

The Early Notification scheme progress report: collaboration and improved experience for families

An overview of the scheme to date together with thematic analysis
of a cohort of cases from year 1 of the scheme, 2017–2018

September 2019



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Foreword

Foreword

Foreword by Gill Walton, Chief Executive of the Royal College of Midwives & Professor Lesley Regan, President of the Royal College of Obstetricians and Gynaecologists

We welcome the publication of this report from NHS Resolution's Early Notification scheme and in particular the benefits that the Early Notification scheme may provide for the system, maternity teams and families.

In addition to the tragedy of avoidable harm for individuals and their families, the increasing costs of clinical negligence in maternity care are an enormous financial drain on NHS healthcare resources. Furthermore, we must not overlook the fact that every incident of patient harm is distressing for the maternity staff involved.

In this report, early admissions of liability have been provided for 24 families within 18 months of the birth compared to a wait of years in the past. These families were provided with a detailed explanation, an apology, independent representation, and financial support for prompt clinical and respite care, as well as psychological support where required. We welcome these interventions along with the recommendation of more help for staff to meet the current duty of candour, and to provide details of investigations to families, including options for their participation.

An additional benefit of the reduction in time taken for liability resolution is a parallel reduction in the burden of the litigation process for staff. The Royal College of Midwives (RCM) and the Royal College of Obstetricians and Gynaecologists (RCOG) recognise the distress reported by staff and are working with NHS Resolution and the wider NHS to develop appropriate, dedicated and confidential post-incident support for staff; support that is urgently required.

The recommendation for a standardised approach to fetal monitoring resonates with other national reports, including Each Baby Counts. The RCM and the RCOG concur that a better understanding of how maternity professionals work with fetal monitoring in practice is long awaited and we commit to working with researchers, clinicians and families to implement an evidence based approach to fetal monitoring.

Two emerging clinical issues have surfaced in this report: impacted fetal head at caesarean section and maternal/fetal hyponatraemia. There is a dearth of research and national guidance in these areas and we agree that more research

is required for both. In the meantime, we will work to provide national guidance and training for maternity teams.

We support the system level approach to recommendations made in this report. It is essential that we simultaneously mobilise these findings down to practice and up to policy to improve care and birth outcomes.

Finally, we are also committed to working collaboratively across the system to reduce the burden of incident reporting on trusts, particularly supporting the development of a single-entry portal for reporting at trust level.

We would like to finish by committing to the report's ambition to improve care and birth outcomes across the UK and improving the experience of families and staff after poor outcomes. This will be best achieved through the collaborative input of women and their families, frontline maternity teams, academics, system level bodies and policy makers. Both the RCM and the RCOG will work collaboratively to facilitate these shared aims.

Executive summary

The Early Notification (EN) scheme is a national programme for the early reporting to NHS Resolution of infants born with a potential severe brain injury following term labour. It aims to support the stated government priorities to halve the rate of stillbirth, neonatal death and brain injury and improve the safety of maternity care while also responding to the needs of families where clinical negligence is identified including through the early admission of liability, where appropriate. The scheme uses the expertise of NHS Resolution in clinical negligence claims handling to proactively assess the legal risk, investigate care, and provide early support to families where liability is established. Furthermore, the scheme aims to improve the experience for NHS staff by time limiting the need for protracted involvement in the legal process and rapidly sharing learning from avoidable harm.

This report describes the development and progress of this innovative scheme to date with an overview of the cases reported in year one from 1 April 2017 to 31 March 2018. Furthermore, it includes an analysis of the issues identified in a cohort of cases with recommendations for future work.

This report is aimed at multiple levels of the system, including staff and clinical teams, trust boards and policymakers. The report is divided into two sections: the first describes the process and outcomes of the first year of the EN scheme, and the second identifies clinical learning from the cases. We have summarised high-level recommendations early in the report with a more detailed description later.

Prior to the establishment of the EN scheme in April 2017, the average length of time between an incident occurring and an award for compensation being made was 11.5 years.

Through the EN scheme, families with a baby affected by a severe brain injury attributable to substandard care are able to receive significantly earlier answers to their questions, avoiding full court proceedings. Through our expert claims handling, timely compensation is provided to families and staff are better supported, significantly reducing the burden of the legal process for all involved.

In its first year of operation – April 2017 to March 2018 – the 746 qualifying cases reported to the EN scheme were cross-referenced against the National Neonatal Research Database (NNRD).

To date, 24 families have received an admission of liability, formal apology and in some cases, financial assistance with their care and other needs within 18 months of the incident. There are a further number of cases currently being reviewed. This short duration is unprecedented for claims related to brain injury and/or cerebral palsy.

Analysis of a pragmatic sample of 96 of the total 197 cases where NHS Resolution panel solicitors were instructed to investigate liability (the clinical trust or internal review classified the case as likely to have involved substandard care, or the family instructed solicitors) identified the following clinical issues:

- Key themes in investigations included limited support to staff, insufficient family involvement, and confusion over duty of candour.
- Issues with fetal monitoring were a leading contributory factor in 70% of cases. In 63%, at least two or more factors were identified; a delay in acting on a pathological CTG was the most common factor.
- Impacted fetal head and/or difficult delivery of the head at caesarean section was a contributory factor in 9% of cases in this cohort. This is a high incidence for a problem that has not previously been reported by NHS Resolution.

- Concurrent maternal medical emergencies in labour occurred in 6% including significant maternal hyponatraemia and were important contributors to neonatal seizures and encephalopathy.
- Immediate neonatal care and resuscitation remains an important but an under-recognised factor affecting 32% of the cohort.

To prioritise further research and safety initiatives, NHS Resolution, together with key partners, provide the following recommendations – summarised below and presented in more detail from page 32.

Recommendations

1

All families, whose baby meets the Early Notification criteria and requires treatment and separation from them for a potentially severe brain injury, should be offered a full and open conversation about their care.

This should include an apology in accordance with the statutory duty of candour, a description of the intended investigation process and options for their involvement in investigations.

For more detail see page 32

2

An independent package of support should be offered to all NHS staff to manage the distress that can be associated with providing acute health services and in particular to those involved in incidents.

Support should address mental health, wellbeing and post-incident care with access to referral for psychological assessment and intervention where required. This should be confidential and independent of appraisal or the revalidation processes.

For more detail see page 34

3

There is an urgent need for an evidence-based, standardised approach to fetal monitoring in England.

Effective improvement strategies for fetal monitoring require in-depth understanding of the social mechanisms underpinning the process, not just the technical issues. Research in this area should be prioritised urgently.

For more detail see page 47

4

Increase awareness of impacted fetal head and difficult delivery of the fetal head at caesarean section, including the techniques required for care.

Research to understand the prevalence, causes and management of impacted fetal head is a priority, along with effective training in the management techniques.

For more detail see page 49

5

Work with existing national programmes to improve the detection of maternal deterioration in labour, including monitoring as well as the implementation of evidence-based guidance in all birth settings.

Research to understand the prevalence and cause of significant hyponatraemia in labouring mothers in England should also be prioritised.

For more detail see page 51

6

Increase awareness of the importance of high-quality resuscitation and immediate neonatal care on outcomes for newborn babies.

This requires collaboration between the whole multi-professional team.

For more detail see page 53

NHS Resolution, through the EN scheme, continues to drive timely and early resolution of cases to benefit both families and staff involved, translate our data into information for the wider NHS and incentivise providers to deliver safe maternity and neonatal services.

We are committed to working collaboratively across the system and we are very grateful to all our partners for their cooperation. A major part of this will be to continue work to reduce the burden of incident reporting on trusts, share learning through strengthening of data collection and build collaborations with academic partners.

Background

NHS Resolution's primary focus is to resolve concerns fairly, share learning for improvement and preserve resources for patient care. Healthcare provision in the NHS is very safe but on the rare occasions when things do go wrong, it is important that those involved are properly informed and supported, compensation is paid fairly, unnecessary costs are contained and that we learn in order to improve. Through our work, we have a unique contribution to make to patient safety and work across systems to drive improvement.

All NHS trusts in England are members of and contribute to NHS Resolution's indemnity schemes, the largest of which is the Clinical Negligence Scheme for Trusts (CNST).

The cost of clinical negligence claims is rising at a faster rate year on year than NHS funding. By far the largest contributors to the incurred cost of harm,

the annual collect from trusts to pay claims and the provision held in the government accounts for clinical negligence, are maternity claims in which long-term severe brain injuries are suffered due to negligent care around the time of birth¹ (see figures 1 and 2). The value of these claims and the level of compensation awarded is a reflection of the complex and long-term care needs of affected babies.

The NHS Resolution EN scheme was established in April 2017. It builds upon strengths across the organisation, in claims management, safety and learning, and advice.

The scheme supports the government priority to address the costs of clinical negligence, which came under the scrutiny of the National Audit Office and the Public Accounts Committee in 2017², as well as the significant work driving improvement in the safety and experience of maternity

care through NHS England's 'Better Births' report³ and the Maternity Transformation Programme⁴. The scheme is further supported by NHS Resolution's maternity incentive scheme (MIS); a set of actions that enable the indemnity scheme to act as a financial incentive for improving safety in maternity care (appendix III). Early notification embodies proactivity in investigation and candour for those affected by brain injury at birth, for the benefit of families and the wider system. Our ambition is that litigation or the fear of litigation should not be seen as a barrier to safety. Through proximity to incidents we are able to highlight contributory factors related to the occurrence of harm to support the national ambition to halve the rate of stillbirths, neonatal deaths and brain injuries associated with birth by 2025⁵ as well as its financial impact.

Figure 1: The number of claims received in 2018/19 by specialty¹

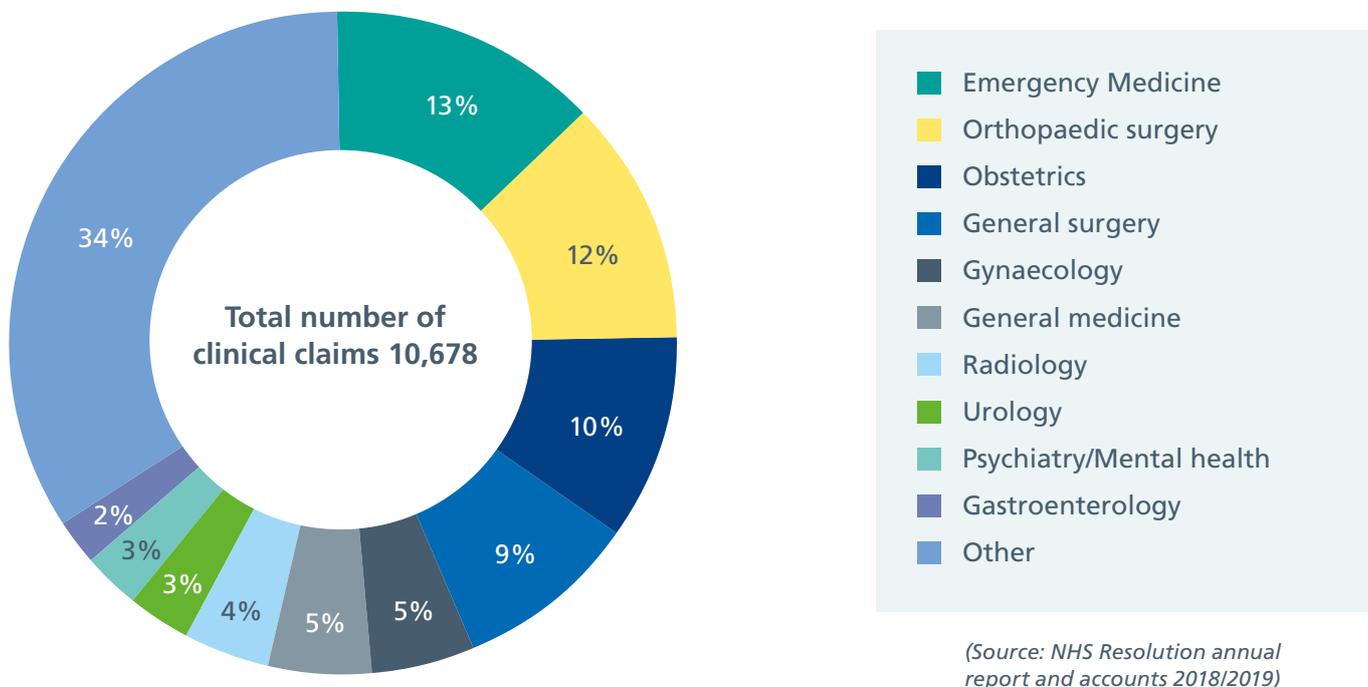
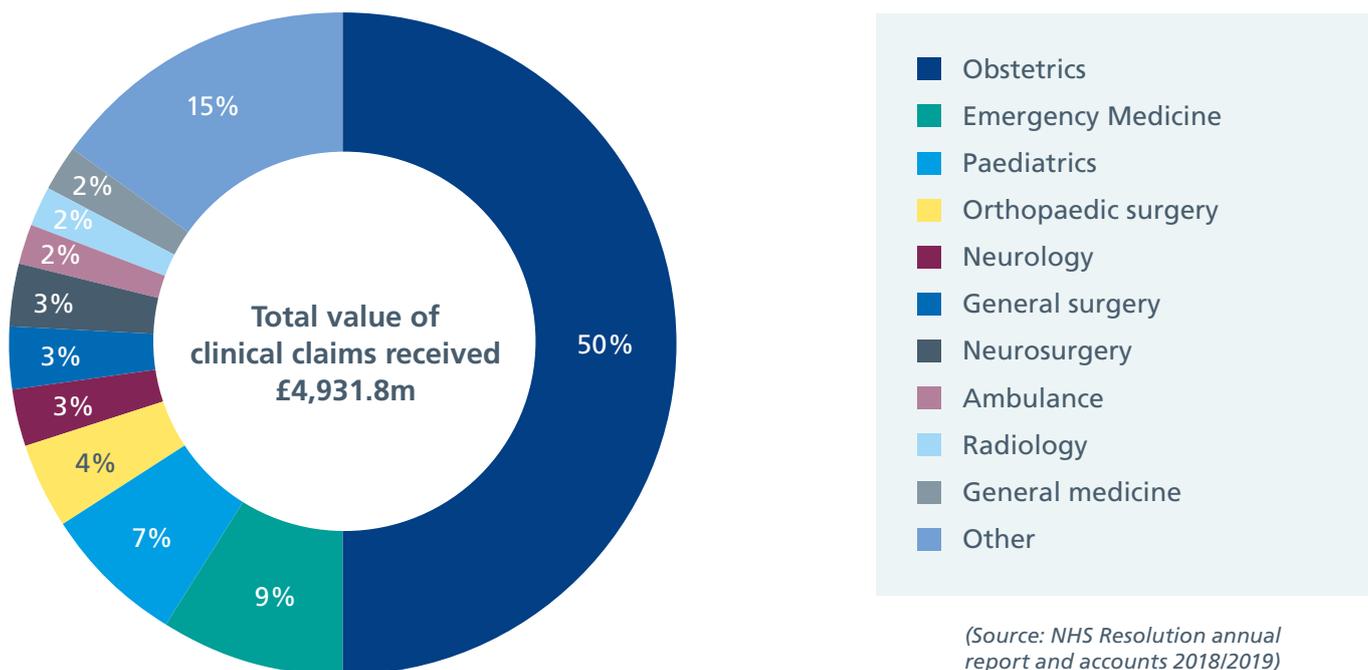


Figure 2: The value of clinical negligence claims received in 2018/2019 by specialty¹



Introduction to the Early Notification scheme

From 1 April 2017, acute maternity trusts have been required to notify NHS Resolution within 30 days of all babies born at term (≥ 37 completed weeks of gestation), following labour, that have had a potentially severe brain injury diagnosed in the first seven days of life, based on the following criteria:

- Have been diagnosed with grade III hypoxic ischaemic encephalopathy (HIE); **OR**
- Were actively therapeutically cooled; **OR**
- Had decreased central tone **AND** were comatose **AND** had seizures of any kind.

These criteria align with the Royal College of Obstetricians and Gynaecologists' (RCOG) Each Baby Counts (EBC) programme⁶. Babies who meet the criteria above are at relatively high risk of being diagnosed with a long-term brain injury or disability in the future (e.g. cerebral palsy), and furthermore the EBC programme has identified potentially avoidable harm in 71–76% of cases⁷⁻⁸. Although this does not directly equate to legal liability (see below),

it is indicative of potential litigation risk and a high value claim.

NHS Resolution recognises the current reporting burden on trusts and are working closely with other stakeholders to streamline this process; and in particular we are working towards a single reporting portal for trusts.

Finally, it would be useful for more collaboration to take place between the national organisations undertaking reviews and investigations. In particular, it would be useful to aggregate the recommendations from all these national investigations to ensure that maternity teams and parents benefit from the findings in a timely and comprehensive way. Moreover, there is an opportunity to reduce complexity, increase involvement for families, reduce duplication, improve the quality of local investigations, improve access to support for families and staff post-event, and finally improve care and reduce avoidable harm in maternity care.

Aims of the Early Notification scheme

1. Carry out early liability investigations where indicated to improve the experience for both families and staff affected and provide early support
2. Reduce formal litigation in the courts and the associated legal costs
3. Identify learning and share at national, regional and local levels

Footnote: Legal liability, risk and causation

To establish clinical negligence, it must be proved that a duty of care exists between the patient and healthcare provider, that the care provided fell below a reasonable standard and that this caused harm.

Claims are made against trusts rather than named individuals under the principle of vicarious liability, meaning the trust takes responsibility for the actions of its employees.

Whether care is reasonable is assessed using the Bolam and Bolitho principles. Care will be reasonable where it is supported by a responsible body of medical opinion and withstands logical analysis. There must also be a link between the care and harm. Causation is established where substandard care led to the harm directly (on the balance of probabilities) and/or materially contributed to it.

The reasonable care test as described above is not directly comparable to avoidable harm which is a concept used in some other jurisdictions.

The benefits of early notification

Early notification enables earlier investigation and resolution of potential litigation cases. Families with a baby affected by a severe brain injury that is attributable to substandard care are able to receive significantly earlier answers to their questions, avoid full court proceedings to get those answers and receive financial support with their care and other needs at a much earlier stage.

For frontline staff involved, the stress of undergoing an incident investigation, potential statement provision and legal process are time limited and more proximate to the incident. Historically, the majority of incidents were not notified to NHS Resolution until a claim was brought. In cerebral palsy cases this was often many years after the birth, as demonstrated in our 2017 report *Five years of cerebral palsy claims: a thematic review of NHS Resolution*

data⁹. For a healthcare professional to be informed that a case they were involved in a number of years prior has become the subject of a litigated claim is stressful, and the quality of the investigation is prejudiced as it can be difficult to accurately recall what happened.

For trusts, EN enables NHS Resolution to provide support to deliver candour, provide mediation if the relationship between the trust and family is at risk of breaking down and carry out a full liability investigation where required. In addition, there is timely feedback on learning from harm.

For the national maternity system and NHS as a whole, it is envisaged that EN will contribute to a wider understanding of why incidents occur and how they can be prevented.

The Early Notification scheme in practice

The EN scheme is a unique initiative and the approach has fundamentally changed how these very serious events are handled when it comes to the assessment of legal liability and compensation. For the first time, cases are analysed by both legal and clinical experts at NHS Resolution, bridging the claims and safety and learning functions of the organisation. The EN team incorporates legal case managers working alongside a clinical panel of senior maternity advisors and obstetric and midwifery clinical fellows under the Safety and Learning directorate. This structure facilitates robust triage and analysis of cases with the opportunity to feedback learning to trusts in real time, as well as to understand local and national maternity safety concerns (see section on managing concerns).

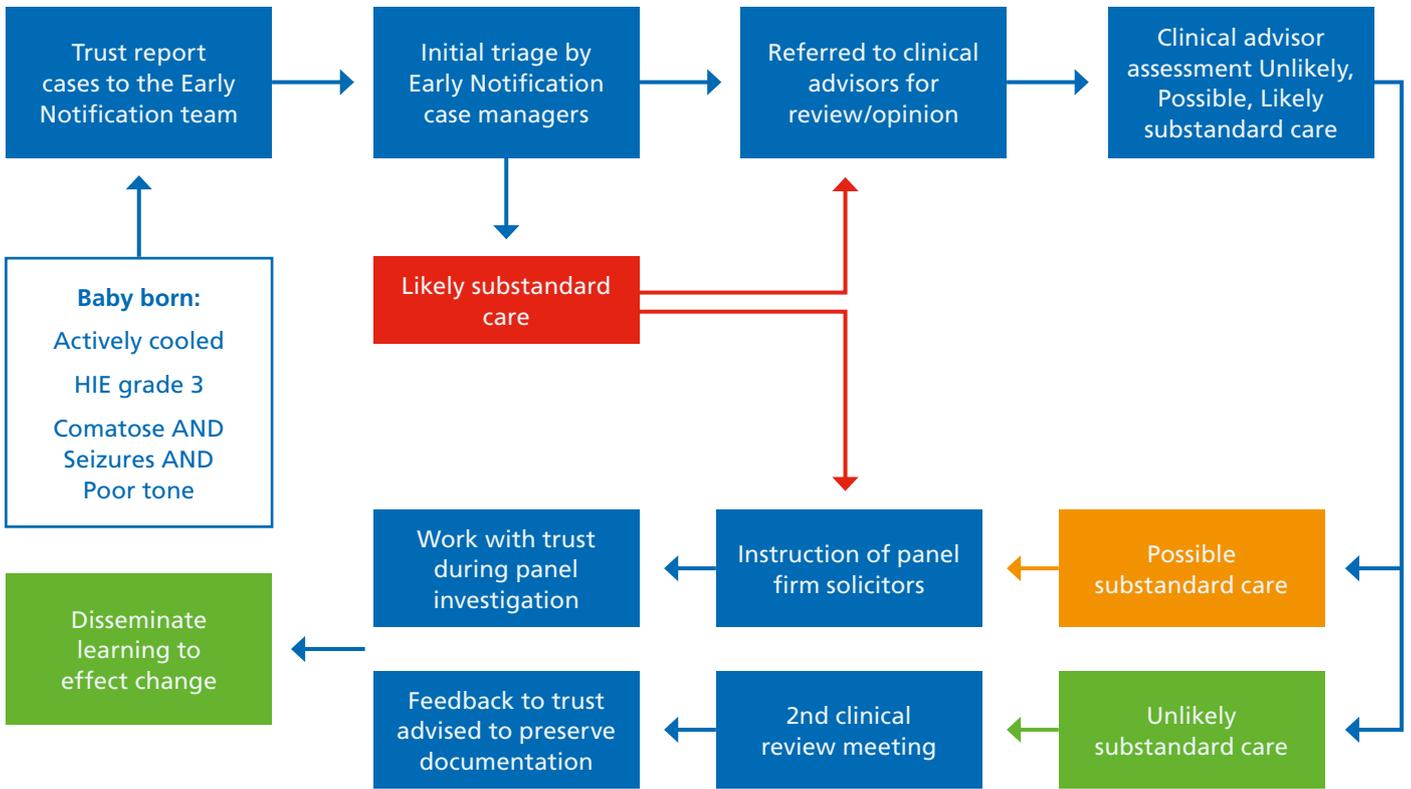
Cases are processed based on the liability risk assessment provided by the trust at the point of notification. In the first year, trusts were asked to provide a risk assessment based on whether there was 'unlikely', 'possible' or 'likely' substandard care. After feedback, this has been updated to reflect standard clinical language (see appendix III).

In addition to the initial case reporting and risk assessment, trusts are asked to provide, in a secure format, a copy of the relevant maternal and neonatal medical records and any investigation documents when available. Reporting is cross-referenced with data extracts of qualifying babies provided by the National Neonatal Research Database (NNRD) so that notifications can be checked and any missing cases identified. This is also the route by which EN cases are externally verified for the benefit of NHS Resolution's maternity incentive scheme (see appendix III).

For cases risk-assessed by trusts as 'likely' substandard care, panel solicitors (see opposite) are instructed directly to begin a liability investigation.

Cases reported to NHS Resolution with 'possible' or 'unlikely' risk assessments are triaged internally by legal case managers and clinical advisors to determine the risk of liability (see figure 3). In cases where the risk assessment is revised to 'likely' or maintained at 'possible', typically there will be a recommendation for panel instruction following internal review.

Figure 3: Flowchart of typical case handling according to risk assessment



Panel solicitors

Liability investigations usually involve the instruction of solicitors on behalf of the NHS trusts, commissioned by NHS Resolution.

There are currently 12 legal firms appointed to NHS Resolution’s panel. Appendix IV lists which firms represent the 129 acute maternity trusts across England (at the time of report publication). Panel solicitors work with us to manage clinical negligence cases. They in turn commission independent expert opinion on the care to understand whether it was negligent and in addition may arrange conferences with counsel (a barrister) particularly in high-value and complex cases where formal court proceedings may be served.

Where an incident is considered by the reporting NHS trust to be 'unlikely' to be related to substandard care and the EN triage concurs, feedback is provided to the trust. However, there may be learning around the case or investigation and these observations are fed back directly to the trust. The trust legal team are advised to preserve relevant records, statements, investigation documents and contemporary guidance as the process does not necessarily prevent a claim being brought by a family at a later date.

The EN scheme has enabled innovative approaches to liability investigation. Historically, for potential cerebral palsy claims, panel solicitors would instruct clinical experts to prepare reports responding to cases put forward by claimant solicitors. Experts, midwives and clinicians would then be convened in conference with panel solicitors and leading counsel to formulate a response to the case made. One advantage of EN is the opportunity to investigate the care provided at an early stage before there are formal allegations and the investigation can therefore be more proactive and flexible.

Other innovative approaches include bringing medical and midwifery expert witnesses and legal teams together to discuss cases in conference without the need to prepare formal reports in advance, thereby reducing the time that experts need to set aside for each case, as well as potential costs. Where the conference attendees agree that liability should be admitted, it may not be necessary to go to the time and expense of preparing a formal expert report. It has also been possible to successfully convene single conferences to discuss several cases in a day with appropriate protections in

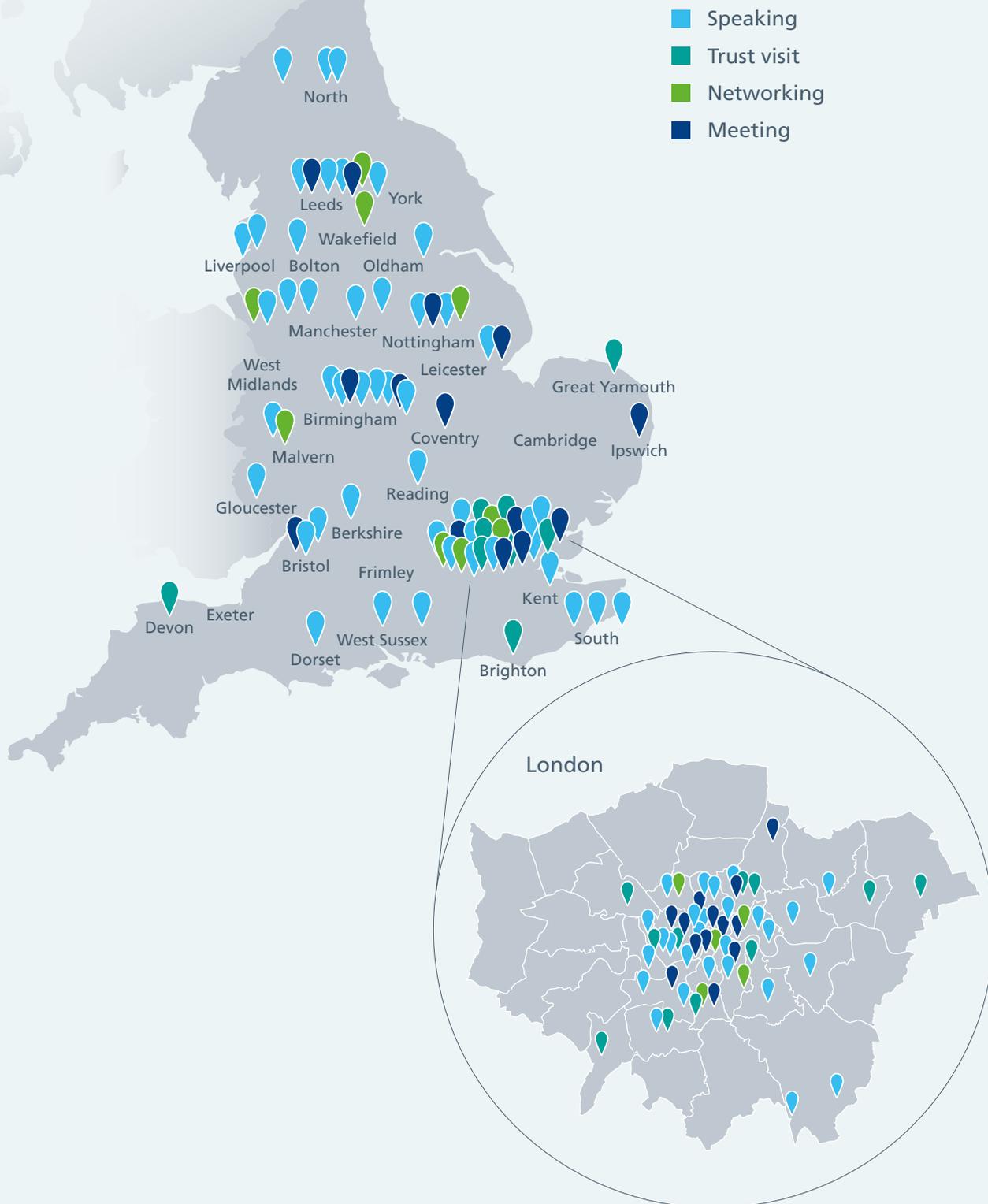
place to preserve confidentiality.

Once liability investigations are concluded, families are provided with details of the outcome. This is usually through the trust legal service, supported by panel solicitors and NHS Resolution. Where relevant this will include informing families candidly where care has fallen below a reasonable standard and legal liability will be admitted.

Where the investigation concludes that the care provided was reasonable, we will explain our findings to the trust and families who are also advised that they can access independent advice and support. Moreover, we will signpost families to the charity Action against Medical Accidents (AvMA). Appendix I includes the contact details for AvMA and other sources of support and advice for families.

In addition to case management work, the EN team are engaged in a number of activities to share learning, liaising with trusts and providing training at local, regional and national levels. The scheme has now been established for two years and during this time the team have attended more than 100 external engagements across England ranging from individual trust and Local Maternity System (LMS) visits to regional events and national conferences (figure 4). There have also been a number of resources developed including case stories and support services, hosted on the NHS Resolution website and circulated through the National Maternity Safety Champions network (see appendix III for further information).

Figure 4: Regional activity undertaken by the EN team from 1 April 2017 to July 2019



Managing concerns

The EN team review incident details, notes and/or investigation documentation related to cases soon after the incident. During the review process there may be a pattern of concerns that should be raised locally with a trust and/or at a regional and/or national level.

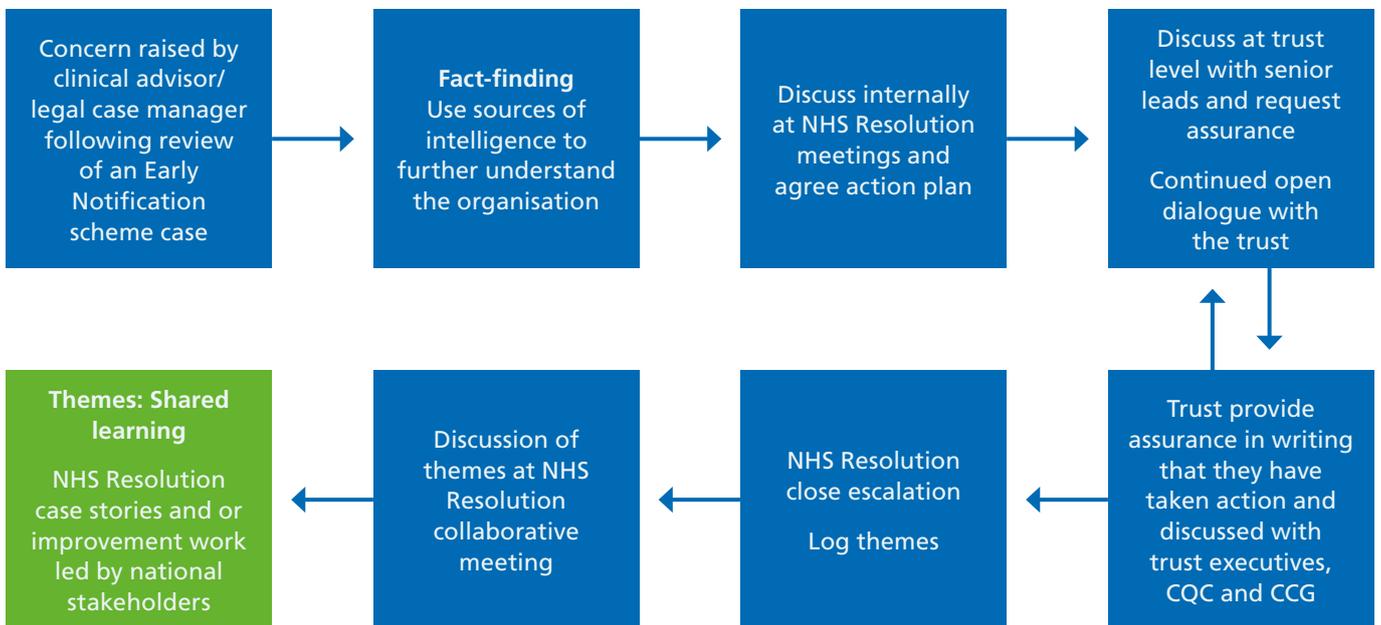
Our role is to highlight concerns and work in partnership with trusts, empowering them to take ownership of the issue and implement their own escalation through appropriate channels.

This is a process developed by NHS Resolution with advice from the EN clinical advisory group and further supports the aims of the EN scheme. NHS Resolution and the

Healthcare Safety Investigation Branch (HSIB) both currently sit in this arena of receiving early information and it is important that unnecessary duplication is reduced along with the burden on trusts. It is vital therefore that our work is collaborative, and we continue to establish ways in which this early intelligence can be shared across organisations.

While the spotlight on safety is generally welcome in maternity services, translation into constructive support is essential and we will continue to consider ways in which we can take concerns forward, particularly those that are likely to have regional or national impact.

Figure 5: The process for managing concerns



The Early Notification clinical advisory group

Throughout the development and ongoing work of Early Notification we are grateful to have the engagement of a skilled clinical advisory group with wide reaching representation. The group meets on a quarterly basis to advise the Early Notification team on strategy, process and managing concerns (see next chapter).

Members of the clinical advisory group include senior representatives of:

- NHS England (NHSE) and NHS Improvement (NHSI)
- The National Maternity Safety Champions
- Healthcare Safety Investigation Branch (HSIB)
- The Care Quality Commission (CQC)
- The Royal College of Obstetricians and Gynaecologists (RCOG)
- The Royal College of Midwives (RCM)
- The British Association of Perinatal Medicine (BAPM)
- Department of Health and Social Care (DHSC)
- Health Education England (HEE)
- Clinical experts in midwifery, neonatology, obstetrics and paediatric neuroradiology.

The findings of this report and recommendations have been made in partnership with those bodies represented in the advisory group and we are grateful for their ongoing support and commitment to the scheme. NHS Resolution is also committed to cross-system working and the advisory group plays a major part in achieving that.

The first year of Early Notification in numbers

Between 1 April 2017 and 31 March 2018, 808 incidents occurred which were then reported to the EN team. Reporting rates were initially steady within the first year and there was an increase in reporting rates that coincided with the introduction of the first year of the maternity incentive scheme. This highlighted the benefit of employing incentive schemes for leverage with clinical teams.

Cases were manually cross checked against qualifying infants identified in the NNRD data set to ensure no qualifying cases were missed. Where there were discrepancies between submissions and the NNRD data, we liaised directly with the trusts to confirm.

Sixty-two cases were reported into, and accepted by, the scheme but later excluded when they did not meet the inclusion criteria. At the point of data collection (30 January 2019), there were 746 eligible EN cases.

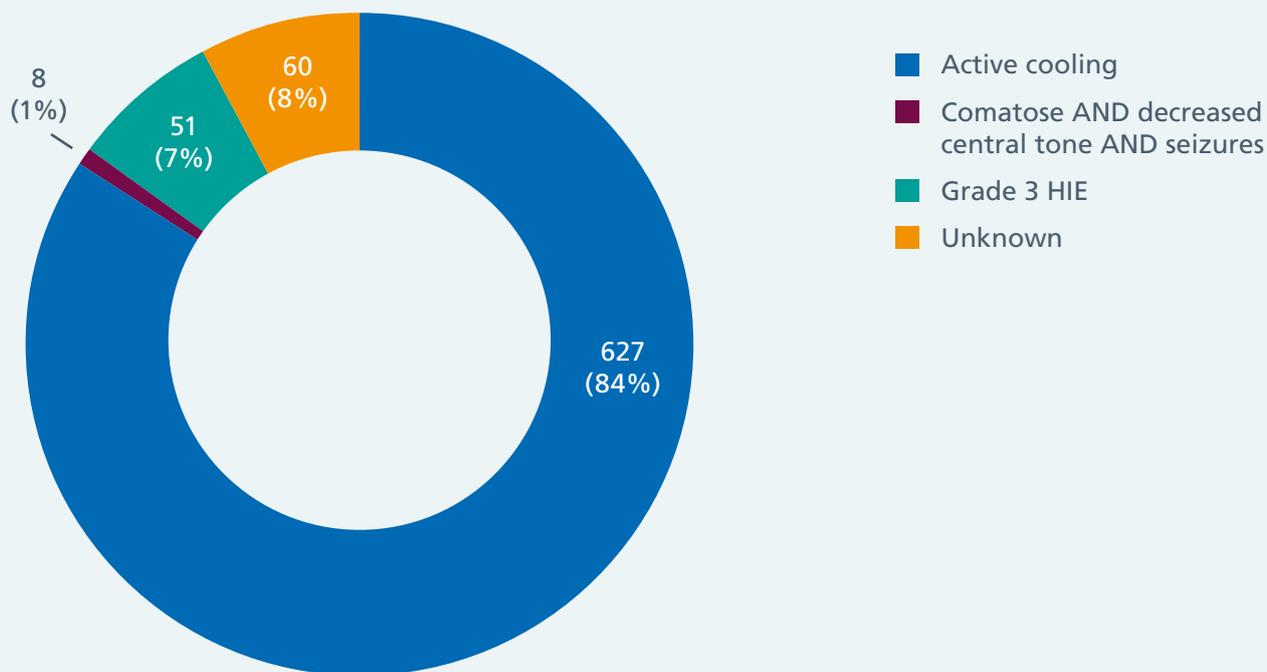
There were 639,984 births in England between 1 April 2017 and 31 March 2018¹⁰. The cases eligible for the EN scheme therefore represent 0.12% of all births in England. Each of these cases is extremely significant, particularly to the families and staff involved. However, it is also important to remember that these represent a very small proportion of births and that England is a safe place to have a baby.

Notification criteria

More than 80% (627/746) of incidents reported to the scheme were newborn babies receiving active therapeutic cooling, a management option where the total body temperature of a baby is lowered by a few degrees shortly after birth to reduce the impact of perinatal hypoxia and brain injury. Therapeutic cooling is performed in specialist neonatal units, most commonly for 72 hours.

However, we recognise that there is a requirement for an agreed national threshold for therapeutic hypothermia in the UK as there can be different thresholds for cooling depending on local availability. It may be useful to consider refining the entry criteria for the EN scheme in the future to reflect this.

Figure 6: Breakdown of the notification criteria met at reporting for 746 cases that met the scheme criteria in year one



Changes in risk assessment between trust and NHS Resolution

Sixty-nine (9%) cases were assessed to be a ‘likely’ risk by trusts and were referred immediately to panel solicitors for investigation. Those cases assessed as ‘possible’ or ‘unlikely’ are reviewed and reclassified by the internal EN team.

There was variation in the number of risk assessments revised following internal review. Of the 125 cases initially assessed to be ‘unlikely’ to be associated with substandard care and reviewed by the internal EN team at the time of this data analysis, 56 (45%) were revised upwards to ‘possible’ or ‘likely’ to have involved substandard care by the team. These cases were referred to panel solicitors to commence further liability investigations (table 1).

This difference is important, and a better understanding of the difference would be useful. The requirement for an early risk assessment by local teams may have affected their assessment. Moreover, different approaches are employed in different settings: NHS Resolution reviews were based on whether care met a ‘reasonable’ Bolam standard, whereas investigations by trusts often adopted a more clinical, best practice approach.

This is likely to reflect the different skill sets and experience of the local and NHS Resolution investigators. We will work with local trusts to understand how best to work together, and whether additional training would be helpful.

Table 1: Comparison between initial trust risk assessment and NHS Resolution’s subsequent internal risk assessment

Cases reported to us with a ‘possible’ risk assessment (73 cases)	
Revised by NHS Resolution to a ‘likely’ risk assessment	37% (27)
Agreed by NHS Resolution as a ‘possible’ risk assessment	47.9% (35)
Revised by NHS Resolution to an ‘unlikely’ risk assessment	15.1% (11)
Cases reported to us with an ‘unlikely’ risk assessment (125 cases)	
Revised by NHS Resolution to a ‘likely’ risk assessment	7.2% (9)
Revised by NHS Resolution to a ‘possible’ risk assessment	37.6% (47)
Agreed by NHS Resolution as an ‘unlikely’ risk assessment	55.2% (69)

Accelerated liability investigations

In the first year of the EN scheme, panel firms (see appendix IV) were instructed to begin liability investigations in 197 (26%) of cases reported.

There have been early admissions of liability for 24 families who have been provided with detailed explanations, admissions of liability and an apology. Providing families with a decision on liability so close to the point of incident is an important outcome of the scheme. We have also been able to provide these responses to families in ways which best meet their needs, through discussion, in writing and by providing them with expert opinions. Mediation is also an option.

When liability is accepted and the baby has additional needs as a result, we have provided those families with financial support for early access to additional care, respite and where needed psychological support, including an offer of counselling. Our involvement with these families will continue. Many of these families now have independent representation and our legal teams are working with them to put together compensation packages that will meet the children's needs for the rest of their lives.

Where care was considered appropriate by the EN process, trusts were provided with clinical feedback and information to share with families.



Sharing of medical records and investigation reports

There has been variation across trusts in engagement with the scheme, particularly with mixed and/or delayed provision of maternal medical records, neonatal records and/or local investigation documents. From April 2018, HSIB has taken on the responsibility for maternity investigations.

Prior to HSIB taking on responsibility, in year one of the EN scheme, in 38% (283) of cases insufficient information was initially provided by the notifying trust for a preliminary assessment of liability.

In a small number of high risk cases where panel solicitors have been instructed, trusts were unable to provide sufficient information to assess liability.

Appendix III details best practice for reporting a qualifying incident and the subsequent provision of records. It is understandable that all investigations require time at trust level; however we encourage all trusts to obtain a good quality copy of maternal medical records and neonatal records including relevant cardiotocographs (CTGs) so that they can be sent to us without awaiting the conclusion of local investigations. We appreciate that copying and sending records can be resource intensive and are grateful to all trusts for their assistance in providing us with records. We also appreciate that similar demands are made on trusts by a number of other organisations for the same cohort of infants and we will continue to work with those organisations to streamline this, including supporting the development of a single reporting portal.

There has also been hesitation from some trusts about disclosure of information to NHS Resolution due to uncertainty about their obligations under the data protection regulations. We have supported trusts in working through this with guidance (see appendix III). Incidents reported to NHS Resolution are cases of unexpected harm in which the possibility of substandard care needs investigation. Patient medical records can be lawfully disclosed to NHS Resolution for this purpose under the General Data Protection Regulation (GDPR) 2016 and the Data Protection Act 2018¹¹. However, it is vitally important that families are aware of NHS Resolution involvement. Families have the right to know where their data is being shared, what investigations are being carried out; and most of all, it is the right thing to do.

We recognise that having these discussions with families soon after birth can be sensitive and family involvement and duty of candour is discussed in more detail in part 1, theme 1.

Finally, we are very aware of the potential for duplication in the current investigation landscape and we encourage more collaboration for a functional alignment of the current systems with less duplication and where all stakeholders contribute their individual strengths to improve maternity care. Going forward, we aim to work with the reports from HSIB, particularly where cases are assessed as low risk for liability.

Analysis of 100 Early Notification cases occurring from 1 April 2017 to 31 March 2018

This section of the report reviews the reporting, investigative and clinical themes from an in-depth analysis of a cohort of 100 EN cases that occurred in the first year of the scheme in which panel firms were instructed to start liability investigations.

Methodology

Part 1: Reporting and investigative themes

Reporting to NHS Resolution

Theme 1: Family involvement and candour

Theme 2: Support for staff

Part 2: Clinical themes

Demographics: Antenatal and intrapartum

Summary of clinical and contributory care factors

Neonatal outcome

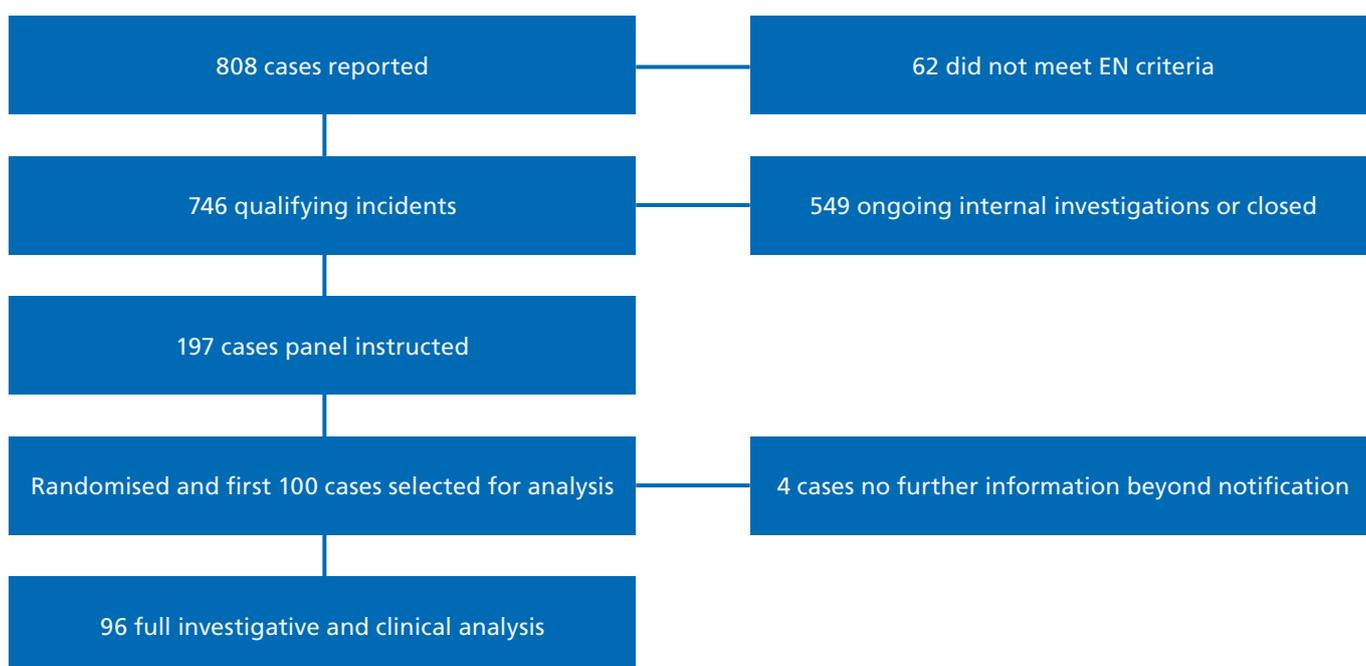
Theme 1: Fetal monitoring

Theme 2: Impacted fetal head and difficult delivery of the head at caesarean section

Theme 3: Maternal deterioration in labour and hyponatraemia

Theme 4: Neonatal resuscitation

Figure 7: Outline of total number of cases reported with incident date from 1 April 2017 to 31 March 2018 and the selection for further analysis within this report



NHS Resolution’s claims management system (CMS) was searched on 28 November 2018 to identify all EN cases, with incident dates between 1 April 2017 and 31 March 2018. NHS Resolution governance processes permitted that a high-risk cohort could be analysed for shared learning within the report, from the 197 cases where panel solicitors had been instructed to perform liability investigations. These cases were assigned a number, sorted numerically and the first 100 cases selected for deeper analysis. The panel firms investigating were asked to complete a standardised data capture pro forma developed by the EN team. This captured anonymised, granular detail including patient demographics, clinical and investigation data.

All 100 completed pro formas were independently checked for quality assurance with further checks where queries arose.

There were four cases in the sample where neither NHS Resolution, nor panel solicitors, received copies of the medical records or any trust investigation report. Therefore, the final analysis comprised 96 cases (figure 7). The analyses build on the previous work published in the NHS Resolution Five years of cerebral palsy claims: a thematic review of NHS Resolution data and while some of the themes are repeated, there were also further insights surfaced in this most recent analysis.

Part 1: Reporting and investigative themes

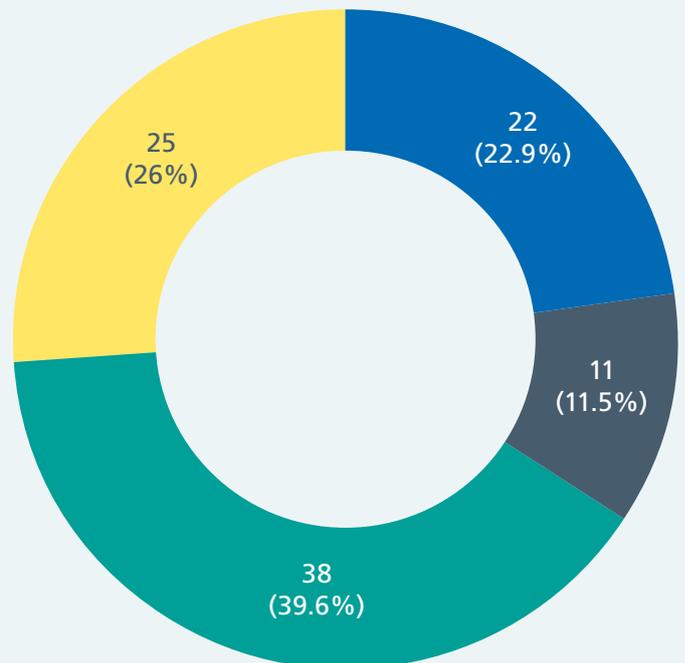
Reporting to NHS Resolution

There was wide variation in the time between an incident occurring and it being reported to the EN scheme. The shortest duration between incident and reporting was two days and the longest was 430 days (median 34 days).

Risk assessment

Figure 8: Preliminary trust risk assessment for 96 cases subsequently referred to panel for liability investigation

- Likely
- Not completed
- Possible
- Unlikely



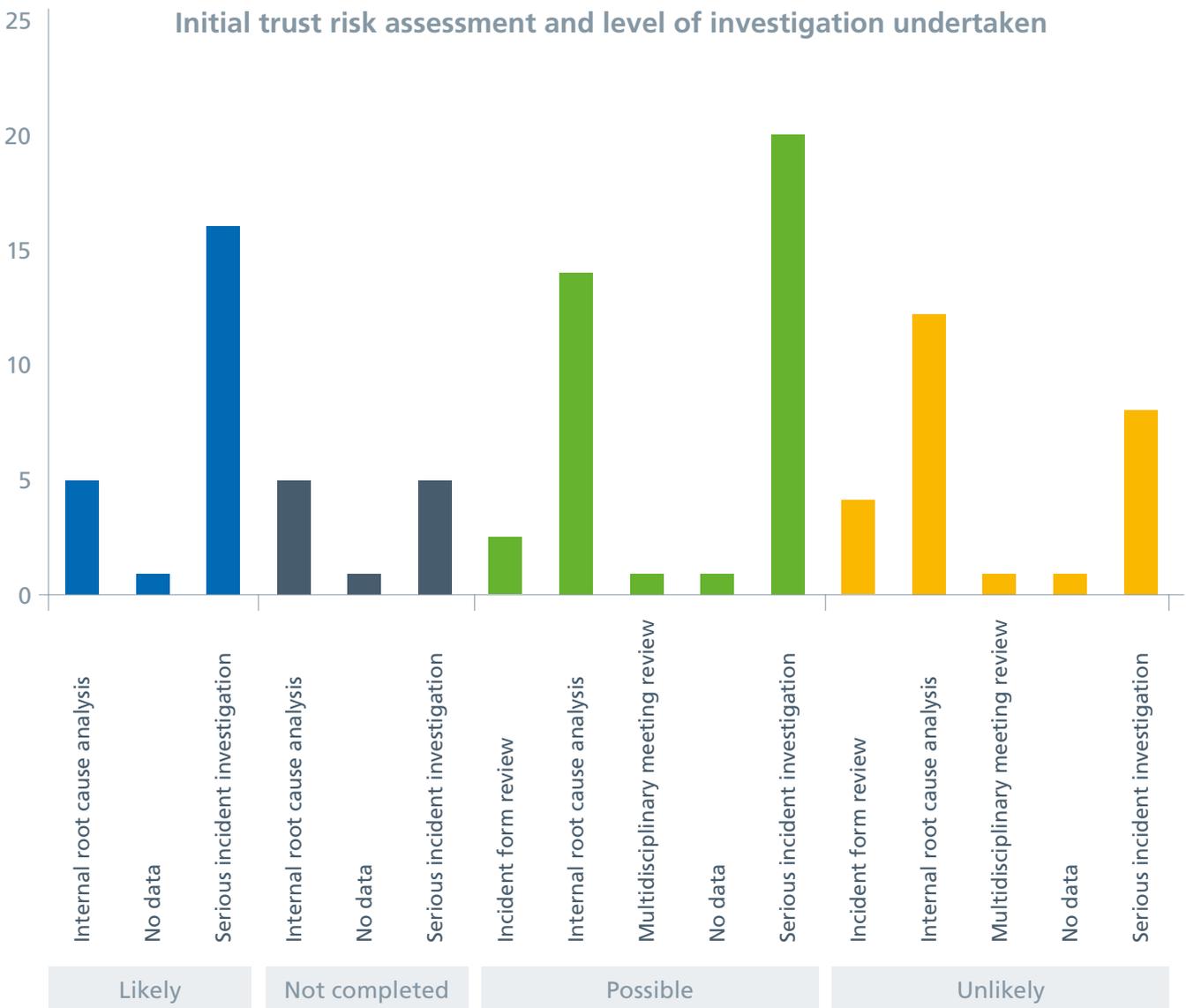
Processing

Following notification, 46 (48%) cases were referred directly to nominated panel solicitors to begin liability investigations. The EN team internally reviewed the remaining 50 (52%) cases. Of these, only 12 (13%) had a complete set of information available at the time of review (defined for the purposes of this analysis as a complete set of maternity notes, any neonatal records held by the trust, any CTG traces and the trust’s final investigation report, if any).

Trust investigative process

There was a local investigation in 96% (92/96) of cases and the methodology employed by trusts is detailed in figure 9. Half overall were externally reported and investigated as serious incidents. The remit of HSIB (see appendix III) includes cases qualifying for EN and therefore, in time, all qualifying cases would be expected to undergo an independent HSIB investigation.

Figure 9: Breakdown of trust investigation methodology according to risk assessment (serious incidents are considered to be investigations externally reported on NHS Improvement’s serious incident reporting framework [StEIS])¹²



Multidisciplinary input in investigations

Of the 92 investigations examined, 39% (36/92) involved input from a neonatologist. Predominantly, this was a consultant neonatologist. This is significantly fewer than reported in the latest EBC report published by the RCOG in 2018 in which 66% of investigations had neonatal involvement⁸.

It is recognised that multidisciplinary involvement in investigations is good practice. All EN babies, by definition of the qualifying criteria, required admission into

a neonatal unit and extensive neonatal care. Therefore we, along with other reports⁷⁻⁸, encourage a broader, more multi-professional approach to investigations.

There was evidence of external/independent peer review in 30% (28/92) of cases. There are known challenges in arranging external panel members to contribute to the investigation process that may explain the lower than anticipated numbers.

Identification of excellence in practice

Examples of excellence in clinical practice documented within local investigation reports were identified in 27% (25/92) of cases. On review they can be grouped into the following broader categories:

Table 2: Examples of excellence in practice documented

Category	Number of times featured
Documentation	3
Response to emergency situation	3
Appropriate plan of care (covers all care episodes)	13
Recognition of risk factors	3
Appropriate discussion of risks with mother	1
Appropriate escalation	2

Theme 1:

Family involvement and candour

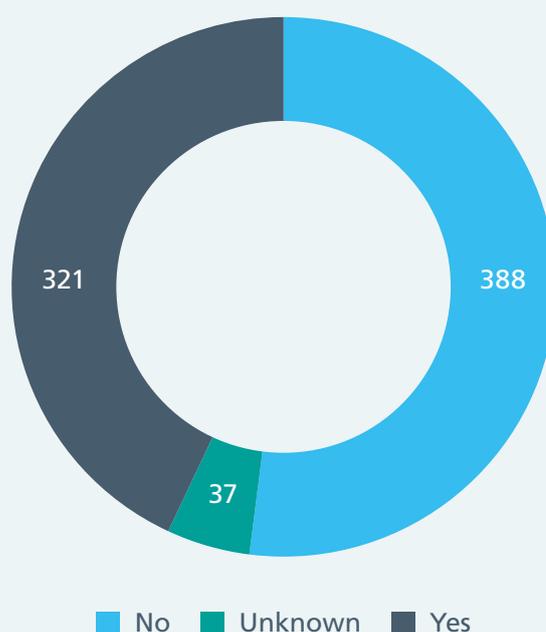
In this cohort, 77% (71/92) of families were notified by the trust that an incident had occurred, and 35% (32/92) were recorded as having been offered an apology. This low figure is concerning. All NHS organisations are required to comply with the duty of candour and urgent action is required by both the trusts and commissioners and the CQC to drive improvement in this area. Nationally there is wide variation in whether a baby requiring therapeutic cooling is considered to meet the need for statutory duty of candour and therefore there is variability in the offer of an apology within discussions. This low figure may represent poor quality of documentation, as well as a failure to offer an apology. However, NHS Resolution advises all trusts that ‘saying sorry’ is always the right thing to do and provides guidance on this issue.

An invitation for families to be actively involved in an investigation was evident for 30% (28/92) of investigations. This is consistent with national publications⁷⁻⁸ although lower than the reported 41% parental involvement evident in the 2016 EBC cohort.⁸

This theme is echoed in the number of families informed of NHS Resolution involvement in their case: 43% (40/92) in year one (figure 10). There is concern that mentioning a legal investigation could give rise to expectations of compensation that may go unfulfilled if the investigation is supportive of the care. However, it is important to note that some families are informed of NHS Resolution involvement after their baby’s care has been reported, so the actual number may be higher. We recognise that on rare occasions, early conversations between clinicians and the family are sometimes brief for compassionate reasons to limit the amount of information they are having to process at a distressing time.

Sample suggested wording has been developed that trusts can use for their own communications to families about NHS Resolution’s involvement and work is ongoing to produce a leaflet to support discussions with families in collaboration with charities, user groups and other stakeholders. In recognition of this challenging aspect of care the EN team also held regional ‘Finding the Words’ workshops developed with the Medical Mediation Foundation specifically to give frontline staff the skills and confidence to have difficult conversations with families and say sorry. This formed part of an offer to support trusts in the practical, local delivery of candour.

Figure 10: Number of families advised of NHS Resolution involvement at time of case reporting to the Early Notification scheme for incidents occurring from 1 April 2017 to 31 March 2018 (n=746)



Trusts are however advised that the involvement of NHS Resolution should be discussed openly with the family, early where possible and in accordance with the statutory duty of candour¹³, the family offered an apology and an account of events. Moreover, there is a responsibility to ensure families know that the wider NHS is working to understand why adverse incidents have occurred and that learning is shared.

Recommendation one

All families whose baby meets the EN criteria and requires treatment and separation from them for a potentially severe brain injury are offered a full, open conversation about their care.

This should include an apology in accordance with the principles of candour, options for their involvement and description of the national agencies involved in investigating their care.

How should this be achieved?

At a national level

NHS Resolution welcomes the current national ambition for universal inclusion of family in the investigation of their care. There is no standard model for family involvement in cases of perinatal morbidity, although the Perinatal Mortality Review Tool (PMRT)¹⁴ is mandated for all cases of perinatal deaths.

Family involvement, in addition to an apology, accords with the statutory duty of candour, as well as contractual and professional or ethical duties of candour^{13,15-17}. The examples in regulation 20 (appendix C) of the statutory duty of candour for maternity do not include therapeutic cooling for HIE; however they are similar in nature and can be generalised to HIE, which is moderate or severe harm in the majority of cases¹³.

National policy and guidance recommend that an apology can be helpful in itself

to maintain good family engagement. Moreover, it helps foster an empathic conversation after an incident. An apology is not an admission of liability and NHS Resolution also recommends apologising with its publication 'Saying Sorry' (appendix III).

Communication and 'difficult conversations' training should form part of national and local training programmes including a curriculum for those discussing care with families who have been involved in harm.

Midwifery staff, neonatal staff, obstetric clinical leads and NHS managers have attended the 'Finding the Words Training' commissioned by NHS Resolution, discussed above. Delegates have expressed how little practical training is available for clinicians in this space despite national recommendations and the

attendee feedback has been extremely positive. We will explore future options for this training as well as promoting engagement from other agencies that can make this type of training more widely available.

At a local level

Local maternity systems and trust leadership should encourage a culture of openness and candour, recognising that the families of all babies who meet the EN inclusion criteria warrant open and inclusive discussions about their care. There should be a review of the training provided to staff members required to have difficult conversations with families and, where appropriate, training should be made available to support staff to get these difficult conversations right.

Theme 2:

Support for staff

Of the 92 cases in which an incident investigation occurred, staff were offered support during the investigation process in only 49% (45/92) of cases. This is similar to the findings in other national reports both in maternity, and the wider NHS^{9, 18-19}.

Examples of support that was offered included staff meeting their named educational supervisor, or midwives meeting with a named manager or professional midwifery advocate (PMA). This was not always for emotional support and particularly in the case of obstetric educational supervisors; the process is not always independent of appraisal and annual review of competence.

There were no documented examples of allied health professionals or non-clinical staff being offered support. In some trusts, any support may be informal or not documented and there may therefore be under-reporting.

There is compelling evidence that healthcare staff involved in serious incidents are deeply affected²⁰⁻²³. Effects range from mild impact on mood, health or work that can be self-managed through to debilitating post-traumatic stress disorder (PTSD) requiring therapeutic intervention²²⁻²³. Recent research in England investigating distress levels in staff has demonstrated that the current provision of support for staff is often inadequate²³⁻²⁴. In addition to the impact on individual wellbeing, midwifery and obstetrics both have high rates of workforce attrition partially attributable to psychological distress, bullying and lack of support²⁵⁻²⁶.

There are national reports recommending a package of post-incident interventions for staff including peer support and counselling services, as well as mandatory educational workshops

to prevent psychological distress²⁴. Where PTSD has developed, there should be referral for psychological assessment and treatment. Non-directive counselling can increase harm in PTSD, and it is essential that support packages are comprehensive, recognise the symptoms of PTSD and have appropriate referral pathways for assessment and treatment²⁷. There have been successful pilots of programmes for UK midwifery staff²⁸ and similar programmes are at a planning stage for obstetricians.

As part of the EN scheme, NHS Resolution offered peer support for all trust staff. However, there has been limited call on this service to date. When the EN team explored this, it was reported that there are already support services, including peer support, available in the system (see appendix II). There is however no evidence widely available on how frequently these services are accessed, or whether they are deemed helpful.

NHS Resolution will continue to provide support and freely available professional advice from a legal, obstetric and midwifery perspective as well as signposting teams to established services. However, it is imperative that action is taken to join up support services, and with NHS trusts recognising and committing to their duty of care to staff. This is vital not only for an individual health professional's wellbeing and ability to provide safe, empathic care but also for the state of the national workforce going forward. Finally, this ambition aligns with both the NHS Long Term Plan and NHS Workforce Plan to support NHS staff better to deliver high quality care.

Recommendation two

An independent package of support should be offered to all NHS staff to manage the distress that can be associated with providing acute health services and in particular those involved in incidents involving possible avoidable harm. Support should address mental health, wellbeing and post-incident care with access to referral for psychological assessment and intervention where required. This should be confidential and independent of appraisal or revalidation processes.

How should this be achieved?

At a national level

In February 2019 Health Education England (HEE) published a report commissioned by the DHSC that reviewed the provision for all NHS staff's mental wellbeing²⁴. It has far reaching recommendations that recognise the urgent need for improvements in the support provided to NHS staff. The recommendations include: the establishment of a workforce wellbeing guardian with board level leadership, dedicated post-incident and mental health support, improvements in rest spaces, and overhaul of occupational health services particularly with regard to mental health referrals.

At a local level

Trusts should review their current support processes. For some trusts, the essence of HEE's recommendations will have already been recognised and put in place; for others it will be a call to action both locally and within the wider commissioning group. Additional services to facilitate support for staff should be seen as an investment in a workforce that will help achieve the ambitions for safer and more personalised maternity care.

A comprehensive package should include psychological therapy services, improvements in occupational health and group reflective sessions for post-incident management.

Examples of group sessions already in use in England with evidence of benefit for participants are Schwartz rounds²⁹⁻³¹ and Trauma Risk Management (TRiM). Schwartz rounds are reflective practice forums for staff from all disciplines to discuss the psychosocial and emotional impact of their work and are supported in the UK by The Point of Care Foundation³². TRiM is a peer-led traumatic stress support package that was developed for UK military services and has been successfully implemented in a number of settings including the NHS and healthcare services³³.

Part 2: Clinical themes

This section reviews the clinical themes arising from analysis of the 96 EN cases in our sample in which panels were instructed and medical records or investigation reports were available for analysis.

Demographics: Antenatal and intrapartum

Table 3: Antenatal booking demographics for 96 women in the high risk cohort analysed

Maternal age (years, range 18–49)	Total number = 96		National average ^{10,34}
<20	4	(4.2%)	2.9%
20–29	47	(49%)	42.2%
30–39	38	(39.6%)	50.6%
40+	4	(4.2%)	4.3%
Unknown	3	(3.1%)	
Booking weight (BMI) range 17–47			
Underweight (<18.5)	1	(1.0%)	7.1%
Normal (18.5–24.9)	40	(41.7%)	45.8%
Overweight (25–29.9)	27	(28.1%)	26.5%
Obese (≥30)	23	(24.0%)	20.6%
Unknown	5	(5.2%)	
Smoking status at booking			
Non-smoker	68	(70.8%)	82.1%
Smoker	12	(12.5%)	12.2%
Unknown	16	(16.7%)	5.7%
Booked for antenatal care			
Booked ≤12 weeks gestation	80	(83%)	78%
Booked >12 weeks gestation	15	(16%)	22%
Unbooked	1	(1%)	
Parity			
0	67	(69.8%)	39.7%
1	17	(17.7%)	35.9%
≥2	12	(12.5%)	24.4%

Table 4: Risk factor categorisation at antenatal booking and breakdown of documented risk factors (n=96)

Risk at booking		
'Low risk' pregnancy	62	(64.6%)
'High risk' pregnancy	34	(35.4%)
Risk factors (not mutually exclusive)		
Pre-existing medical condition (DM 1, HTN 1, Severe asthma 1, CKD 1, UC 1, CHD 1)	6	(6.3%)
Previous obstetric history (previous CS 4, GDM 2, previous SGA 1)	5	(5.2%)
Raised BMI >35	11	(11.5%)
Anaesthetic issues	0	
Social issues	4	(4.2%)
Other: Maternal mental health 3, advanced maternal age 4, late booker 1	8	(8.3%)

(DM – diabetes mellitus, HTN – pre-existing hypertension, CKD – chronic kidney disease, UC – ulcerative colitis, CHD – congenital heart disease, CS – caesarean section, GDM – gestational diabetes mellitus, SGA –small for gestational age)

The antenatal demographics for the cohort are demonstrated in tables 3 and 4. Younger and overweight mothers are slightly overrepresented in the cohort compared to national figures. Babies born to nulliparous mothers are overrepresented making up 70% of this cohort compared to 40% nationally³⁴.

Intrapartum demographics

Table 5: Intrapartum demographics

	Study cohort n=96 (%)		National average ^{10, 34-35}
Gestation (weeks)			
37–39	41	(42.7%)	48.6%
40–42	55	(57.3%)	43.2%
Place of birth			
Standalone midwifery led unit	2	(2.1%)	1.6%
Alongside midwifery led unit	7	(7.3%)	10.2%
Obstetric unit	85	(88.5%)	86.6%
Home (unplanned)	2	(2.1%)	
Planned home birth	0		1.4%
Onset of labour			
Spontaneous	58	(60.4%)	52%
Induction of labour	35	(36.5%)	32%
Not in labour	3	(3.1%)	NA
Mode of birth			
Spontaneous vaginal birth	25	(26%)	58.2%
Vaginal breech	4	(4.2%)	0.4%
Instrumental birth	18	(18.8%)	12.5%
Emergency C-section	49	(51%)	16.2%
Elective C-section	0		12.6%

(C-section – caesarean section, NA – not applicable)

Fourteen women (14.6%) were transferred in the peripartum period. One mother and baby were transferred following birth for ongoing neonatal resuscitation. The remaining thirteen transferred in labour, eleven from alongside midwifery led units, one from a free-standing midwifery led unit and one from home.

The reasons for intrapartum transfer were:

- Maternal indications – vaginal bleeding, abnormal observations (2/13)
- Slow progress in labour (5/13)
- And/or suspicion of fetal compromise (6/13).

Transfer was considered delayed (>60 minutes) and to have had a negative impact on outcome in four cases (31%); two cases

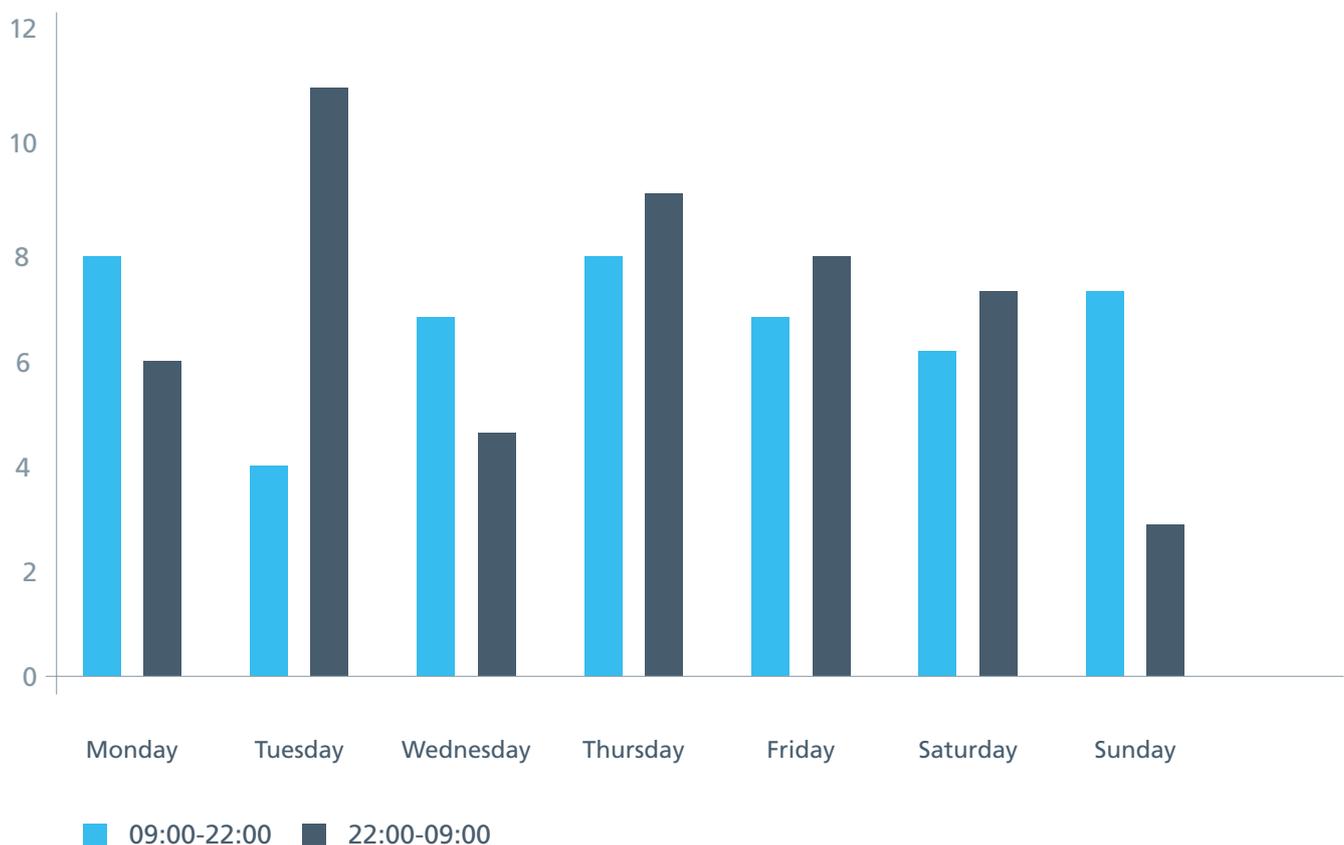
requiring transfer from home or standalone unit and two from an alongside unit.

Births from 40⁺⁰ weeks gestation to 42⁺ weeks were overrepresented, 53.8% (7/13) compared to 43.2% of births nationally³⁴ occurring beyond 40⁺⁰ weeks gestation.

The average gestation at birth of 37 weeks or less in multiple pregnancies means that they are largely excluded by the qualifying criteria for EN and as a result, singleton pregnancies are overrepresented – 100% of this cohort of 96 cases.

There were no babies born by elective caesarean section in the sample, as the scheme is limited to intrapartum care.

Figure 11: Day of week and time of birth in two time cohorts, 09:00 – 22:00 and 22:00 – 09:00 (n=96)



Two arbitrary time periods were selected to represent time of birth based on typical working day and way in which time of birth data was collected. The daytime period from 09:00 hours to 22:00 hours incorporates the typical working day, evening handover and typical consultant daytime presence in units without resident consultant night cover; although we recognise this is not completely consistent nationally. The 22:00 hours to 09:00

hours period reflects the typical time frame of a night shift and the morning handover period that can vary from 07:00 hours to 09:00 hours, depending on weekend versus weekday rotas and variability in combined multi-professional handovers versus separate handovers.

These figures resonate with other national reports.



Summary of clinical and contributory care factors

Contributory factors remain diverse and multifactorial. Our findings confirm there is most often more than a single contributory factor, and this resonates with the findings in the latest EBC report where on average seven critical contributory factors can be identified in cases where different care may have changed the outcome⁸. Unfortunately, the quality of some local investigations and/or the availability of these to NHS Resolution limit the analysis performed by the EN team.

Although independent experts will be instructed to comment on the care provided, the focus of their reports will be to determine whether the legal duty and standard of care was breached, rather than to provide a system-based understanding of why any harm might have occurred.

This issue has been recognised in previous national reports and provided much of the impetus for the standardised approach to investigations and learning proposed by HSIB.

Table 6: Known peripartum clinical or care factors believed to have had an impact on neonatal outcome

	Number n=96 Not mutually exclusive		National average ^{8, 10, 34-35}
Delay in birth	60	(62.5%)	41%
Problems with fetal monitoring	67	(69.8%)	81%
Recurrent reduced fetal movements	18	(18.8%)	Not known
Shoulder dystocia	5	(11.6% vaginal birth)	0.58–0.7% (of vaginal birth)
Cord prolapse	1	(1.0%)	0.1–0.6%
Placental abruption	9	(9.4%)	~3–5%
Vaginal breech birth	4	(4.2%)	0.4%
Failed instrumental birth	11	(11.5%)	6.5–9.5% (of attempted)
Uterine scar rupture	2	(2.1%) [25% of VBACs in cohort 2/8]	0.2–0.7%
Difficult delivery of the head at C-section	9	[18.4% of all caesarean births]	Not known
Evidence of infection in labour	15	(15.6%)	Not known

(VBAC – vaginal birth after caesarean section)

Vaginal breech birth

Vaginal breech birth appears to be overrepresented in this sample – 4% compared to a 0.4% prevalence nationally¹⁰. The NHS Resolution report *Five years of cerebral palsy claims*⁹ identified 12% of cases involved vaginal breech birth. This may be related to the small sample size or potentially that practice around vaginal breech birth in the last five years may have improved. Of note: the national guidance for breech birth⁴² was updated in early 2017 to include recommendations to reduce the duration between birth of the buttocks and head as well as updates on maternal position in breech labour among other elements of care.

In this cohort all the vaginal breech births were unplanned, three were in spontaneous labour, and none of the women had an opportunity to make an informed choice regarding their mode of birth. Three women who laboured spontaneously gave birth in standalone

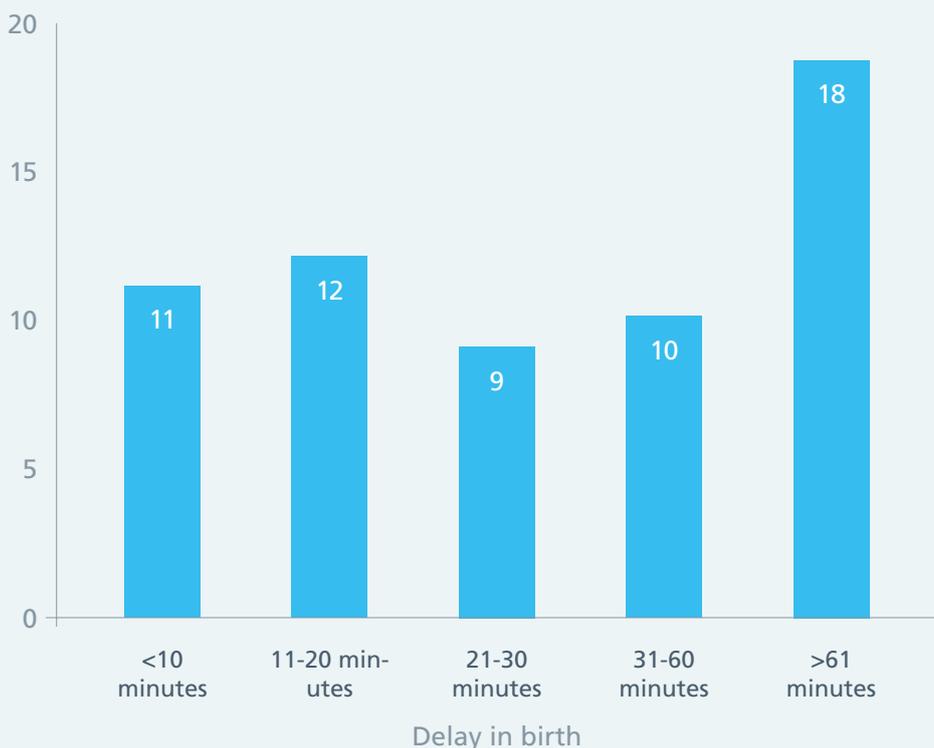
midwifery led units or were unplanned home births. All four babies had abnormal cerebral function monitoring during the neonatal period with three having clinically evident seizures and of the two where magnetic resonance imaging (MRI) report findings were known, both had features of hypoxic injury.

Strategies to increase the detection of breech presentations should be considered; a recent paper identified that universal late pregnancy ultrasound for presentation in nulliparous women would virtually eliminate undiagnosed breech presentation and would also be cost effective.⁴³

Delay expediting birth

Of the 96 cases analysed, in 60 (63%) there were identified avoidable delays expediting the birth that impacted on outcome.

Figure 12: Number of cases in which there was a delay in birth that impacted on outcome, and the estimated time delay



This breakdown generally included two scenarios: 0–20 minute delays in the event of fetal bradycardia and longer delays with abnormal fetal heart tracings that do not mandate category 1 birth for example, category 1 C-section⁴⁴, however earlier birth may have impacted on outcome.

Two avoidable scenarios were common in the event of fetal heart rate bradycardia:

1. Assumption that loss of the fetal heart recording is an equipment failure whether by CTG or fetal scalp electrode (FSE) rather than bradycardia.
2. Bradycardia in the second stage of labour, where the team expect the baby to be born spontaneously ‘any minute’ when in reality the birth could have been expedited, thereby reducing the duration of exposure to a potentially damaging fetal bradycardia and hypoxia.

There were also delays acting on abnormal antenatal CTGs.

Overall, the most common contributing factor was delay in escalation of, or delay in acting on, a CTG abnormality – 20% (12/60).

Other potentially important factors identified included:

- delay in achieving adequate analgesia
- delay in the after-coming head in a vaginal breech birth
- issues with availability of theatre
- transferring to labour ward rooms in event of bradycardia (instead of straight into an operating theatre)
- team communication problems

Fetal growth surveillance

Overall, 16% (15/96) of babies in the cohort were identified as being small for gestational age (SGA) at birth, defined in this analysis as those babies born with a birthweight of less than the 10th centile (customised or national) or less than 2500 grams. Of these, 33% (5/15) were detected antepartum. This group had an average maternal age of 28 (range 21–39), maternal BMI of 27 (range 17–42), 67% (10/15) were women with stated ethnicity as white British and 33% (5/15) of mothers smoked at antenatal booking, which is more than double the national figure for smoking at booking¹⁰.

Based on version one of the Saving Babies’ Lives care bundle⁴⁵ and the RCOG SGA Green-top guidance⁴⁶, 34% (33/96) of women in the whole cohort were identifiable as having risk factors for an SGA baby at booking. This included women with BMI greater than 35 and smokers. Of this group with risk factors, 27% went on to give birth to a baby who was SGA. However, 36% of the women with risk factors (12/33) did not receive the recommended enhanced surveillance with third trimester growth scans^{45, 46}. These women had single risk factors for SGA, e.g. BMI of greater than 35, smokers without additional risk factors, and/or maternal age 40 years or above, that may have been missed.

Risk assessment forms a key element of fetal growth surveillance in the recently published second version of NHS England’s Saving Babies’ Lives care bundle⁴⁷ and it is important for regional leads to raise awareness with NHS commissioners and providers that women with increased risk factors require the surveillance recommended in the Saving Babies’ Lives care bundle.

Finally, we will collaborate with other national academic partners, including the new Tommy’s Centre for Maternity Improvement, the royal colleges and NHS England to develop a digital platform to improve personalisation of risk and care for both women and the service.

Neonatal outcome

Table 7 gives an overview of the neonatal outcomes for the 96 babies in the high-risk cohort of cases. 81 babies had an MRI of their brain in the neonatal period – on average on day eight of life (range 2–26 days). These data demonstrate that approximately one third of cases had either abnormal neurology on discharge home with evidence suggestive of a hypoxic injury on MRI or a diagnosis of hypoxic ischaemic encephalopathy (HIE) grade III.

Male infants are overrepresented in the cohort with 61.5% of affected babies being male compared to 51.3% male infant births in England in 2017.³⁴

Table 7: Breakdown of neonatal demographics and outcomes (n=96)

Gender	
Male	59 (61.5%)
Female	37 (38.5%)
Abnormal neurology on examination at discharge	
Yes	36 (37.5%)
No	32 (33.3%)
Not known	28 (29.2%)
MRI findings (81 MRIs performed) – not mutually exclusive	
Hypoxic injury (subtype not specified)	37 (39%)
Acute/profound hypoxic injury	13 (13.5%)
Chronic/partial hypoxic injury	4 (4.2%)
Normal	22 (22.9%)
Findings not known	14 (14.6%)
HIE diagnosis at discharge	
HIE I	13 (13.5%)
HIE II	25 (26.1%)
HIE III	32 (33.3%)
No HIE	8 (8.3%)
Not known	18 (18.8%)

The next chapter reviews four key clinical themes and recommendations from the analysis and also includes some emerging themes that have been identified by the EN team during the analysis of EN cases.

Theme 1:

Fetal monitoring

In our cohort of 96 high risk cases, 70% (67/96) were identified to have included complications with fetal monitoring in whichever form it was undertaken and in 84% (56/67) the complications were linked to the adverse outcome for the infant.

Problems with interpretation of the fetal heart rate as a single factor are rare and multiple problems with fetal monitoring are often identified simultaneously. Sixty-three per cent (42/67) had two or more adverse factors involving fetal heart monitoring as identified by experts. Most common in this cohort was:

- delay in acting on an abnormal/pathological CTG or abnormal fetal heart on intermittent auscultation (51.7%)
- delay in escalation (44.6%)
- incorrect classification (42.8%)

These figures highlight that human factors, including escalation, communication and timely decision-making, are as important for good care as classification of the CTG. Future research and interventions may usefully focus on the socio-technical issues around fetal monitoring, rather than focusing on technical solutions alone for which the evidence is not conclusive⁴⁸. Our findings resonate with the most recent EBC report⁸.

Problems with fetal monitoring persist as the major contributing factor in poor outcomes at birth. This has previously been identified in numerous national publications^{7,8,49}, as well as previous reviews of legal cases^{9,50}. These problems persist despite widespread initiatives and recommendations to improve

interpretation, classification and documentation of CTGs⁵¹ as well as nationally mandated training and competency assessment^{45,47}.

However, current approaches to CTG classification, training and competency testing are heterogeneous in both content and format and there are currently no data with any predictive validity to inform the assessment of competence or thresholds.

Interpreting and reacting to a CTG trace is a complex socio-technical process involving individuals from multiple professions and disciplines, taking place over a number of stages and in highly pressurised contexts. Given this, it is possibly not surprising that purely technical interventions and individual-based training have not fully addressed these challenges. We concur with a research team from THIS Institute (<https://www.thisinstitute.cam.ac.uk/research-projects/improving-electronic-fetal-heart-monitoring/>) who have proposed that understanding what can go wrong when electronic fetal monitoring is used requires full characterisation of the work and social practices involved, the multiple professions who conduct such practices, and the context where the process takes place.

Antenatal CTG

In addition to fetal monitoring in labour we have identified an important but small number of cases where the interpretation, escalation and management of the antepartum CTG has been a significant failing in care. This was not identified prior to data collection for this analysis and therefore we are unable to quantify incidence for this report.

Antenatal CTG interpretation has been previously identified as a problem⁴⁹. A Cochrane review has demonstrated that the use of computerised CTGs antenatally conferred a five-fold reduction in perinatal mortality compared to traditional CTG⁵². There may be similar benefits for care with perinatal mortality and the latest version of the Saving Babies’ Lives care bundle recommends increased use of computerised CTGs⁴⁷.

Table 8: Demonstrates the method of fetal monitoring used in the cohort. There are two women who had no fetal monitoring due to unplanned and unattended home birth.

Method of fetal heart monitoring		
CTG alone	65	(67.7%)
Intermittent auscultation followed by CTG at some point in labour	20	(20.8%)
Intermittent auscultation alone throughout	6	(6.3%)
No fetal heart monitoring	2	(2.1%)
Unknown method	3	(3.1%)
Total	96	

Recommendation three

There is an urgent need for a standard approach to fetal monitoring based on the NICE guidance. Computerised CTGs should be used for antenatal assessment.

Effective improvement strategies for fetal monitoring require in-depth understanding of the technical and social mechanisms underpinning the process and there should be more research in this area.

How should this be achieved?

At a national level

Policy makers, academic partners and NHS bodies should collaborate to commission national research for in-depth understanding of the technical and social mechanisms underpinning the fetal monitoring process, and its current issues.

NHS Improvement through Workstream 2 of the Maternity Transformation Programme (MTP) – promoting good practice for safer care, will in 2019/20 lead on developing a national standardised core competency curriculum for maternity which aims to address some of these issues.

The second iteration of the Saving Babies' Lives care bundle⁴⁷ also strengthens the requirement for CTG interpretation training, competency assessment and 'buddying' as well as the introduction of Fetal Monitoring Leads for each trust. These actions are supported by NHS Resolution's maternity incentive scheme. However, trust feedback has highlighted a lack of clarity or evidence for specific methods of CTG training and competency assessment to use, leading to significant

variation. The Fetal Monitoring Lead introduced by the new version of the bundle could play a key role in informing a wider piece of work on what the current fetal monitoring practices are in England as well as supporting safer practice.

NHS Resolution also welcomes the updating of NICE 'Intrapartum care for healthy women and babies' guidance that was announced in February 2019 and the invitation to inform this update with learning from EN cases and claims.

We will also collaborate with the research team at THIS institute to improve our understanding of the issues around CTGs and fetal monitoring.

At a local level

Local Maternity Systems to further support uptake of the Saving Babies' Lives care bundle including recommendations for trusts to use computerised antepartum CTG and the nomination of a Fetal Monitoring Lead to improve local implementation of fetal monitoring guidance in addition to championing training and the culture

around fetal monitoring locally, including appropriate escalation. This will require support from clinical commissioning groups (CCGs) for funding and procurement.

At trust level, maternity safety champions should monitor safety and outcomes in services regularly drawing on data from national reports including those from EBC, MBRRACE-UK and NHS Resolution as well as findings from local incidents. There should be close working with Fetal Monitoring Leads. The trust board should have oversight of local outcomes and safety data through the maternity safety champion and ensure that appropriate action is taken to address concerns.

Trust boards should encourage and support an open culture including publication of local indicators, including neonatal outcomes such as HIE and the need for therapeutic cooling at term. Caveat: we recognise there are different thresholds for therapeutic cooling in different units across the UK. Indicators can be subject to benchmarking and external scrutiny.

Theme 2:

Impacted fetal head and difficult delivery of the fetal head at caesarean section

Difficult delivery of the fetal head and/or an impacted fetal head at caesarean section is an emerging problem in our Early Notification sample and nationally. This has been recognised in the wider system, where the National Institute for Health Research (NIHR) has awarded funding to determine the feasibility of future trials and other UK groups are conducting research in this area. The UK Obstetric Surveillance System (UKOSS) has also recently launched this as a subject for surveillance and will be collecting data on cases from 1 March 2019 for six months.

However, the reasons underpinning this increase in problems are not clear; theories include possible contributory changes in obstetric management, including increasing rates of induction of labour, prolonged labour, Syntocinon use, full dilation caesarean section and changing training and/or the skill set of obstetricians conducting caesarean sections.

Difficult delivery of the head or impacted fetal head was encountered in 9% (9/96) of cases. As a comparator, shoulder dystocia complicated 12% of all vaginal births in the cohort. There are established national training and management protocols for shoulder dystocia that have been

associated with improved care and reduced avoidable harm⁵³. There are currently no such protocols for impacted fetal head, although the RCOG has committed to commission and publish a Scientific Impact Paper for impacted fetal head to address this.

Of the nine cases there were no positive correlations with birthweight or maternal BMI; however there are too few data for any epidemiological analysis. All nine babies weighed less than 3700g at birth with a maximum maternal BMI at booking of 28. All mothers were white British or white European ethnicity from booking data and the nine cases were equally distributed across the South, London and Midlands and East regions with no cases from the North of England.

Forty-four per cent had a failed forceps attempt prior to emergency caesarean section. Counterintuitively, there were no cases of failed ventouse, or multiple instrumentation. In 56% of cases the mother's labour was induced and 67% had Syntocinon administered as part of induction or augmentation of their labour.

Recommendation four

Increase awareness and research to understand the prevalence, cause and management of impacted fetal head and difficult delivery of the fetal head at caesarean section. Standardise taxonomies for impacted fetal head and difficult delivery of the fetal head at caesarean section to improve generalisability of research.

How should this be achieved?

At a national level

NHS Resolution welcomes the work being carried out by academic partners nationally in this area and as an organisation we are committed to sharing intelligence from claims and improving internal processes to make this more accessible and efficient while protecting claimant confidentiality.

We will work with the royal colleges and academic partners to understand the problem and develop evidence-based guidance on management protocols and skills drills for impacted fetal head. This should also be considered in curricula for obstetric trainees.

As for shoulder dystocia, clear protocols and training can improve management in time pressured and stressful situations that can reduce the harm associated with similarly unpredictable events.

At a local level

Services managers, trainers and practice development teams consider what guidance and supervision is in place to train obstetricians in how to release an impacted fetal head. Consider including a scenario in local multi-professional simulation training for difficult delivery of fetal head at caesarean section.



Theme 3:

Maternal deterioration in labour and hyponatraemia

Intrapartum maternal medical emergencies

In this cohort of mothers, 6% (6/96) experienced a concurrent maternal medical emergency in labour. In five of these six emergencies, it was considered that there were avoidable delays acting on the emergency, or inappropriate action taken to address it that impacted on the outcome for the baby.

Maternal and neonatal hyponatraemia

In particular, significant maternal hyponatraemia (serum sodium <130 mmol/L) appears to be an emerging issue in labour, with concurrent hyponatraemia in the newborn and neonatal seizures. It is not clear if this has been a longstanding but under recognised problem or is a secondary effect. Examples of activities that may have impacted include healthy living promotion to increase daily water consumption, guidance suggesting increased maternal fluid infusion can impact on fetal heart patterns in labour and improvements in sepsis management in labour with fluid resuscitation.

There has been a small but consistent reporting of cases particularly from the South of England and London and we are aware of six cases of significant concurrent maternal and neonatal hyponatraemia within EN qualifying cases to date. This had not been considered when the data collection pro forma was developed, and a complete dataset to fully understand the prevalence is not known. Often the low sodium level is evident on review of the baby's cord gas blood results but not immediately recognised for either mother or baby.

There are no recently reported prevalence rates within the general English maternity population, although in a European cohort of women who received more than 2500mls of ingested or intravenous fluid during labour, 26% were hyponatraemic⁵⁴. It is probable that the full extent of asymptomatic hyponatraemia with potential for deterioration is not understood but awareness is increasing^{54,55}. Clinicians in Northern Ireland have recently recognised the deficiency in guidance on hyponatraemia for labouring women. With funding from the Guidelines and Implementation Network (GAIN) in Northern Ireland they have published guidance that is relevant and useful for birth settings in England⁵⁶.

Hyponatraemia is not an isolated issue, it links into the importance of skilled vital signs observation, fluid balance monitoring and vigilance for deviation from normal with timely escalation that is essential in all birth settings from home to obstetric led units. This is rooted in ongoing risk assessment throughout labour and the challenge is achieving this without impacting on birth experience.

Recommendation five

Ongoing work to improve the detection of maternal deterioration in labour, understand monitoring practices, use evidence-based guidance and ensure these are implemented in all birth settings. Further research is required to understand the prevalence and cause of significant intrapartum hyponatraemia.

How should this be achieved?

At a national level

NICE have committed to review the guidance on intrapartum care for healthy women and babies⁵⁷ and NHS Resolution welcomes their invitation to inform this update with learning from claims data. In addition, there is a commitment to work with the royal colleges, academic partners and policy makers to share learning from claims and particularly EN cases. The ongoing work of the Maternal and Neonatal Health Safety Collaborative is also vital and we welcome evaluation of the changes made and impact on safety to inform future practice. Key work of the Safety Collaborative related to this recommendation will be work on prevention, recognition and response to the deteriorating mother. It is hoped that changes made from this programme are supported at a regional and national level such that they are sustainable where evidence demonstrates an impact on reducing harm. Nationally we should look to use quality guidance already in existence – for example by promoting the Northern Ireland guidance⁵⁶ to improve standardisation and avoid duplication of efforts unnecessarily.

At a local level

Escalate the early recognition and management of the deteriorating mother as a driver for quality improvement work as part of the trust's engagement with the Maternal and Neonatal Health Safety Collaborative. One aspect of this could be to review and update fluid balance monitoring and guidance in labour for all birth settings within a trust and regionally within the LMS. Fluid balance monitoring is notably absent from partograms, particularly those used in low risk birth settings, but is especially important in relation to hyponatraemia and oral fluid intake as well as monitoring bodily fluid loss and management of suspected sepsis. Trusts and LMS's could consider whether the NI GAIN guidance⁵⁶ is transferrable to their unit and implements its recommendations.

Theme 4:

Neonatal resuscitation

Neonatal care is rarely the focus of investigations at a local level or when care is being reviewed from a legal liability perspective. Despite this, in 32% (31/96) of this high risk cohort there were problems in neonatal care that were considered to have contributed to the outcome. These findings are comparable to the 27% identified in the latest EBC report⁸. Approximately half (15/31) were specifically related to resuscitation.

Issues included seniority of the neonatal clinicians attending the birth, communication between professionals, timely calling and arrival of neonatologists, inappropriate airway management or newborn life support technique, equipment failings or lack of timely escalation when further assistance was required.

There has been significant progress and attention in recent years on the national maternity and neonatal safety agenda, but with limited reference to immediate neonatal care and resuscitation. In part, this is a system-wide failure to always work collaboratively and is reflected in the limited involvement of the whole multi-professional team in maternity incident investigations. In this cohort of babies who were all born alive and required significant input of neonatal clinicians, there was no evidence of neonatal involvement in 61% (56/92) of investigations.

Table 9: Neonatal care and clinical factors associated with outcome for the 96 babies in the cohort (not mutually exclusive)

	Number (%)	
Neonatal care or resuscitation	15	(15.6%)
Meconium aspiration syndrome	20	(20.8%)
Small for gestational age	15	(15.6%)
Hypoglycaemia contributing to outcome	8	(8.3%)
Jaundice contributing to outcome	8	(8.3%)

Recommendation six

Awareness of the importance of high quality resuscitation and immediate neonatal care on outcomes for newborn infants. This requires collaboration of the whole multi-professional team in setting maternity safety agendas, guidance, investigations and local protocols recognising that neonatal and allied specialties such as anaesthetics are intricately linked with safe maternity care.

How should this be achieved?

At a national level

Policy makers and national bodies are consistent in recommending neonatal involvement and engagement to inform future work improving the safety of maternity care. There have been a number of initiatives that have improved care, particularly transitional care for babies. However, there has been limited work guiding the systems that support immediate care and resuscitation of the newborn outside that done by the Resuscitation Council (UK).

NHS Resolution recognise this within our own organisation, and we are working towards greater representation within our clinical advisory group. The importance of neonatal medical staffing and mandatory training can also be incentivised and recognised within the maternity incentive scheme and updates in the safety actions for year three are in development.

At a local level

Consider what communication and escalation pathways are in place locally and work across multi-professional teams to improve them. For example, embedding a Situation-Background-Assessment-Recommendation (SBAR) model for requesting neonatal attendance at births or other ways of adapting emergency calls that give clear instruction on the level of neonatal expertise required. Efficient, skilled team working can also be supported by inclusion of neonatal teams in relevant maternity emergency simulation training and skills drills.

Conclusions

This report provides a preliminary exploration of the EN scheme, an innovative scheme in this area of legal practice. The scheme arose from a national focus on safer, kinder and more personalised maternity care, along with the need to reduce the cost of preventable harm to both families and society. The scheme also brings together all the functions of NHS Resolution to provide expert advice, fair resolution, and share learning from harm.

The data in this report present a national view of the number of babies unexpectedly requiring treatment for a potential severe brain injury, following labour, at term, from 1 April 2017 to 31 March 2018 and how a number of these cases have translated into preliminary liability investigations.

Early admissions of legal liability for substandard care have been made in 24 cases to date. This is 24 families that we have been able to provide with early answers to their questions, financial support and interventions that provide them with a degree of closure. These admissions were made from three months to two years from the incidents, which is unprecedented in this area of complex clinical claims and demonstrates the benefits of getting closer to incidents and utilising skills across the organisation to trial innovative solutions in case management. Prior to EN, in a significant number of cases NHS Resolution would not have been made aware of the incident until solicitors, instructed by the family, made a request for disclosure or possibly served a letter of claim. This may have been preceded by an arduous journey to get answers and the passing of a number of years. In contrast EN has achieved the key aim of providing families with essential support as early as possible.

It is hoped that this process has simultaneously reduced the burden on staff involved in recounting events, avoiding protracted legal investigations and attending court.

This report has included an analysis of a cohort of the most high-risk cases, from a legal perspective, reported to the scheme. The antenatal, intrapartum and neonatal demographics demonstrate a cohort in which first-time mothers, male babies and those who were born beyond 40 weeks gestation compared to national data are overrepresented. Six investigative and clinical themes are explored including some new and emerging themes of impacted fetal head at caesarean section and maternal and neonatal hyponatraemia.

Key recommendations include: a national call for a better understanding of how best to reduce the recurring issue of fetal monitoring as a factor in harm as well as more research to identify the staffing required to provide high quality maternity care and support for an independent programme of staff wellbeing interventions to reduce the psychological distress that may occur through providing acute maternity care.

The experience of EN is that the first step, namely recognition of harm, is not always straightforward. The majority of qualifying incidents fall under the therapeutic cooling criteria, and while this provides a reasonably clear indication of the condition of baby at birth it does not always equate to long-term injury. In the absence of national thresholds for therapeutic cooling, there also remains local and regional variation in the babies selected.

The EN team will continue to work across the system, collaborating with other national NHS bodies, the royal colleges, user groups, charities and trusts in England to share learning from EN cases. In addition, we will continue to work closely with key stakeholders to reduce the burden of reporting incidents.

NHS Resolution is also committed to developing existing databases and governance processes so that we can work with academic partners to improve the access to and quality of claims data for learning.

We will continue to drive timely and early resolution of cases to benefit both families and staff, translate our data into information for the wider NHS and incentivise providers to deliver safe maternity and neonatal services.

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- Professor Jacqueline Dunkley-Bent OBE, Professor of Midwifery, Chief Midwifery Officer, Head of Maternity, Children and Young People at NHS England, and National Maternity Safety Champion for the Department of Health and Social Care
- Michelle Upton, Head of Maternity and Neonatal Transformation Programmes, NHS Improvement
- Dr Edward Morris, Consultant Gynaecologist, Vice President Clinical Quality at Royal College of Obstetricians and Gynaecologists.

All NHS Resolution panel firm solicitors.

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Appendix I – Support services for families

Following is a list of organisations and charities that can provide emotional, practical and legal support to families.

Bliss

Bliss provides emotional and practical support to the families of babies born prematurely or sick. Their helpline is open Monday to Friday between 10am and 12pm and again between 7pm and 9pm. Call 0808 801 0322 for information and support. Support is also available via email (hello@bliss.org.uk). Alternatively, visit <https://www.bliss.org.uk/parents/support/support-in-your-area/support-in-your-area-map> to see what face-to-face support is available in your area.

Sands

Sands provides support to anyone affected by the death of a baby. Their helpline is open from 9.30am to 5.30pm Monday to Friday and also between 6pm to 10pm on Tuesday and Thursday evenings. Call 0808 164 3332 or email helpline@sands.org.uk. Sands also provides an app, designed to provide bereaved families with information and support.

Rainbow Trust

Rainbow Trust provides emotional and practical support to families whose son or daughter is affected by a life-threatening or terminal illness. This includes parents, carers, the unwell child, brothers, sisters, grandparents and help with extended family members to support each other. Any family can receive support from the moment of their child or young person's diagnosis (including antenatal and neonatal periods when diagnosis has been made). Anyone can refer a family to Rainbow Trust (for example, a family member, friend, health, education or social care professional) provided consent from the family has been given for the referral to be made. Details of how to apply for support can be found at <https://rainbowtrust.org.uk/support-for-families/ask-for-support>.

Action against Medical Accidents (AvMA)

AvMA is a charity focusing on patient safety. Self-help guides are available on its website, including information about how to make a legal claim for compensation, including a specific guide to birth injuries available at https://www.avma.org.uk/?download_protected_attachment=Claims-for-birth-injuries.pdf. AvMA can also put families in touch with solicitors specialising in clinical negligence. Their helpline is open between 10am and 3.30pm, Monday to Friday. Call 0845 123 2352.

NHS Improving Access to Psychological Therapy (IAPT)

The NHS provides free access to psychological therapy on a regional basis through the IAPT service. This can be accessed by the following link and services in your area located including self-referral details – [https://www.nhs.uk/Service-Search/Psychological-therapy-\(NHS-IAPT\)/LocationSearch/396](https://www.nhs.uk/Service-Search/Psychological-therapy-(NHS-IAPT)/LocationSearch/396).

The Samaritans

The Samaritans provide a free 24-hour listening and advice service 365 days a year. They can be contacted from any phone anytime by calling 116 123 from the UK and Republic of Ireland.

Appendix II – Support services for staff

Following is a list of supportive services for NHS staff provided by professional organisations, social media and charities, as well as those available to the public.

The Royal College of Midwives (RCM)

The RCM is able to provide support to members on a wide range of issues including employment, professional regulation, whistleblowing, clinical negligence, and harassment and bullying. This is largely provided through elected workplace representatives with the support of full time regional and national officers. Details of workplace representatives can be obtained by contacting the RCM on: 0300 303 0444.

The Royal College of Obstetricians and Gynaecologists (RCOG)

The RCOG provides a supporting doctors peer-to-peer support service for members and trainees. Further information on the support available can be accessed at <https://www.rcog.org.uk/en/careers-training/workplace-workforce-issues/supporting-our-doctors/support-members-trainees/>. This includes a link to submit an enquiry form logging a request for support in addition to details on Workplace Behaviour Champions in your own or a neighbouring region.

The British Medical Association (BMA)

The BMA offers a counselling service and a peer support service to provide help, personal support and counselling to doctors (including those who are not BMA members). The counselling service is staffed by members of the British Association for Counselling and Psychotherapy and counsellors are bound by strict codes of confidentiality and ethical practice. Telephone counselling is available 24 hours a day, seven days a week. In addition, the counselling service can offer up to six structured telephone or video counselling sessions.

The peer support service puts doctors and medical students in touch with another doctor for confidential peer support, with an emotional focus. Both services can be accessed by calling 0330 123 1245 and further information is available at: <https://www.bma.org.uk/advice/work-life-support/your-wellbeing/counselling-and-peer-support>.

The Royal College of Nursing

RCN members can access free confidential support and assistance to help deal with challenging, emotional issues whether work-related or personal via a range of services including a counselling service. To seek advice or make an appointment, members can call the RCN on 0345 772 6100 (or +44 207 647 3456 if calling from overseas) between 8.30am and

8.30pm, seven days a week, 365 days a year. Practical employment advice is also available on the 'Get help' section of the RCN website: <https://www.rcn.org.uk/get-help>.

NHS staff support on social media

The Tea and Empathy group is a national peer-to-peer support network aiming to foster a compassionate and supportive atmosphere throughout the NHS. Its Facebook home, created in 2016, now has nearly 7,000 members, with a purpose of providing non-judgmental, informal listening and emotional support to colleagues across the health service who are finding work difficult. For further information, visit the Tea and Empathy site: <https://www.facebook.com/groups/1215686978446877/>.

Second Victim Support – secondvictim.co.uk

This is a website designed as a resource for clinicians who are involved in a patient safety incident, their colleagues and the organisations they work for. A team from the Yorkshire Quality and Safety Research Group and the Improvement Academy has developed it. The National Institute for Health Research (NIHR) Yorkshire and Humber Patient Safety Translational Research Centre supports it. The team includes researchers, academics, and clinicians from a range of backgrounds including psychology, nursing, medicine and allied health professions. <http://secondvictim.co.uk/>

Medical indemnity organisations

Medical indemnity organisations all provide some form of advice or supportive services for members in addition to representation and advice on statement writing, with contact details available through their respective websites.

NHS Improving Access to Psychological Therapy (IAPT)

The NHS provides free access to psychological therapy on a regional basis through the IAPT service. This can be accessed by the following link and services in your area located including self-referral details – [https://www.nhs.uk/Service-Search/Psychological-therapy-\(NHS-IAPT\)/LocationSearch/396](https://www.nhs.uk/Service-Search/Psychological-therapy-(NHS-IAPT)/LocationSearch/396).

The Samaritans

The Samaritans provide a free 24 hour listening and advice service 365 days a year. They can be contacted from any phone anytime by calling 116 123 from the UK and Republic of Ireland.

Appendix III – Additional resources

Following is additional information on the Early Notification scheme including links to case stories and resources, data sharing regulations, the CNST maternity incentive scheme and Healthcare Safety Investigation Branch.

Early Notification

For up to date information on the EN scheme including reporting form, case stories and support services please see our website below:

<https://resolution.nhs.uk/services/claims-management/clinical-schemes/clinical-negligence-scheme-for-trusts/early-notification-scheme/>

In addition case stories can be accessed at the following links:

<https://resolution.nhs.uk/wp-content/uploads/2019/02/Case-story-Hyponatraemia.pdf>

<https://resolution.nhs.uk/wp-content/uploads/2019/02/Case-story-Learning-lessons-from-Darnley-revised.pdf>

<https://resolution.nhs.uk/wp-content/uploads/2019/02/Case-story-Sepsis.pdf>

<https://resolution.nhs.uk/wp-content/uploads/2018/10/Case-story-Fetal-heart-rate-monitoring.pdf>

<https://resolution.nhs.uk/resources/good-practice-management-of-the-antenatal-ctg/>

<https://resolution.nhs.uk/resources/fetal-surveillance/>

NHS Resolution – Saying Sorry

<https://resolution.nhs.uk/wp-content/uploads/2017/04/NHS-Resolution-Saying-Sorry-2017.pdf>

Sharing medical records and GDPR

Copies of a patient's medical records relating to an incident reported to NHS Resolution, in which there is the possibility of substandard care or where there is a notified claim, can be provided lawfully to NHS Resolution without consent, as the sharing relates to the investigation of potential claims and so is subject to litigation privilege, a category of legal professional privilege. The sharing of information in such privileged circumstances does not involve a breach of confidentiality at common law.

It is also not necessary to rely on patient consent for the sharing with NHS Resolution to be lawful under the General Data Protection Regulation (GDPR). The GDPR provides that personal data can be processed by an organisation if any of the lawful bases under Article 6 is satisfied.

Here, the GDPR processing (sharing with NHS Resolution) will be justified under the following bases:

- Article 6(1)(c): processing is necessary for the compliance with a legal obligation. Specifically, the requirement to provide NHS Resolution with

the information required under the Scheme rules applicable to the National Health Service (Clinical Negligence Scheme) Regulations 2015;

- Article 6(1)(e): processing is necessary for the performance of a task carried out in the public interest which is laid down by law. Specifically, NHS Resolution's function in connection with "advice about and assistance with litigation or potential litigation which involves an NHS body", in accordance with the National Health Service Litigation Authority (Establishment and Constitution) Order 1995.

Where the personal data is "special category" data, including health information, a "condition" under Article 9 must also be met. Processing can be justified under the following conditions:

- Article 9(2)(f): processing is necessary for the establishment, exercise or defence of legal claims (including prospective legal claims); and/or
- Article 9(2)(h): processing is necessary for the purposes of the management of health or social care systems and services on the basis of UK law. Specifically, NHS Resolution's function in connection with "advice about and assistance with litigation or potential litigation which involves an NHS body" in accordance with the National Health Service Litigation Authority (Establishment and Constitution) Order 1995 and members' need to ensure appropriate indemnity for any clinical negligence claims arising out of the performance of their relevant functions.

Paragraph 5 of Schedule 2 to the Data Protection Act 2018 expressly dis-applies those portions of the GDPR which might otherwise prevent the sharing of information with NHS Resolution in this context, such as the data subject's right to object to or restrict processing.

The CNST maternity incentive scheme

The initiative rewards trusts meeting ten safety actions as agreed by the national maternity safety champions and in partnership with the Department of Health and Social Care, NHS Digital, NHS England and NHS Improvement, Royal College of Obstetricians and Gynaecology, Royal College of Midwives, MBRRACE-UK, Royal College of Anaesthetists and the Care Quality Commission.

The maternity incentive scheme will continue to support the delivery of safer maternity care through the use of an incentive element to members' contributions to the CNST.

The ten safety actions for year two were:

1. Are you using the National Perinatal Mortality Review Tool to review and report perinatal deaths to the required standard?
2. Are you submitting data to the Maternity Services Data Set to the required standard?
3. Can you demonstrate that you have transitional care services to support the Avoiding Term Admissions Into Neonatal Units Programme?
4. Can you demonstrate an effective system of medical workforce planning to the required standard?
5. Can you demonstrate an effective system of midwifery workforce planning to the required standard?
6. Can you demonstrate compliance with all four elements of the Saving Babies' Lives care bundle?
7. Can you demonstrate that you have a patient feedback mechanism for maternity services and that you regularly act on feedback?
8. Can you evidence that 90% of each maternity unit staff group have attended an 'in-house' multi-professional maternity emergencies training session within the last training year?
9. Can you demonstrate that the trust safety champions (obstetrician and midwife) are meeting bi-monthly with Board level champions to escalate locally identified issues?
10. Have you reported 100% of qualifying 2018/19 incidents under NHS Resolution's Early Notification scheme?

Further information can be found at <https://resolution.nhs.uk/2018/12/12/nhs-resolution-launches-second-year-of-maternity-incentive-scheme/>.

Healthcare Safety Investigation Branch

The Healthcare Safety Investigation Branch (HSIB) was established by an expert advisory group following recommendations from a government inquiry into clinical incident investigations. It became operational on 1 April 2017, with the purpose of conducting effective investigations, sharing learning, improving patient safety, raising standards and supporting learning across the healthcare system in England. Their remit originally was to carry out national investigations. In November 2017 the Secretary of State for Health announced a new maternity strategy, calling on HSIB to undertake independent maternity investigations into incidents meeting the EBC criteria. The maternity investigation arm of HSIB became operational in April 2018 and has now rolled out to all maternity trusts across England.

Further information can be found at <https://www.hsib.org.uk/maternity/>.

Appendix IV – Panel solicitor firms

Following is details of the panel solicitor firms who support NHS Resolution services.

We have a panel of specialist solicitors that work with us on our behalf providing services related to clinical and non-clinical liabilities, and regulatory, health and disciplinary law.

We use our unique purchasing power to help ensure that the NHS receives value for money and to allow us to maintain the high quality legal services for our members. There are currently 10 firms on the clinical panel for the 129 trusts providing maternity care in England (at the time of report publication).

- Bevan Brittan
- Browne Jacobson
- Capsticks
- Clyde and Co
- DAC Beachcroft
- Hempsons
- Hill Dickinson
- Kennedys
- Ward Hadaway
- Weightmans

In addition, Acumension and Keoghs sit on NHS Resolution's costs panel.



151 Buckingham Palace Road
London SW1W 9SZ
Telephone 020 7811 2700
Fax 020 7821 0029
DX 6611000
Victoria 91 SW

Arena Point, Merrion Way
Leeds
LS2 8PA
Telephone 0113 866 5500

www.resolution.nhs.uk

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