed in isolation within individual organisations which can limit the dissemination of learning (83).

To ensure that a wider systems view is taken, when conducting a RCA, the NPSA recommended using the contributory factors classification framework (84) This is based on the three-part systems analysis model (82) which looks at all the people involved from management to those working on the front line;

1) Care delivery problems eg. failures to act or incorrect decisions
2) Clinical context
3) Contributory factors (see table 6)

Table 6: Framework of contributory factors influencing clinical practice, taken from the London Protocol (82)

Factor types	Contributory influencing factor
Patient factors	Condition (complexity and seriousness) Language and communication Personality and social factors
Task and technology factors	Task design and clarity of structure Availability and use of protocols Availability and accuracy of test results Decision-making aids
Individual (staff) factors	Knowledge and skills Competence Physical and mental health
Team factors	Verbal communication Written communication Supervision and seeking help Team structure (congruence, consistency, leadership, etc)
Work environmental factors	Staffing levels and skills mix Workload and shift patterns Design, availability and maintenance of equipment Administrative and managerial support Environment Physical
Organisational and management factors	Financial resources & constraints Organisational structure Policy, standards and goals Safety culture and priorities
Institutional context factors	Economic and regulatory context National health service executive Links with external organisations

Example of a good RCA

An example demonstrated in table 7, taken from one of the 50 claims, demonstrates how the contributory factors described in table 6 can be applied in practice.

The details have been adapted to ensure it remains anonymous.

Table 7: Good quality RCA demonstrating contributory factors

Factor types	Contributory influencing factor
Patient factors	Distressed in early labour and wanted partner to stay which altered the midwife's thinking as to where she could be cared for best.
Individual staff factors	Midwife had previous experience caring for women >4cm dilated on the antenatal ward, which then became routine practice. There did not seem to be a rush to escalate for earlier transfer due to this ingrained culture.
Task factors	Patient was settled once she realised she was allowed to labour without transfer which made the task of caring for her easier. This became a positive reinforcement to not transfer her to labour ward.
Communication factors	Midwife should have discussed in more detail the potential risks of this deviation from policy and acknowledge that it is outside of the guidelines.
Team and social factors	Prior experience that transfers to labour ward was difficult until contracting strongly 4:10 even at 4cm dilated. This therefore became normal practice and was not challenged.
Equipment and resources	Induction of labour suite was filled with postnatal women and babies and midwifery staffing was less than minimum standard.
Organisation and strategic	Obstetric and midwifery staff who worked limited shifts were not keeping up-to-date with service changes and protocols. There was a lack of clinical governance surrounding part time workers.

This example demonstrates part of the SI investigation report but does seem to be an open and honest account of what happened, while also identifying why the error occurred. It mentions individual staff without blame, but recognises that the system allowed the error to occur.

External reviews

Only 4% of the claims had an external review. The SI framework does not mandate that an external reviewer is required however it does state that:

> ***"those involved in the investigation process must not be involved in the direct care of those patients affected nor should they work directly with those involved in the delivery of that care. Those working within the same team may have a shared perception of appropriate/safe care that is influenced by the culture and environment in which they work. As a result, they may fail to challenge the 'status quo' which is critical for identifying system weaknesses and opportunities for learning" (38)***

Excluding level 3 independent external investigations (38), the definition of an external reviewer is not always clear. It could define someone who doesn't work directly with the staff involved in the incident, someone from another department or another hospital or an independent investigator performing a peer review.

In this review, external reviewer is used to define someone involved in the investigation who is outside of the hospitals maternity or usual risk management team, for example an obstetrician or midwife from another hospital. Peer review is used to define an independent external investigator who could provide expert advice on the investigation process.

Having an external reviewer join the RCA process could benefit both organisations involved. The trust performing the RCA gets a second viewpoint on their incident and it could facilitate sharing of lessons and knowledge between the two trusts involved. The external reviewer brings with them knowledge of how it is done in their trust but also takes away learning to be shared with their organisation.

An example of this system is within the Cheshire and Merseyside maternity, children and young people strategic clinical network (85, 86). They have devised a system whereby all babies that meet the RCOG EBC criteria will have an external review.

The two external reviewers, one midwife and one obstetrician, are centrally coordinated by the strategic and clinical network (SCN) from the 15 regional panels, incorporating six NHS trusts and one stand-alone midwifery unit. They plan to collate themes within the region and share the learning to develop regional guidelines and reduce variation in practice.

Although it is too early to demonstrate an improvement in clinical outcomes they have recently analysed the experience of the external reviewers and found that;

> ***"…it adds value to the individual participants; their organisation and the wider network in terms of reducing bias, encouraging transparency, providing external challenge and viewpoint. The learning from these panels is being collated by the SCN special interest group in order to encourage network wide learning" (87)***

An alternative would be to have a peer review by an individual or group of individuals that would bring expert analytical and investigative skills, however this would require additional funding from trusts. There is evidence that a group peer review process using a structured methodology, such as that used in confidential enquiries, can be beneficial (88). They produce a significantly higher chance of identifying areas of good practice, suggest a higher number of alternative clinical approaches, identify more improvements that might have made a difference to the outcome and produce wider actions for quality improvement throughout the whole care pathway (88).

The total cost per case for this style of independent review was £2100 (88). If this translates to improved clinical outcomes and reduced litigation costs then this cost may be worthwhile. However, until this is demonstrated the cost is likely to be prohibitive and it is "therefore important to focus on optimising the local review process" (88). The improvements seen with peer review could be due to the structured and standardised way the reviews were carried out and that all the assessors receive the same training. If this is the case then "improvements in local reviews may be achieved by local assessors undertaking similar training" (88).

The RCOG EBC project found that in 2015 only 9% of their reports involved external assistance (65). One of the key recommendations from the EBC project is that "all local reviews must have the involvement of an external panel member" (65).

There is early evidence that having some form of external or peer review is positive, however it is not yet clear which method is most beneficial.

Theme 3:

Recommendations which are unlikely to prevent recurrence due to a lack of focus on systemic changes

Identifying areas for change

The fundamental purpose of conducting a SI investigation is to learn from the incident (38). Possibly, the most important part of this process is the creation of an action plan that does not focus on simply completing tasks but identifies improvements that will prevent the same situation occurring again (38).

The evidence strongly supports that improving systems, rather than focusing on individuals is the key to patient safety (89).

This review analysed the action plans and recommendations from all 50 SI investigations to identify if there were any trends that could be shared more widely.

Most reports identified multiple recommendations ranging from a change in staffing levels to ensuring consultants were present for high risk births, however as demonstrated in table 8, a recurring theme was recommending or reminding staff to follow current guidelines and policies.

Table 8: Evidence of recommendations that focus on continuing with the current situation

Evidence of recommendations that focus on continuing with the current situation
Staff should be expected to escalate as per current policy
National neonatal guidelines should be adhered to
Staff to reflect on RCOG and local guidelines and follow them
Staff to adhere to trusts escalation policy
The recognition of severely ill pregnant woman guidelines must be followed
To follow current CTG and fetal monitoring guidelines
Staff reminded about level of documentation required
Staff to do abdominal palpation prior to VE as per guidelines
All staff to strictly adhere to handover of care guidelines
Ensure all MWs aware of water birth guidelines
Staff to follow RCOG guidelines, unless good reason not to

It appears that the individuals involved were expected to follow guidelines that were in place the next time a similar incident occurred, without identifying why they were not followed in this instance. Identifying an issue with the guidelines that could be changed may result in better care for someone else.

For example, updating an out-of-date guideline, identifying and changing variation between two hospitals that share a similar guideline or making protocols easily accessible in an emergency may improve future patient care. Simply reminding people to follow current guidelines is unlikely to prevent someone else making the same mistake again.

Although this was a common theme it was not prevalent in all reports and there was evidence of good practice. Problems with staffing were identified and corrected, new orientation programmes that cover specific topics were introduced and induction processes revamped to ensure all emergencies were covered.

Evidence from elsewhere

The findings of this review are very similar to those identified within the RCOG EBC programme, that only 56% of the investigations they analysed had actions or recommendations that took a systemic approach, 23% focused solely on individuals, often to attend training, and 21% contained no actions or recommendations (78).

The CQC report on SI investigations also highlighted the same problem. They found that "too many reports concluded that the actions of staff were the key causes of the incident" (9) and many investigations focused their recommendations on staff failing to "follow trust policy and procedures" (9). Only 35% of investigations had recommendations that could reduce the risk of recurrence and many focused on reminding staff be more vigilant or to follow guidelines (9).

The wider picture of incident reporting

Three key reports provide a wider picture of incident reporting in England; The Parliamentary and Health Service Ombudsman's (PHSO) 2015 Review into the quality of NHS investigations (13) and 2016 report Learning from mistakes (12), and the 2017 response to those reports from the House of Commons Public Administration and Constitutional Affairs Committee's (PACAC), Will the NHS never learn? (90)

The 2015 PHSO report identified that the quality of investigations was "not consistent, reliable or good enough" (13) with 40% inadequate to identify why the errors occurred. It also demonstrated that in 73% of cases where the reviewers identified failings, the trust failed to do so.

The report identified that investigating staff do not feel adequately supported and do not have adequate protected time to perform the investigation. It also highlighted concerns that there is no national guidance on the level of training required for an investigator or how independent quality can be assured. The report recommended that a national accredited training programme needs to be developed.

The 2016 report highlighted two areas of improvement that align with the findings in this review; firstly, that there is "a lack of competence and sufficient independence" (12) in NHS investigations and secondly, that families and staff are "insufficiently involved" (12). The report also restated that "training and accrediting sufficient investigators to operate locally is crucial to the long-term improvement of local investigations" (12).

The PACAC 2017 report (90) received evidence from multiple sources on all aspects of patient safety investigations which reiterated the need to involve the family and that better training in investigations is required. Healthwatch England were quoted as stating that "families and patients find the investigative process difficult to navigate and feel excluded from investigations, [that] their valuable input is not effectively engaged and that they need "support to ensure their voices were heard" (90) and therefore recommended that "families and patients should, as a matter of course, be included in investigations" (90). The report also recommended that "training should be provided to staff across the health service in England on how to conduct investigations" (90).

The Perinatal Mortality Reporting Tool (PMRT) programme

The PMRT programme is a collaboration led by MBBRACE-UK which has designed a tool, in conjunction with women and service users, which will standardise and improve the quality of perinatal mortality investigations across England, Scotland and Wales (91). This will launch as a free-to-use tool in 2017. The tool will assist investigators perform high quality, systematic, multidisciplinary reviews of all stillbirths and neonatal deaths up to 28 days. It will also support communication with, and contribution by, parents and provide a structured process for learning and creating actions to improve future care. It will also produce national thematic reports enabling lessons learnt to be shared.

Alongside the introduction of the tool will be training materials aimed at supporting those carrying out the investigations to ensure they are conducted to a high quality (91). From what has been made public, this tool will capture babies that are born with brain injury but die within 28 days but it is unclear whether the tool or the methodology will be extrapolated to babies born with brain injury that do not die. It is likely that those individuals within a trust using this tool, will also be responsible for investigating all maternity serious incidents, including those where children develop CP. It is therefore likely that any improvement in the investigation process that occurs from using the PMRT and the greater involvement of parents will translate into wider improvements in the SI investigation process within maternity.

The role of commissioners

All SIs are reported to commissioners who are "accountable for quality assuring the robustness of their providers' serious incident investigations and the development and implementation of effective actions, by the provider, to prevent recurrence of similar incidents" (38). It is also the commissioners who 'close' the incident when they "are satisfied that the investigation report and action plan meets the required standard" (38). It is therefore worrying that all the SIs in this review have been quality assessed and closed by the relevant commissioners. Moving forward, commissioners must ensure the process of regulation and quality assurance meets the required standard. National support to help commissioners achieve this will be needed.

Recommendations for part 1

The evidence provided in part 1 of this review demonstrates three recurring themes that require a collective and systematic approach to address them. Multiple reports have provided recommendations but there is little evidence of any significant improvement.

Therefore, this review not only makes recommendations but outlines what is needed, both nationally and/or locally, for the recommendations to be implemented.

1

Women and their families offer invaluable insight into the care they received. To ensure this is included in all SI investigations, commissioners should take responsibility by ensuring SIs are not 'closed' unless the woman and her family have been actively involved* throughout the investigation process.

*As a minimum, active involvement is defined as ensuring that the woman and her family have been;

- Given a sincere, individualised and heartfelt apology for the harm that has occurred
- Made aware an investigation will take place
- Given the opportunity and encouraged, to inform the terms of reference at the beginning
- Empowered to contribute to the investigation process by providing an account of events, if they wish to do so
- Given the draft report and allowed to comment, ensuring it is written in language they can understand
- Given the final report and given an opportunity to discuss the report findings.

Active involvement should not be seen as simply asking women to be involved but a process of engaging with women and their families, acknowledging that this is vital to the investigation process.

How should this be achieved?

National level

The new serious incident framework, which is due to be published in 2018, is expected to reinforce the importance of patient and family support. Compliance with this guideline will be supported by incorporating these expectations into the Care Quality Commissions' new inspection regime.

NHS Improvement are developing a new national standard investigation quality assessment tool that will be used by those trained and experienced in conducting good quality investigations to assess the quality of investigation reports. This tool will have parental involvement as a key assessment criteria. NHS Improvement will use this tool to collect data on compliance, which could then be used to facilitate improvements.

Effective implementation of the statutory duty of candour is an important part of actively involving women. NHS Resolution provides support for staff to say sorry after an incident, which can be found at http://resolution.nhs.uk/saying-sorry-leaflet/ and the early notification scheme provides;

- Support, advice and practical help in delivering the duty of candour at an early stage
- Point of incident mediation when the relationship between the trust and family is at risk of breaking down

Local level

As outlined in NHS England's resource pack for local maternity systems – Implementing Better Births (92), local maternity systems are expected to produce a local maternity transformation plan by October 2017. This should include ensuring that services are "investigating and learning from incidents and sharing this learning through their LMS and with others". As part of this, local maternity systems are recommended to identify a lead commissioner for maternity safety who will be responsible for holding providers to account for improving quality.

The oversight of SIs will therefore remain with commissioners, however improving the quality of investigations requires a local implementation of national recommendations. Therefore, the lead for each local maternity system, supported by their STP strategic partnership boards, should take responsibility for improving the investigation process ensuring that:

- Women and their families are actively involved* in all SI investigations
- They set up and engage with their local maternity voices partnerships (LMVP) to co-design how the national recommendations can be included effectively into their local SI process
- Use the perinatal mortality review tool when released

Time frame for implementation

Commissioners should implement this recommendation with immediate effect.

Local maternity systems should ensure this recommendation is included within their transformation plans by October 2017.

2

The quality of SI investigations has repeatedly been found to be poor with very little or no training for investigators across the NHS. A working party, involving, and possibly led by the Healthcare Safety Investigation Branch (HSIB) should discuss creating a national standardised and accredited training programme for all staff conducting SI investigations. This should focus on improving competency of investigators and reduce variation in how investigations are conducted.

How should this be achieved?

National level

Multiple parties are currently working on improving the quality of incident investigations. These include;

- HSIB, who aim to "raise the standard of local investigations of healthcare safety incidents by establishing common standards and skills development" (93)
- MBRRACE-UK who will release training materials alongside the PMRT to help support high quality reviews. This will provide a greater understanding about the care and treatment provided and help identify cases which need to be fully investigated (91)
- NHS Improvement whose national standard investigation quality assessment tool, will be used by those trained and experienced in conducting good quality investigations to monitor and improve the quality of investigation reports
- The Maternity and Neonatal Health Safety Collaborative, which was launched on 28 February 2017, working with all NHS trusts over the next three years to build local quality improvement capability with the ultimate goal of improving clinical practice and reducing unwarranted variation (94). As part of this programme, they will support clinical leaders to create an effective learning system and safety culture within their trust
- NHS Resolution, via the ENS clinical advisors and in collaboration with those responsible for oversight of the SI process, will review the quality of SI investigation reports received for potential brain injury (making use of the national standard investigation quality assessment tool once available) and work with local trusts to improve the quality. NHS Resolution will liaise with NHS Improvement to deliver the support required for improvement

These organisations should come together alongside NHS England and Health Education England (HEE) to explore the creation of a mandatory, standardised national training package or alternative options, to address the clear gap in investigation capability and capacity.

Acknowledging that guidelines already exist, in the form of the SI (38) and Being Open (68) frameworks, this working group should consider whether training in the following areas of weakness is required:

- How those conducting investigations engage with women and families after an incident
- Cognitive interviewing skills
- Investigative methodology, including RCA methodology
- Human factors analysis
- How to write reports that are in the first instance for women and their families
- How to produce effective recommendations

Time frame for implementation

A working party should be set up immediately to discuss how a national training package could be implemented. However, creation and implementation would be slower with completion by 2020/21.

3

In line with the Kirkup and RCOG Each Baby Counts reports, all cases of potential severe brain injury, intrapartum stillbirth and early neonatal death should be subject to an external or independent peer review. However, the most appropriate model requires further national clarification.

How should this be achieved?

National level

Implementation of this recommendation will be at a local level by local maternity systems, however this will require national guidance and support. The results of national discussions are currently awaited before the most appropriate model for investigations can be clarified.

Firstly, a task and finish group was set up by the Department of Health to identify any gaps or areas for improvement within maternity and neonatal services to ensure serious incidents are investigated, lessons are learnt and shared, service quality improved and service users are satisfied quickly and consistently across England. This group, which included representatives from NHS Improvement, NHS Resolution, NHS England, the Care Quality Commission and the national maternity safety champions, discussed the feasibility of both approaches, amongst other potential models and fed back to the maternity transformation programme board (MTPB) on 1 August. The MTPB will consider these findings and if appropriate, incorporate them into their plan for implementing the recommendation set out in Better Births - that when things go wrong, LMS ensure there is a rapid, consistent and high-quality investigation and swift learning occurs across the LMS and beyond (15).

Secondly, the results of the consultation for the proposed rapid resolution and redress scheme (RRR) (95), set out in Better Births (15), should be available in 2017. If RRR was implemented, it may introduce a system of independent investigations for all instances where there may have been severe avoidable birth injury. This could potentially mean external reviews are not required.

Local level

It is envisioned that local maternity systems will be responsible for implementing this recommendation; however, it seems prudent to recommend a specific model for external or independent peer review until the results of national discussions are made clear.

Time frame for implementation

Local maternity systems should implement the recommendation by 2020/21.

4

Adverse events within maternity can have serious negative effects on staff, who are often provided with inadequate support. Trusts' obstetric and midwifery leads, with support from their board level maternity champion, must ensure that improving emotional support for staff throughout an investigation, irrespective of whether it becomes a compensation claim, is a priority.

How should this be achieved?

National level

Support packages and strategies to prevent post-traumatic stress disorder (PTSD) after staff are involved in an adverse event are currently being investigated in two studies, led by Professor Pauline Slade, at the University of Liverpool. These should provide an evidence base for how future support services could be set up.

- The programme for the prevention of PTSD in midwifery (POPPY project) is a feasibility study investigating a stepwise approach which includes; an educational package for midwives which aims to reduce the risk of PTSD developing, a confidential peer support system provided by trained midwives and referral to a clinical psychologist if required. The results are expected in October 2017
- The INDIGO study (96), in collaboration with RCOG, aims to better understand the experience of obstetricians and gyanecologists who have been involved in traumatic work-related events and subsequently, identify what support is needed and how best to provide it. Results are expected in July 2018

NHS Resolution will provide a national, self-referral, peer support network for affected individuals via the Early Notification Scheme.

NHS Improvement, via the maternity and neonatal health safety collaborative will support the development of a safety culture within trusts, ensuring that working environments for all staff are safe.

Local level

Although there are national initiatives in progress and local maternity systems will have a role to play, the main responsibility for ensuring staff are supported lies with trusts. The trusts' obstetric and midwifery leads, with support from the board level maternity champion, should ensure all staff are provided with emotional support, the departmental culture supports staff after an adverse event and accessing support services is easy and not stigmatised. The trust board must ensure adequate resources are allocated to support services.

The national maternity and neonatal health safety collaborative will provide a culture survey to all trusts within their allocated wave. This could be used, along with the local staff survey, to monitor, identify and improve how staff can be better supported.

Time frame for implementation

A national peer support network will be set up by September 2018.

All staff going through a SI investigation or litigation claim should be offered support immediately and improvements in culture should be demonstrable by six months.

Part 2: Clinical themes

Part 2 focuses on the clinical details identified from the antenatal, intrapartum and neonatal periods and focuses on the common themes that emerged from reviewing the 50 claims.

Antenatal

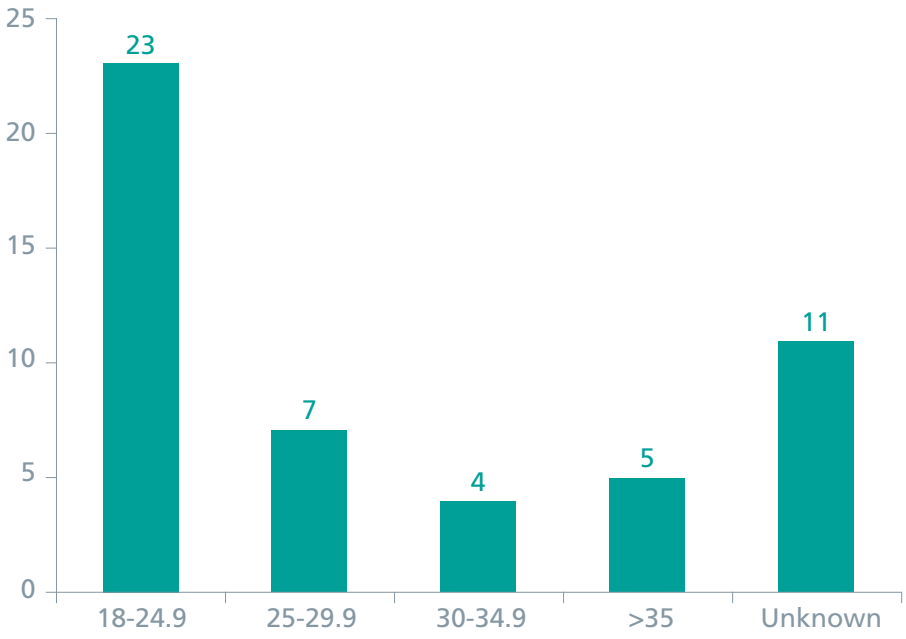
Risk factors at booking

The demographics are identified in table 9. No obvious themes were identified from these details. The majority (62%) were low risk at booking.

Table 9: Demographics at booking

	Total n=50
Maternal age (Median 31yrs, Range 18-47yrs)	
≥35yrs	11
≥40yrs	3
BMI (Median 24, Range 17-40)	
18-24.9	23
25-29.9	7
30-34.9	4
≥35	5
Unknown	11
Smoking status	
Non-smoker	40
Smoked at booking	5
Unknown	5
Risk at booking	
Low risk pregnancy	31
High risk pregnancy	19
Risk factors (not mutually exclusive)	
Diabetes	0
Hypertension	1
Hypothyroidism	3
Previous caesarean	6
Twin pregnancy	3
Late booker	2
Shoulder dystocia	1
Previous pre-eclampsia	2
Previous preterm delivery	1
Other (BMI, maternal age, depression, 3rd degree tear)	15

Figure 11: Distribution of BMI



Risk factors during antenatal period

Infections

None of the 50 women had an antenatal TORCH (toxoplasma, other –syphilis, varicella-zoster, parvovirus B19, rubella, cytomegalovirus and herpes) infection which is a known risk factor (97, 98).

One woman had a group B streptococcal infection but this was unrelated to the cause of CP in this claim.

Missed fetal abnormalities

There were no missed fetal abnormalities on ultrasound which could have resulted in, or increased the risk, of brain injury. Although this is a small cohort, this is a promising sign as previous reports have highlighted that missed fetal abnormalities during antenatal ultrasound scanning, although rare, were a high source of compensation (40).

Intrapartum

The basic intrapartum details are outlined in table 10, alongside national data for comparison.

Table 10: Intrapartum details

	Study cohort n=50	2012-2016 HES data (99) *
Gestation		
37-42 weeks	45 (90%)	91.8%
<37 weeks	4 (8%)	7.8%
Unknown	1	
Single or multiple pregnancy		
Singleton	47	
Multiple (Twins)	3	
Presentation at delivery		
Cephalic	44 (88%)	
Breech	6 (12%)	0.4%
Onset of labour		
Did not go into labour	2	
Spontaneous	31 (62%)	60.7%
Induction of labour (IOL)	16 (32%)	19.8%
Elective Caesarean	1 (2%)	13.6%
Place of delivery		
Labour ward	46 (92%)	84%
Birth centre attached to hospital	4 (8%)	15.6%
Type of delivery		
Spontaneous vaginal delivery	24 (48%)	60.3%
Instrumental (forceps or ventouse)	7 (14%)	12.9%
Failed instrumental then emergency caesarean	6 (12%)	
Emergency caesarean	12 (24%)	15.3%
Elective caesarean	1 (2%)	11.1%

*Available Hospital Episode Statistic (HES) data between 2012-2016 has been collated to cover the period of this review. HES data does not cover all fields and is reliant on accurate coding.

Neonatal

Neonatal resuscitation

Problems with neonatal resuscitation, demonstrated in table 14, were identified in nine of the 50 claims. The problems were wide ranging, did not occur in isolation and were often not the main focus of the compensation claim.

Although few in number, they demonstrate the importance of an effective multidisciplinary team, adequate training, effective communication and ensuring neonatal involvement in SI investigations.

Table 14: Problems with neonatal resuscitation

Problems with neonatal resuscitation	Number
Delay in neonate receiving care	3
Difficulty with intubation	3
Not escalating when help needed	2
Equipment problems	1

Neonatal medical conditions

Table 15 demonstrates the four claims that were due to neonatal medical conditions. Neonatal hypoglycaemia has been covered in a separate review article (100) and was uncommon in the cohort in this review. The most common complication was neonatal jaundice.

Table 15: Neonatal medical conditions

Neonatal medical conditions	Number
Jaundice	3
Hypoglycaemia	1
Neonatal meningitis/encephalitis	0
Neonatal stroke	0

Themes identified in clinical care

The 50 claims were clinically varied but by reviewing them all together to get a national picture it was possible to identify common themes:

1) **Errors with fetal heart rate monitoring**
2) **Breech birth**
3) **Inadequate quality assurances around staff competency and training**
4) **Patient autonomy and informed decision making**

Other important topics highlighted in a previous report (40), including the use of Syntocinon, vaginal birth after caesarean (VBAC) and shoulder dystocia are also commented on.

Theme 1:

Errors with fetal heart rate monitoring

There were 32 claims (64%) that involved errors in fetal heart rate monitoring. 91% of those, (29 claims) involved a cardiotocograph (CTG).

This is the most common theme and has been highlighted as an area for improvement in other reports (40, 65).

What were the errors?

Trying to classify what went wrong into single mutually exclusive categories is difficult as the errors are often multifactorial, however table 11 explains the common problems identified on reviewing the 29 claims.

Table 11: Errors using CTGs

Errors using CTGs	Number
CTG misinterpreted	11
CTG not started when should have been	8
False reassurance with an uninterpretable trace	5
Too slow to act once CTG identified as pathological	3
Monitoring maternal HR	2

In these 29 claims, 24 had a RCA performed, of which 18 focused on errors in CTG use as a root cause. The root causes were frequently described as a problem with individuals' due to a "deficiency in CTG interpretation" or that an individual had "not followed CTG guidelines". However, on reviewing these claims in more detail there appear to be other organisational, systemic and cultural factors that were not mentioned as a root cause. An example, was a SI investigation for a preterm pregnancy which identified the root cause as the midwife misinterpreting the CTG and not escalating for an obstetric review. On reviewing the timeline, combined with the expert statements, it was notable that there were multiple missed opportunities and the root cause does not lie solely with the individual midwife. The CTG was abnormal for 3.5 hours and during this time there were no 'fresh eyes' assessments, an hourly review of the CTG by another midwife, despite this being the hospital policy, the labour ward coordinator was in the room twice but did not review the CTG and there was no obstetric review despite this being a high-risk pregnancy. Why these potential fail safes did not work was not stated in the investigation. This is an excellent example of Reasons' Swiss cheese model of accident causation (77) but the report seemed to blame an individual.

The second most frequent error was in women who were high risk, or became high risk, where a CTG was not started when it should have been and therefore fetal heart rate abnormalities were missed. An example was a claim where a fetal tachycardia was noted on auscultation using a handheld doppler and did not settle after IV fluids, yet this was not escalated and a CTG was not started.

The third largest error was in claims where the CTG was uninterpretable but staff were falsely reassured that this was probably loss-of-contact and a wait-and-see approach was often taken. There is limited time to act if the fetal heart rate is low before irreversible hypoxia ensues and a wait-and-see approach will be harmful in these cases. Rapid escalation, assessment and decision making is important in cases of uninterpretable CTGs. It is important to quickly identify what the fetal heart rate pattern is before classifying the CTG as loss of contact. Possible methods of doing this are use of a fetal scalp electrode or portable ultrasound scanners.

This rapid approach also aligns with those claims where the CTG had been correctly identified as pathological, but the decision to delivery time was too long. An example was a fetal bradycardia that never improved but the time to delivery was 43 minutes. Why this delay occurred was not clear from the SI investigation report. Not only is rapid escalation, assessment and decision making important but so is the multidisciplinary teamwork required to ensure quick action is taken once a decision has been made.

Who made the errors?

As multiple claims focus on individuals, this review has classified who was implicated in making the error, which is displayed in table 12. Twenty four claims involved a midwife but only one involved a consultant.

Table 12: Who was implicated in CTG error

Who was implicated in CTG error	Number
Midwife	13
Midwife and registrar	8
Registrar	5
Midwife and SHO	2
Midwife and consultant	1

Evidence from elsewhere

The evidence suggests that very little, if anything, has changed over the last 20-25 years (101, 102). A 1991 review of 110 cerebral palsy compensation claims identified that 70% were related to CTG abnormalities and CTG interpretation (101), while a 2004 review of medicolegal aspects with cardiotocography identified identical themes to this review; recording of maternal pulse, poor quality erratic tracing, misinterpretation, inaction with suspicious or abnormal CTGs and failure to incorporate the clinical picture (102).

There was no evidence from the literature comparing CTG interpretation between midwives and consultants, however CTG interpretation has large inter and intra observer variation (103, 104), even between experts (105) and therefore the difference observed in this review is unlikely to be because consultants are better than midwives at CTG interpretation. A possible explanation is that the individual midwife caring from the woman performs the majority of the CTG assessments and therefore has more chances for error.

The RCOG EBC report, published in 2017, identified fetal monitoring as the most common theme (65). It was a contributing factor in 74% of adequately reviewed preventable cases (65).

Evidence for improvement

The most recent Cochrane review demonstrates that, compared to intermittent auscultation, continuous fetal monitoring using a CTG, is associated with a 50% reduction in neonatal seizures (RR 0.50 95% CI 0.31-0.80) (106). However, it does not reduce the risk of developing CP and is not associated with any other benefits in fetal wellbeing (106). These findings were consistent in high and low risk pregnancies and in preterm births (106). Access to fetal blood sampling as an adjunct, did not influence rates of neonatal seizures or other measures. Despite these findings, continuous fetal monitoring using a CTG is recommended as best practice in high risk women (107), or low risk women who subsequently develop risk factors (108).

A systematic review evaluating the impact of CTG training, identified an improvement in CTG interpretation, increased CTG knowledge, higher inter-observer agreement and better intrapartum management (109) but not an improvement in neonatal outcomes. Making CTG training compulsory can reduce suboptimal care (110) and improve safety attitudes (111) but there is no evidence it reduces the rate of CP.

There is evidence that, rather than focusing on CTG interpretation alone, a wider strategy is required. The implementation of a comprehensive patient safety strategy that included compulsory certification of CTG interpretation, team training based on crew resource management principles, anonymous event reporting and nine interventions significantly reduced an adverse outcome index (10 adverse fetal and maternal outcomes) which included five minute APGARs <7, intrapartum or neonatal death, traumatic fetal injury and unexpected admission to NICU (112). However, this strategy did not improve any individual fetal outcomes.

Due to the lack of evidence for CTG training, especially in isolation, alternative methods have been attempted to improve the earlier recognition of an unwell baby. This includes the use of ST Segment Analysis (STAN) as an adjunct to improve the detection of fetal acideamia. However, a Cochrane review found no statistically significant difference in severe fetal acidosis, pH <7.05 and base deficit >12mmol/L, (RR 0.78, 95% CI 0.44-1.37), low APGAR scores at 5 minutes (RR 0.42, 95% CI 0.11-1.62) or rates of neonatal encephalopathy (RR 0.54, 95% CI 0.24-1.25) (113). Another alternative method studied was the use of a computerised CTG decision support tool (INFANT), which was designed to improve the recognition of abnormal CTGs and thereby improve outcomes. The INFANT study found no difference in the incidence of poor neonatal outcomes between those randomised to receive the decision-support tool or not (114).

Although many reports and the local SI investigations, often focus on CTG misinterpretation as a root cause, it is evident that the issues are more widespread and therefore harder to measure and change. The errors often include inadequate or inappropriate risk stratification, a lack of situational awareness, delays in decision making and escalation and performing CTG interpretation in isolation while ignoring maternal and fetal risk factors (65). It is important that attempts to reduce fetal harm do not focus solely on errors with fetal heart rate monitoring but take a holistic approach.

As there is a lack of evidence based interventions to reduce CP due to CTG errors (115) an alternative improvement strategy is to use a human factors approach, which focuses on maternal and fetal wellbeing when interpreting a CTG. An example of this new approach is at the University Hospitals of Leicester NHS Trust, who used the financial incentive provided as part of the Sign up to Safety campaign (116) to produce a short set of videos and accompanying training resources based on their experience of compensation claims. The resources focus on three key steps to provide better care; time, escalation and decision making (TED). This free resource, which will be formally evaluated, is designed to be used as a communications and safety culture training too and can be accessed at http://voiceinside.co.uk.

Theme 2:
Breech birth

In this review 12% of the deliveries were breech and therefore over represented compared to the national average. At term only 3-4% of pregnancies are breech (117) and a proportion of these will have an external cephalic version and therefore be cephalic at delivery. The national vaginal breech birth rate based on HES data in 2013/14 was 0.4% (103). This figure may be slightly inaccurate and could be as high as 2.7%, as 1.9% of deliveries were "unknown" and 0.4% were classified as "spontaneous other" (118).

In the six claims that were related to breech presentation, four were at term and two at 34 weeks. All six were born out of hours. Five were an undiagnosed breech in labour, either transferred to delivery suite or identified at full dilatation. Five were delivered by a registrar without a consultant present. All six had an attempted vaginal delivery with three ending up as an emergency caesarean.

The RCOG guidelines during the period covered in this review made no recommendations specifically for a breech presentation diagnosed in labour, except that a vaginal delivery is not always contraindicated (117). In the five claims that were diagnosed late in labour, there was less time to have a detailed discussion with the woman regarding the risks and benefits of mode of delivery, compared to an antenatal diagnosis. They also did not have continuous fetal monitoring throughout the whole of labour as recommended (117). The evidence is unclear as to whether vaginal breech diagnosed in labour has a higher neonatal morbidity (119) or not (120) but there is evidence of lower five minute APGAR scores for those diagnosed in labour compared to antenatally (119). Nevertheless, since these articles were published the rate of vaginal breech birth and therefore familiarity with techniques required for safe delivery has dropped (121).

Evidence from elsewhere

The publication of the term breech trial in 2000 demonstrated improved neonatal outcomes for term babies born by elective caesarean compared to vaginal delivery (122). Even before its publication there was an increasing trend towards elective caesarean for breech presentation, especially for primigravidae women (123) and by 2001 88% of breech presentations were delivered by caesarean (124). Despite the reducing vaginal breech birth rate, a higher proportion are managed by trainees (117). Therefore, trainees who have had less exposure are performing more deliveries. There is evidence that having an experienced practitioner at delivery is a vital component for safe delivery (123) and vice versa (122) and the 7th annual report of the confidential enquiries into stillbirth and deaths in infancy demonstrated that consultants were only informed in 50% of the cases and in 75% of the cases there was a delayed response to fetal compromise (125).

The new RCOG guidelines released in March 2017 make more specific recommendations for women with an unplanned breech in labour, which takes on board more recent evidence (126, 127) and acknowledge that "a lack of experience has led to a loss of skills essential for [breech] deliveries" (121) for all obstetricians. The key messages involve individualisation of mode of delivery based upon stage of labour, whether there are any additional risk factors, such as an extended fetal neck, and availability of skilled supervision. The guidelines also recommend that all units create a protocol for women presenting in advanced labour with an undiagnosed breech. There is a large emphasis on the need for a skilled birth attendant being vital for a safe vaginal breech birth and it is clear that "clinicians should counsel women in an unbiased way to ensure a proper understanding of the absolute and relative risks" (121) regarding mode of delivery.

This review highlights that unplanned breech deliveries are over represented in high value claims for cerebral palsy and that delivery was often by a registrar, out of hours, without a consultant present. This review cannot comment on the skills of those individuals but it is likely that current obstetric trainees have less experience of vaginal breech birth than in the past.

Evidence for improvement

There is evidence that simulation training improves the performance of breech birth (128) and that training in obstetric emergencies, including breech birth, are effective in reducing poor neonatal outcomes (129). The RCOG now recommend that "simulation equipment should be used to rehearse the skills that are needed during vaginal breech birth by all doctors and midwives" (121).

Setting up local multidisciplinary obstetric emergency training is expensive, estimated to be 148,806 Euros in one UK unit (130), however the cost of a child born with CP due to medical error can be greater than £20 million. The benefits of evidence based training are widespread. In one UK unit there was a 91% reduction in obstetric compensation costs (131) and evidence from both America (132, 133) and the Victorian Managed Insurance Authority in Australia (134), that the introduction of PROMPT (PRactical Obstetric Multi-Professional Training) has reduced incidents and compensation costs. Its introduction in parts of the USA over a 7-year period demonstrated significant improvements in rates of fetal acidosis and brachial plexus injuries and a decrease in rates of HIE (135) with the cost of training less than the estimated cost of avoidable health care costs (135).

Theme 3:

Inadequate quality assurances around staff competency and training

In 29 of the 50 claims (58%) the SI investigation recommended that the staff involved needed extra training. Within the investigation reports there was a large focus on individual competence and error and a lack of focus on system faults and organisational error. Part 1 of this review describes this focus on individuals rather than systems and explains why this should change. Despite this, each SI investigation was analysed in depth and it was identified that the training that was frequently recommended was not a new training need, but one that was in place prior to the incident. An example was a neonatal registrar who had not completed their resuscitation training and this was said to have resulted in the error. This was training that was mandatory but the registrar was allowed to work despite not having undertaken the training and therefore potentially not competent.

Further examples of this were, two cases of registrars who performed breech deliveries where the SI investigation stated they had no training in this procedure, a qualified midwife who had never seen a case of second stage delay before but was working independently and multiple examples of staff either not up-to-date or who had not completed their CTG training. From analysing the SI investigation reports it is not possible to comment on the individual training packages suggested and their evidence base. Nevertheless, this review highlights a recurring theme whereby staff are allowed to work despite not being trained to the standard their employing organisation deemed necessary.

Remembering that these recommendations were taken from the trusts own SI investigation reports, it is important not to blame individuals but to consider how best to learn from this and improve. Clinicians have a duty to "be competent in all aspects of [their] work… keep professional knowledge and skills up-to-date… and regularly take part in activities that maintain and develop [their] competence"(136). Nevertheless, it is the trusts who are members of the CNST scheme and face rising costs to the litigation bill and they need to urgently review whether the training provided in their trust allows staff to reach and maintain their competence. There are also recommendations made to HEE by the Commission on Education and Training for Patient Safety that "major changes are needed in multi-specialty and team working, greater emphasis on human factors is required, simulation should become commonplace in all sorts of scenarios and a much more transparent and open reporting system needs to be established where we move from a blame culture to a learning one" (137).

High quality, effective, multi-professional training will have an additional short-term financial burden on an NHS that is already under financial pressure, with around 90% of the costs potentially required to release staff to attend training (130). However, this review demonstrates that the long-term financial implications of inadequate staff training are significant. For example, in one of the claims a community midwife who specialised in low risk births and who had not had any CTG training, was seconded to work on labour ward due to staff shortages. The midwife was required to look after a high-risk woman who required continuous CTG monitoring and the error that led to the woman's child developing CP was said to be due to deficiencies in CTG interpretation by the midwife. The subsequent compensation claim, which could cost the trust in excess of £20 million, will be significantly higher than the costs of ensuring all staff had adequate training.

Evidence from elsewhere

This raises multiple questions around staff training. Is it evidence based, does it make the service safer, who should attend and how often, what importance does the organisation place on training and if training is required, then why can staff work without having completed their training? There is evidence that local, multi-professional training of obstetric emergencies that incorporates clinical skills with human factors and teamwork, improves neonatal outcomes (129) and reduces litigation (131), if it is mandatory and 100% of staff attend.

A recent presentation from the Victorian Managed Insurance Authority in Australia demonstrated that making this type of training mandatory for all units is hugely cost effective (134) and evidence from America that it reduces incidents of harm and compensation costs (132, 133, 135).

The national maternity review is clear, that improved multi-professional training would break down the barriers between midwives, obstetricians and other professionals to deliver safe care. It recommends that those "who work together should train together" (15) and that multi-professional learning should be a core part of training for midwives and obstetricians at all stages of their career.

Despite the same message in Safe Births, the 2008 Kings Fund report into maternity safety; that "those who work together should train together" (2), mandatory training is hugely variable across NHS trusts (138). Training should be done together, using simulation of emergencies, ideally on the labour ward and the training should not involve clinical skills in isolation but embedded with teamwork, leadership and communication skills (2). The main barriers to implementation were identified as difficulty in securing money for training and arranging time off clinical duties for staff to attend (2).

Theme 4:

Patient autonomy and informed decision making

The fourth theme revolves around the importance of patient autonomy and informed decision making and when this process is inadequate, how it can result in successful litigation. Informed consent and the dialogue involved is a patient safety issue.

Evidence of a lack of informed consent was evident throughout the 50 claims reviewed. An example was a woman who opted to have a vaginal birth after caesarean section (VBAC) but her initial caesarean was complicated by a difficult delivery that involved making a J-shaped incision on the uterus. This is not an absolute contraindication to VBAC but there is "insufficient evidence to support the safety for VBAC in women with previous T or J incisions" (139) and there should have been a documented discussion by a consultant which made an individualised assessment around the suitability for VBAC and the possible increased risk of uterine rupture (139). The issue here is not that the woman was offered a VBAC but that she was not adequately given the information on which to make an informed decision.

Further examples of the same theme are evident in many of the claims that involved breech birth, where there was inadequate counselling, or documented evidence, of the potential risks and what alternative options were available. The majority of these claims were at full dilatation which makes a lengthy discussion difficult and it is therefore important to provide appropriate information quickly to allow the woman to make an informed decision. Another claim revolved around a woman with a previous shoulder dystocia who had a macrosomic baby in this pregnancy where an elective caesarean had not been discussed as an option. These claims also highlight the importance of documenting clearly any discussion that has been had. It is not acceptable to write 'risks discussed' as this does not demonstrate which risks were discussed. Further examples include a woman with twins who had regular growth scans but there was no documented evidence that a discussion about mode of delivery had taken place and a woman with a previous 3rd degree tear where the potential risks of a vaginal delivery were not discussed and the option of a caesarean were not documented.

Evidence from elsewhere

There is evidence that informed consent and patient education results in fewer medical errors (140, 141) and that effective doctor-patient communication results in improved patient outcomes (142, 143) and fewer compensation claims (144).

A respect for patient autonomy and competent decisions by adults is a cornerstone of medical law; "An adult patient who…suffers no medical incapacity has an absolute right to choose whether to consent to medical treatment" (145). The practice of autonomy and patient consent revolves around the key feature of informed decision making, whereby the healthcare professional and the patient engage in dialogue about treatment options, their benefits, risks, consequences and alternatives. In accordance with the GMCs guidance on good medical practice, this information must be clear, accurate, balanced without bias, take into consideration the individual patient, the nature of their condition and in a language that they understand (146).

The recent Supreme Court judgement of Montgomery v Lanarkshire Health Board also ensures that doctors must consider whether "a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is, or should reasonably be, aware that the particular patient would be likely to attach significance to it" (147).

However, this is not a radical change in medical practice as the judgement simply aligns the law to GMC guidance from 2008 that states that the amount of information shared with patients should depend on the individual patient and what they need, or want to, know (148).

Other topics explored

This thematic review was performed to establish clinical themes which may arise, however the sample size may have limited the identification of some rare events. The scenarios below were not identified as themes in this cohort but the findings are worth discussing.

Gestation at delivery

Despite prematurity being the largest risk factor for CP (25, 149), it is an expected finding not to have high numbers of preterm births in this cohort, as it is very difficult to prove negligence as the cause of neonatal brain injury in those born less than 34 weeks. This is due to multiple confounders, the risk caused by prematurity itself and the criteria to determine if CP was caused by an intrapartum event only includes those with encephalopathy born at 34 weeks and above (150).

Pregnancy beyond the estimated date of confinement is a well-known risk factor for stillbirth (151) and there is evidence that "post-term" births are at a higher risk of CP (29). In this cohort, there was a trend towards higher numbers of babies born ≥41 weeks compared to the national average. The majority of these were born at 40+12 or greater.

Table 13: Gestation at delivery

	Study cohort n=50	2012-2016 HES data (99) *
Gestation		
≥ 42 weeks	1 (2%)	3.3%
≥ 41 weeks	15 (30%)	18.4%
≥ 40 weeks	8 (16%)	27%
37-39+6 weeks	21 (44%)	43%
<37 weeks	4 (8%)	8.2%
Unknown	1	

* Hospital Episode Statistic (HES) data between 2012-2016 has been collated to cover the period of this review. HES data is reliant on accurate coding.

Use of Syntocinon in labour

The inappropriate use of Syntocinon was highlighted in a previous report (40) as a potential area for harm and therefore litigation. In this review, the inappropriate use or mismanagement of Syntocinon use did not feature heavily. Syntocinon was used in 11 of the 50 claims but it was only related to the poor outcome in one of these, where it was used despite a suspicious CTG and hyperstimulation.

Uterine rupture

Uterine rupture was a theme in a previous report (40) with 42% of those claims involving women attempting a VBAC. Of the 50 claims in this review, five attempted a VBAC, four of which were spontaneous labour, none had Syntocinon and only one had a uterine rupture. The substandard care in the remaining four were not directly related to the fact they had a VBAC.

Time of delivery

Analysis of the data demonstrated that 32 claims (64%) occurred out-of-hours, defined as outside Monday to Friday 08:00-20:00, see table 14. However, when the number of hours in a week are split between in and out of hours this also equates to 64% demonstrating no difference. It must also be remembered that the time the error occurred is not the same as time of delivery.

Table 14: Time of delivery

Time of Delivery	Number of claims (n=50)	%
Monday to Friday 08:00-20:00	18	36%
Outside Monday to Friday 08:00-20:00	32	64%

Shoulder dystocia

Three of the claims were for shoulder dystocia with the time between delivery of the head and body ranging from 4 to 22 minutes. The error in the first case was essentially that the midwife did the delivery alone and did not call for help at all. The second was a shoulder dystocia after an instrumental delivery by a registrar where the management was disjointed and not structured and the third was a consultant led delivery in a woman with a previous shoulder dystocia and a macrosomic baby, where the antenatal counselling and option of an elective caesarean was not offered.

The first two cases involved poor management of the emergency with a lack of teamwork while the third revolved around informed consent. Apart from CP, the risk of Erb's palsy is another litigation risk from shoulder dystocia and it is also important for all trusts to review whether training in shoulder dystocia is adequate. There is evidence that local, multi-professional training where 100% of staff must attend can decrease the rate of brachial plexus injuries (152), low APGARS, HIE (129) and compensation costs (131).

Recommendations for part 2

Part 2 of this review has provided the clinical details and themes associated with the 50 claims. While identifying areas for improvement similar, recurring topics have become evident; multi-professional training, human factors and the processes to ensure adequate training and competency. Therefore, this review recommends;

5

Trust boards, alongside their obstetric and midwifery leads, must ensure that all staff undergo annual, locally led, multi-professional training, which includes simulation training for breech birth. This training should focus on integrating clinical skills with enhancing leadership, teamwork, awareness of human factors and communication. Staff should not provide unsupervised care on delivery suite until the competencies have been achieved.

How should this be achieved?

National level

The Royal College of Midwives (RCM) standards for maternity services in the UK (153) and the joint RCM and RCOG framework for maternity services (154) highlight the importance of multi-professional learning and acknowledge that it is the registered service providers (employers) that must ensure all healthcare and support staff undertake multi-professional training.

The Department of Health, along with HEE have demonstrated a commitment to improve multi-professional training by distributing £8 million in 2016 to 136 trusts for training courses (155). Trusts choose from a catalogue of approved courses (156) which are being delivered in 2017-18, however there is no mandate to ensure all trusts provide mandatory annual, locally led, multi-professional simulation training in the manner described above.

Implementation of such training may be hindered by widespread shortages of midwifery (157) and medical staff and gaps in medical rotas, due to a shortage of middle grade doctors (158). This particularly affects those "…units that rely extensively on trainees… [which] struggle to sufficiently protect training opportunities" (158).

Therefore, it is recommended that NHS England and the national bodies responsible for training, including HEE, RCOG and the RCM work with the Department of Health to;

- Create a long-term strategy that focuses on ensuring staff can both attend and deliver local training and that their posts are backfilled to cover service provision.
- Ensure that all trusts implement multi-professional training as described above.

Local level

Within the resource pack from NHS England to local maternity systems on how to implement Better Births (92), it is clear that all provider trusts must have one midwife and one obstetrician who are jointly responsible for championing maternity safety in their trust. One of the key roles of those champions is to ensure multi-professional working.

These two clinical leads should be for responsible for implementing this recommendation and be accountable to the trust board.

Training should ensure that midwives, obstetricians, student midwives and junior doctors train together using simulation in a real-world setting, which is likely to be on delivery suite.

The leads should decide on what equipment is required locally but the purchase of expensive simulation equipment should not be routinely required.

The leads should be responsible for ensuring the training is competency based and that all staff complete annual training before they can work unsupervised on delivery suite.

Training will likely need to be run multiple times throughout the year to ensure all staff can attend and are trained.

Time must be made available for staff to attend and for trainers, who are often working clinicians, to participate.

Time frame for implementation

This should not be seen as additional work or setting up a new service but become part of everyday practice for maternity departments. Nevertheless, it will take time for the service to be set up and for all staff to be trained. All staff should be trained by September 2020.

6

Cardiotocograph (CTG) interpretation should not occur in isolation. It should always occur as part of a holistic assessment of fetal and maternal wellbeing. CTG training should incorporate risk stratification, timely escalation of concerns and the detection and treatment of the deteriorating mother and baby.

How should this be achieved?

National level

Recent recommendations from RCOG that "key management decisions should not be based on CTG interpretation alone" (65) provide support for this recommendation, that interpreting CTGs should be part of a holistic assessment. This should therefore be taken as best practice and trusts should modify and update their current CTG training packages accordingly.

This recommendation could be incorporated with the implementation of the Saving Babies' Lives Care Bundle (159), which recommends annual training and competency assessment on CTG interpretation along with the use of a buddy system for the review of CTGs, with an escalation process if concerns are raised.

One of the key areas of focus of the national maternity and neonatal health safety collaborative is improving the early recognition and management of deterioration in either the mother or baby during labour. The support provided by the collaborative will help trusts that focus on this area to implement this recommendation with a locally sensitive improvement plan.

Local level

The trust level midwifery and obstetric clinical leads, responsible for championing maternity safety, should incorporate this recommendation by providing annual multi-professional clinical training for all staff, set out in recommendation 5. This should include the incorporation of e-learning resources, including e-Fetal Monitoring (160), ATAIN – Avoiding Term Admissions Into Neonatal units (161) and human factors training, for example on ensuring TED – Timely review, early Escalation of concerns and Decision making (162).

The clinical leads should also work with their local designated lead for the maternal and neonatal health safety collaborative who can use LIFE, the online quality improvement software platform (163), provided as part of the collaborative, to identify those trusts working on the deteriorating mother and baby work stream and work collaboratively to implement the shared learning.

Time frame for implementation

The collaborative is a 3 year programme with wave 3 trusts finishing in March 2020 and therefore all trusts should have implemented this recommendation by then.

7

Trusts should monitor the effectiveness of their training by linking it to clinical outcomes. Trust boards should encourage units to publish their local indicators, which can then be subject to benchmarking and external scrutiny.

How should this be achieved?

National level

In-line with Better Births which states that "all teams should routinely collect data on the quality and outcomes of their service, measure their own performance and compare against others' so they can improve" (15) and as part of the maternity transformation programme, NHS England are commissioning a nationally consistent but locally configurable maternity dashboard that will enable maternity providers and commissioners to monitor effectiveness. The new maternity data viewer tool, which is due for release in 2018, will include:

- Descriptive data (activity and demographics)
- Quality improvement metrics (14 metrics, analysed monthly, that can be used to assess clinical quality – these will initially be published in 2017 via the NHS Digital iView tool)
- National maternity indicators (providing a holistic view of the service and collated from multiple sources)

This data will be visible at commissioner, local maternity system and maternity strategic clinical network level. Trusts will be able to use the tool to monitor their data, compare performance and identify if they are an outlier.

NHS Resolution are working in close collaboration with the Getting It Right First Time (GIRFT) project which provides benchmarking of clinical and financial indicators to help support local improvement in areas with the biggest variation. Information can be found at: www.gettingitrightfirsttime.co.uk. The GIRFT team will visit every maternity unit in England to help them identify how best to use their data for improvement.

Local level

The trust level midwifery and obstetric clinical leads, accountable to the board level maternity champion, should use local data to monitor the effectiveness of the training provided. It is not possible to monitor effective training using single indicators and therefore the maternity data viewer tool will provide balancing metrics which can be monitored for improvement over time.

Trust boards should support an open culture by publishing their local indicators.

Time frame for implementation

Implementation will be easier once the maternity data viewer tool is live. However, trusts should start linking training to available local indicators immediately and be compliant by 2020.

Conclusion

This review identified 50 claims for CP and neonatal brain injury that occurred in the last five years. Every claim was potentially avoidable and the costs to the child, family and carers will always be immeasurable. The potential litigation costs could exceed £390 million, however this does not include the potential future NHS costs of prolonged hospital stays, neonatal care and paediatric outpatient follow up.

NHS Resolution is keen to use its dataset to demonstrate areas of potential learning so that it can reduce future incidents and subsequent claims. The national maternity review highlights that learning from incidents is vital and currently an "open culture that welcomes learning is… inconsistently distributed, with many units missing the opportunities for improvement that are needed" (15). This review shares lessons learnt on a national scale and demonstrates the importance of an open culture as a platform for learning and improvement.

This review has looked at the quality of trusts own serious incident investigation reports and the clinical features that are demonstrated from these claims.

Common themes identified when looking at the investigation process were a lack of family involvement and support, the RCA process often focused on individuals was of poor quality in determining why the incident occurred and subsequently focused on making recommendations that were unlikely to prevent recurrence of the same problem. When reviewing the clinical details four main themes were identified; errors with fetal heart rate monitoring, breech birth, quality assurance of staff training and patient autonomy.

This review also provides supporting evidence from other studies and reports which demonstrates similar findings and areas where there has been scarce improvement. The recommendations of this review take this wider evidence into consideration and outline not only what should be done but provides an idea of how and by when.

While the limitations of this review have been highlighted, in relation to sample size, there is a strong appetite to learn from compensation claims to prevent recurrence and this review intentionally chose to focus on claims that occurred within the last five years, to ensure any learning is relevant to current obstetric practice. The creation of the NHS Resolution early notification scheme will hopefully have a role in helping trusts in the investigation process so that lessons can be learnt at a local level and in a more prospective way than is possible currently.

Overall, maternity care in England is very safe; however, there are areas in need of significant improvement, especially when things go wrong. By focusing on these 50 claims where practice could have been improved and highlighting areas for improvement, it is hoped that this review will improve patient safety and reduce the incidence of future harm.

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