



Department
of Health

A Rapid Resolution and Redress Scheme for Severe Avoidable Birth Injury: Government Summary Consultation Response

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Families and health service users (particularly those affected by severe birth injury)

Patient Groups

Charities

NHS foundation trusts

NHS trusts

Professional Body Representatives

Commissioning bodies

The Legal community (including clinical negligence lawyers and representatives, legal professional bodies)

Medical Defence Organisations

Expert Witness Organisations

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Background

England is a safe place to give birth, and every year thousands of babies are safely delivered to delighted parents by experienced and dedicated NHS staff. This is the outcome that all families expect and the vast majority of families experience. However, tragedies can sometimes occur, and babies can suffer serious harm during delivery. Thankfully these incidents are rare, but it is clear that there is still more that we can do to achieve our vision to make NHS maternity services among the safest in the world.

Evidence tells us that the current system for providing redress for these birth injuries is not working as well as it could. Currently when substandard care occurs during labour and delivery which results in the most severe forms of birth injury (cerebral palsy/brain damage), the only means by which families can secure compensation is through the adversarial and often lengthy process of litigation. The average length of time between an incident occurring and an award for compensation being made is 11.5 years. This process takes time because the Court has to wait until the injured child's prognosis is clear in order to decide a full and final compensation settlement. This is amplified by the adversarial culture associated with litigation, and adds further uncertainty and stress for the families involved.

Alongside efforts to improve the experience for families in these difficult circumstances, the Government is also committed to reducing such incidents in future. International evidence demonstrates that improvements in investigations and learning from when things go wrong can be highly effective in doing this; collating and disseminating evidence and providing clinicians with additional support for learning, so that individual tragedies become lessons that can save many more families from such heartache in the future. Several maternity services in England have already achieved significant reductions in harm and litigation claims, and these successes can be built upon. The cost of these incidents is not just a human tragedy, but the rising cost of litigation against the NHS also contributes to pressure on health service funding and risks diverting funds away from frontline care.

The national maternity review (*Better Births, 2016*) independently chaired by Baroness Cumberlege made recommendations to improve the safety of maternity services. One of the key recommendations was that the Department of Health consider a Rapid Resolution and Redress (RRR) scheme for families affected by severe avoidable birth injuries. The intent is to provide a viable alternative to the current litigation route for affected families with the purpose of achieving three principle aims:

- Reducing the number of severe avoidable birth injuries by encouraging a learning culture;
- Improving the experience of families and clinicians when harm has occurred; and
- Making more effective use of NHS resources.

On the 2nd of March 2017 the Department of Health launched a twelve week public consultation into the potential parameters of a Rapid Resolution and Redress scheme which concluded on the 26th of May. The consultation aimed to gather a wide range of views to inform policy development. The consultation discussed options around the proposed scheme design including:

- How the scheme would be structured and administered;
- The eligibility thresholds for investigation and compensation; and
- How learning would be disseminated and actioned to reduce future harm.

The Maternity Transformation Programme Board (MTPB) has been set up to implement the recommendations made by Better Births. Our development of the RRR scheme contributes to work stream two of the MTPB: *Promoting good practice for safer care*. Delivering the Maternity Transformation Programme and implementing the vision set out in Better Births will support the Secretary of State’s ambition to halve the number of stillbirths, neonatal and maternal deaths and brain injuries by 2030.

Introduction

We would like to thank everyone that took the time to contribute to the public consultation on the potential introduction of a Rapid Resolution and Redress Scheme for Severe Avoidable Birth Injury. The consultation received over 200 unique responses from a wide range of stakeholders, including family members with personal experience of birth injury, the organisations that support them, and frontline clinical and legal professionals.

Due to the technical complexity of policy development in this area and the need to ensure any final policy design can meet its objectives, this response is not a full policy proposal, but rather a summary of consultation responses received.

We are in the process of giving full consideration to points raised through the consultation to ensure the parameters of any final policy proposal have the best chance of achieving our main system objective of reducing future incidence of avoidable harm.

We are currently working with partners on areas requiring further development, and modelling alternative parameters as suggested through consultation responses. It is our intention to present a final policy option in Spring 2018.

Consultation analysis methodology:

A copy of the consultation document is available alongside this response and provides additional detail on the proposals as set out in the consultation (<https://www.gov.uk/government/consultations/rapid-resolution-and-redress-scheme-for-severe-birth-injury>). The consultation received 217 unique responses. The proportion of responses received from respective groups can be broken down as follows:

Respondents	Total	Percent
Midwife	103	47%
Legal professional	33	15%
Family member with personal experience of obstetric negligence	26	11%
Obstetrician	22	10%
Other healthcare professional	19	8%

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Other	16	7%
Third sector group	12	5%
General public	8	3%
Not Answered	2	0.9%
GP	0	0%

Some respondents provide multiple affiliations, for example a respondent may be a health professional, but also a family member with personal experience of bereavement or birth injury.

Some responses represent the opinions of a single individual. Others represent multi-membership organisations such as patient representatives, the medical Royal Colleges or legal societies. Some people have responded individually and also have their responses included or summarised within the response of an umbrella organisation of which they are a member.

As this was a public consultation responses were invited from any interested party, including members of the public. Therefore no sampling frame was drawn up to select a statistically representative sample. Consequently, we have not attempted to weight responses, and the percentages provided below should not be treated as a representative statistical exercise, but rather an indication of respondent positions on particular issues.

What is of key interest to us is the large amount of qualitative detail provided through respondents' narrative comments. In many cases individuals have not answered yes or no, but have expressed their opinions through the comments section.

Where there is a notable difference in the opinions provided by one respondent group over another we have expressed this.

During the process of analysing responses we coded qualitative comments in relation to their key themes. These themes have been expressed below with the assistance of direct quotations to illustrate general or individual viewpoints. In some instance we have grouped responses to different questions together where more relevant to do so.

Respondents raised a large number of points, some of which were outside the scope of the consultation questions. Where we have not captured these points within the response we will, where relevant, take them into consideration when making future decisions relating to the RRR scheme.

Note: *As of April 2017, the former NHS Litigation Authority (NHSLA) has been re-named NHS Resolution (NHSR). For the purpose of this response we have continued to use the terminology interchangeably, as utilised by respondents.*

Rapid Redress and Resolution Scheme (RRR) Summary Consultation Response:

1ai. Do you agree that the scheme should include early investigations, conducted by professionals independent from the trust involved, potentially including at least one obstetrician and one midwife?

96% of respondents answered this question and of those who answered, 92% agreed. This is a compound question bringing together a number of different elements related to the timing, independence and composition of the investigation. In responding yes or no to this question, respondents may have agreed or disagreed with one or all of the elements referenced. Many respondents provided more qualitative detail on the nature of their responses.

Respondents agreed that the scheme should include early investigations, but these should not replace trusts' own internal investigations, which should be instigated in line with the Serious Incident (SI) framework, irrespective of RRR. The variable quality of trusts' own internal investigations was noted and it suggested that RRR would provide an opportunity for trusts' own systems and processes to be 'reviewed and explored independently':

"The investigation team should provide feedback on the quality of the SII¹ report once they have completed their investigations, to improve the standard of future SIIs" (Legal professional)

Independence was identified as key to ensuring impartiality, and the subsequent confidence of both families and clinicians in investigation findings. This theme is picked up in more detail under question 1b below.

Respondents put forward a range of opinions on the composition of RRR investigations. A multi-disciplinary panel with external representation was noted as an effective format successfully tested in other areas, and some respondents noted they have already adopted this approach in their own investigations. In addition to obstetrics and midwifery, clinical representation from neonatology, paediatrics, neuroradiology and obstetric anaesthesiology were cited as potentially necessary to represent the case under investigation. It was also noted that representation should reflect the nature of the birth setting, for example, involving a community midwife in the case of a home birth.

One legal professional noted that clinicians can come to different conclusions on their interpretation of the same facts and recommended independent oversight from an experienced QC². Another noted that:

"Clinicians rarely have to establish whether an injury was avoidable in their day to day work. This is perhaps why so many SII's conclude that any learning points may have affected the outcome without any real analysis of whether an injury was avoidable"

"The experts who currently investigate what is termed 'avoidability' in instances of neurological injury at birth are claimants' lawyers and the medico-legal experts they instruct" (Third sector organisation)

¹ Serious Incident Investigation

² Queen's Council

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Another respondent commenting on the current composition of the investigation panel noted:

“Clearly, this will be dealing with issues surrounding the standard of care provided. It will not determine whether those issues around the standard of care have caused the baby's injuries”. (Legal professional)

In addition to clinical experts, respondents advocated for the inclusion of causation experts and legal professionals, as well as representatives from the unit risk team, patient advocacy groups, and trust governance boards.

A number of respondents cited the need for investigations to be run, not by a panel of clinicians but by independent, trained incident investigators.

“The experience from other schemes in the UK and beyond is that efficiency, accuracy and low cost are more likely to result from the use of specialist investigators with experience in the sorts of issues involved than subject matter experts with limited investigative skills”.

“I believe this scheme should use trained independent investigators to ensure that the investigations are carried out in a timely manner and to an excellent and consistent standard” (Third sector organisation)

Multiple respondents noted the difficulties in securing clinical time to engage in investigations, whether internal or external to the trust involved. One respondent cited their concern that a requirement for clinicians to take part in investigation panels ‘will put an additional strain on an already overstretched workforce’ noting that:

“It may be more appropriate for investigations to be led by trained investigators whose roles are focused on the scheme, and who are able to call on the input of clinicians to offer clinical expertise as needed. Trained investigators may also be best placed to take an objective view of evidence and provide reassurance for families of impartiality.” (Third sector organisation)

Other central themes were the importance of consistent investigation standards and clear guidelines, and the need for adequate training of all individuals involved in conducting and facilitating investigations. Some criticisms were raised of the current standard of maternity investigations with respondents citing lack of investment in training and an absence of protected time for participation; however, these themes relate to the standard of serious incident investigations in general, and not solely to the application of RRR:

“Investigations needs to be transparent, independent and open-minded, should adhere to standards of investigations undertaken by HSIB³ and shouldn't be performed by clinicians unless they receive thorough and appropriate training” (Midwife)

Some respondents noted that the key issue is not the composition of the investigation panel but what powers and resources, if any, the investigating team will have at their disposal.

1bi. If yes, how independent would the investigating team need to be in order for families to have confidence in the findings?

94% of respondents answered this question and of those who answered:

³ The recently formed Healthcare Safety Investigation Branch

- 162 agreed that investigations need to be conducted outside the trust involved, for example through regional Maternity Clinical Networks (proposed by Better Births).
- 76 agreed that investigations need to be conducted with oversight from the Royal Colleges or other independent bodies.
- 44 agreed that investigations need to be conducted by Clinicians in the trust, that were not involved in the incident being investigated nor had direct management of those involved.

Note: Respondents were able to select multiple answers for this question and some respondents selected all three options as being applicable in different situations.

As highlighted above, respondents placed significant emphasis on independence in ensuring both families' and clinicians' confidence in the investigation and its findings.

Some respondents felt investigations should be externally led but include participation of the local team to ensure access to local knowledge and insight which may otherwise be missed:

“Investigations need to involve representation both internal and external to the Trust to ensure the right balance of local knowledge and objectivity” (Obstetrician)

“Investigations should continue to involve the Trust where the incident occurred, as in depth knowledge of the trust and its culture can bring to light specific human factors that need to be addressed that may not otherwise be recognised” (Midwife)

Others felt any involvement of the local Trust would discredit the investigation due to the potential for bias. Some also questioned whether a neighbouring Trust would provide sufficient independence suggesting a North/South mirror may work better.

Some respondents noted the ideal scenario would be for investigations to be externally led, but that pragmatically it may be more realistic for investigations to be led by the local unit, involving contributions from independent expertise where necessary.

Other suggestions of organisations which could lead or contribute to external investigations included:

- Maternity Clinical Networks;
- The Royal Colleges;
- The Nursing and Midwifery Council (NMC);
- MBRRACE-UK (Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK); and;
- The Healthcare Quality Improvement Partnership (HQIP);

Another suggestion was the establishment of a new ombudsman style scheme to co-ordinate investigations led by single independent trained investigators, and arbitrate over decisions of avoidability, causation and eligibility.

Respondents also noted that RRR should complement and not overlap with the work of the newly formed HSIB, whom it was also suggested should take responsibility for the training of external investigators.

No matter who conducted the investigations, the importance of sharing information and learning was emphasised.

2ai. We are aiming to launch an investigation into the incident within 90 days. Do you agree with this approach?

97% of respondents answered this question and of those who answered, 80% agreed with the approach to launch an investigation into the incident within 90 days.

Some respondents felt an investigation should be launched within a far shorter time frame, with recommendations made from 7 days, 14 days and 30 days to 42 days. Respondents noted an investigation needs to be commenced as soon as possible after the event to preserve necessary evidence. Some respondents felt any investigation should be concluded, not launched, within 90 days.

Other respondents noted there may not be sufficient information available within 90 days to commence or complete an investigation; in particular, investigations may be influenced by clinical outcomes, which may not be completely defined within this time frame. For example, one neonatologist responded that:

“There is no reason why standard of care issues cannot be identified within 90 days, however I think from a prognostic viewpoint investigation within 120 days would be more informative”.

Respondents also noted that during the early weeks and months, parents will still be learning to care for their new-born and coming to terms with the enormity of what has happened, and hence may not be in a position to participate in an investigation - physically or emotionally - that quickly. The pressures of an investigation may add to their burden at what is already a very stressful time.

Conversely, some respondents noted it was important for families to see that things were being done at an early stage, to find out what had happened and potentially give them earlier access to support. Some questioned whether there would be flexibility and the opportunity to launch the process after 90 days, if more appropriate to facilitate the facts of the case or family involvement, stating that 90 days should be a ‘benchmark’ not an ‘absolute’. One respondent suggested that:

“There should be a preliminary review of the notes within 30-60 days so that external investigators can at least influence the scope and approach taken by Trusts own internal process” (Legal professional).

A key theme among responses was the need for RRR to complement any existing investigatory frameworks such as a Trust’s own investigation, the Serious Incident Framework and professional regulatory processes. How an RRR investigation intersects with these processes, and whether information from prior reviews can be fed into the RRR investigation has a key bearing on necessary timeframes, and a standardised process would need to be clearly defined.

Some respondents also noted that where clinical staff are involved, there will likely be a delay in securing time to participate in investigations. This needs to be dealt with whatever the time or resource constraints.

Other respondents cited the lack of investment in investigation skills such as Root Cause Analysis (RCA) noting that *‘since (the) demise of the NPSA RCA⁴ training programme, (their) trust has failed to find an alternative provider’* (healthcare professional).

⁴ National Patient Safety Agency Root Cause Analysis

Multiple respondents queried whether HSIB could support RRR investigations or provide appropriate training.

3a. How can we ensure alignment with, and avoid duplication of, other investigative processes, such as the Serious Incident framework and the role of Regulators?

80% of respondents answered this question, providing a range of comments. Some took the stance that duplication is unavoidable, and in some cases beneficial as RRR can provide a mechanism for reviewing existing processes.

Others took the view that separate investigative processes are necessary as they have different purposes and outcomes. An RRR investigation should be conducted alongside a Trust's own investigation, and any regulatory investigation that may have been instigated with:

- Detailed understanding, local ownership and knowledge and identification of immediate actions being instrumental in the trust's own investigation;
- Independent and objective review of events on a no-blame basis exercised through RRR; and;
- Professional investigation conducted by regulatory bodies on an individual basis where appropriate.

Respondents noted that a Trust is responsible for instigating its own investigation under the SI Framework within 48 hours – irrespective of the involvement of RRR. However, the results of this internally instigated investigation could form key documents to be fed into the RRR process:

“The process should be a continuum, with the SI process carried out by the trust and regulators having oversight of both processes and outcomes” (Obstetrician)

It was noted that the fact an independent investigation is occurring, or will occur under RRR, may improve the quality of a trust's own internal investigation as the investigating team will be mindful that their processes and findings will be subject to external review.

It was also noted that mechanisms should exist for referring cases to the regulatory bodies where appropriate, from either a trusts' own investigation or RRR, although some respondents signalled concerns with such an approach which could undermine clinicians' willingness to participate openly in the process.

“It must be clear that participation in the integrated process must not be seen to constitute acceptance of responsibility or fault in any form. The principle must also attach to the prospect of referral to any professional regulator” (Legal professional)

Other respondents noted that the number of parallel investigation processes should be minimised and that a hierarchy should be established to avoid duplication. In addition to the duplication of scarce resources, other potential negative consequences were cited as:

- Additional stress for affected families to recount details of what happened to them multiple times to multiple investigations, and also to health professionals to be investigated multiple times for the same incident;
- Lack of consistency if different investigations come up with different conclusions. Although other respondents assert this as a principle purpose of conducting multiple levels of investigation;

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- Lack of coherence in navigating a complex system for families, clinicians and trusts.

Suggestions for avoiding duplication were effective communication and coordination between processes; the need for standardised templates/processes such as the Perinatal Mortality Review Tool (PMRT)⁵; and the use of multi-organisational meetings to ensure consistency of approach. It was suggested that investigations should feed into one another and where appropriate, any documentation or findings be shared:

“It would be sensible if everyone used the same template/process to investigate so that work can start at a local level then details/data/evidence collected by the Trust can then be verified by the Investigating Team” (Midwife)

Although others queried the principle of sharing information between different processes and highlighted the potential for conflict between the duty to be open and transparent enshrined within the Duty of Candour, and the ‘safe space’ initiative being forwarded by the newly founded HSIB:

“If evidence put forward for a no blame claim is to have special status, it is vital there is absolute clarity about its use in a regulatory setting” (Legal professional)

Some respondents noted concerns over the adequacy of existing RCA methodology and the importance of using a systems approach to identify system/process/complex human factors.

4ai- Do you agree that the scheme should include an early apology to families, in the form of an early expression of regret?

95% of respondents answered this question and of those who responded, 90% agreed that the scheme should include an early apology to families, in the form of an early expression of regret⁶.

Responses noted that an early apology can make a huge difference to families, where conversely, an absent or delayed apology can compound families’ suffering. One affected family member noted that *‘above all, my experience could have been made much less painful if the trust apologised’* and another noted *‘this is all I wanted’*.

Respondents noted that early acknowledgement of what has occurred and recognition of families’ distress can prevent further suffering, improve relations, and encourage families’ confidence in the investigation process.

However, to be effective, it was noted any apology must be genuinely offered, not merely a procedural step or ‘tick-box’ exercise. It was also noted that an apology should be made in person by a senior representative of the care giving organisation, not by the RRR scheme on

⁵ [A collaboration](#) led by [MBRRACE-UK](#) has been appointed by the Healthcare Quality Improvement Partnership ([HQIP](#)) to develop and establish a national standardised Perinatal Mortality Review Tool (PMRT) to standardise the approach to investigating perinatal deaths.

⁶ Whilst an apology should not be seen as an admission of liability and should be provided independently of whether care could or should have been delivered differently, the RRR consultation proposed making an early apology to families in the form of an ‘expression of regret’ to overcome the recognised persistent fear associated with an admission of liability amongst some staff and providers, and thereby facilitate the fast and effective acknowledgment of a family’s distress. It is estimated that this may be changed over time as cultural shift occurs within the NHS.

the Trust's behalf, for it to carry any weight. It was noted that any 'formulaic' response could undermine relations with families' and their ultimate trust in the investigation process.

Many health professionals noted they already see providing an early apology as part of good clinical practice under the Duty of Candour and responses also referenced existing Good Medical Practice guidance on apologies and NHS guidance on 'Saying sorry'. However, a common concern expressed by many respondents was that an apology could be viewed as an admission of liability with potential professional and legal consequences. Similarly, some respondents noted that an apology would only be appropriate if and when it is confirmed that negligence has occurred, to avoid pre-empting the outcome of any ongoing investigations, and to manage families' expectations with regards to avoidability and subsequent access to compensation.

As expressed by one respondent:

"One has to be cautious about using the terms apology and expression of regret interchangeably since the former tends to suggest that the birth injury is the result of some failure in the standard of care provided to mother and child. This would pre-suppose the outcome of (RRR) Stage 2" (Legal professional)

A small number of respondents suggested it would be better to ensure that affected families are treated with empathy as opposed to regret, which would include recognition of their concerns, an intention to investigate objectively and commitment to provide conclusions within a specified timescale. Some family members noted a commitment to investigate their child's case was more important than receiving an apology.

Some respondents also noted that training should be provided to ensure those in contact with affected families are equipped with the necessary skills to provide appropriate apologies, recognising the need for great sensitivity at this difficult time.

4bi. Do you agree that the investigations should offer families the opportunity to be involved in the investigation process, with the option for a face-to-face meeting to discuss the findings?

97% of respondents answered this question and of those who answered, 98% agreed that investigations should offer families the opportunity to be involved in the investigation process, with the option for a face-to-face meeting to discuss findings.

A common theme was that family involvement in the investigative process is a necessity and should be happening already; however, the difficulties of face-to-face meetings for all involved were also noted. Some families may want to meet with the clinicians involved in their case; others may prefer to meet with a representative or an intermediary. Respondents noted that family involvement should be the choice of the family concerned, but that this option should at least be extended to the family in all cases.

Respondents also noted that families should be offered a dedicated support worker, independent of the clinical team involved in their care, who can act on their behalf in ongoing involvement in the investigation. Some examples of trusts utilising this practice were cited (i.e. Cheshire and Merseyside).

Some respondents highlighted that there may be certain parts of the process in which it is not appropriate for the family to be involved, and in such cases this would need to be made clear with transparent reasoning provided.

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It was recognised by many that the involvement of families increases the amount of learning that can happen as a result of the investigation as different questions are asked. Families should be given opportunity to feed into investigation terms of reference (ToR).

It also gives an opportunity for the families to learn and understand why a mistake may have happened and for them to receive reassurance that this event will not happen again.

It was noted that whoever interacts with the family needs to be appropriately trained and there should be an appropriate chair or mediator to facilitate the meetings. Some respondents highlighted that face-to-face involvement is crucial to obtain the benefits for both sides.

5a. Do you agree the scheme design should ensure learning is disseminated locally, regionally and nationally, building upon existing systems where possible?

97% of people responded to this question and of those who responded 99% agreed that the scheme design should ensure that learning is disseminated locally, regionally and nationally, building on existing systems where possible.

Key themes arising included the importance of building on existing channels whilst minimising the risk of duplication and the additional resources this would consume within the system.

Responses differed as to the relative utility of locally tailored over nationally mandated approaches, with a balance of both being cited as necessary to ensure a general common standard, whilst allowing space for appropriate tailoring to local contexts and local ownership.

At a national level the following were all cited as examples of respected existing channels:

- The Royal College of Obstetricians and Gynaecologists (RCOG) Each Baby Counts (EBC) programme;
- MBRRACE;
- The Royal College of Midwives (RCM);
- The NMC;
- The NHS Improvement (NHSI) Maternal and Neonatal Health and Safety Collaborative,
- The NHS Resolution safety and learning team,
- The National Institute for Health and Care Excellence (NICE);
- The Academic Health Science Network (AHSN); and,
- The ATAIN (Avoiding Term Admissions into Neonatal Units) programme.

Some respondents noted there may also be a role for HSIB as its remit develops.

Local maternity clinical networks and Trust buddy systems were cited as appropriate regional networks.

At a local level, existing clinical governance mechanisms such as multidisciplinary perinatal morbidity and mortality meetings were referenced. Benchmarking with appropriate system partners was also raised with one suggestion being that avoidable harm could be a new data field within the revised Maternity Services Data Set (MSDS).

Respondents also noted the importance of gaining consent from families for cases to be used in learning and the importance of anonymising cases to avoid identification of families, clinicians

and organisations. Some respondents noted that due to the small number of such cases each year the practicalities of this may be difficult.

Respondents also referenced the importance of effective follow-up to test that implementation and learning have been successful, through for example localised audit or follow up by national regulators.

A small number of respondents questioned how having a national database would change anything, noting that without investment in units and staffing, mistakes will still happen, despite learning.

One respondent also noted that blanket rulings can have unintended consequences and felt that learning should be tailored to individual contexts: *'Changes to practice need to be evidence based and not a knee jerk reaction'* (Midwife).

5b. Do you agree to the use of a central learning database to collate findings from investigations, which will then feedback nationally to trusts?

92% of respondents that answered this question, and of those who responded, 98% agreed to the use of a central learning database to collate findings from investigations that would then be fed back to Trusts.

One midwife noted the importance of sharing learning when things go wrong to prevent similar events from occurring again:

“Having moved from another hospital, I feel saddened to see similar incidents occurring at my new unit. Sharing what we had learnt may have prevented these”.

Some respondents noted existing initiatives that carried weight in the system such as RCOG Each Baby Counts and MBRACCE perform this function already and should be built upon to avoid duplication. NICE guidance and Care Quality Commission (CQC) safety alerts were also cited as appropriate existing vehicles for disseminating significant findings and issues. It was noted that RRR learning could be disseminated through such existing channels, although it was also noted that over time the RRR scheme may become a trusted and respected vehicle for the dissemination of learning in its own right. Some respondents queried why this wasn't being doing already and questioned the need for an RRR scheme to achieve this approach.

“There is no bar whatsoever under the current system for implementing and encouraging a learning culture and indeed there are existing initiatives in place to achieve that aim”.

“We recommend that the NHSLA considers whether they can put these processes in place, with or without the RRR scheme, so the implementation of lessons is not delayed”.
(Legal professional)

One respondent noted that any central learning database should have relevant links to Health Education England (HEE), the Royal Colleges, NICE and the NHS Resolution Faculty of Learning *'to ensure that lessons are properly disseminated and best practice is adopted across the board as quickly as possible'*. Another noted that effective links should be made with coronial support for learning.

To be effective, respondents noted that a central contact point should exist within each unit, trust or Local Maternity System (LMS) to receive updates from the centre and disseminate them locally and regionally. Suggestions made included trust clinical educators or practice development staff.

However, it was also noted that the database should be easily accessible to all clinical staff for it to be successful. One respondent highlighted that this should include independent providers,

noting that The National Reporting and Learning System (NRLS) is not currently available to these providers.

The suggestion was also made that regular audits of cases should include 'near-misses' or 'great-saves' and examples of cases where things had gone well to ensure the most thorough learning and the identification and dissemination of best practice.

6. How could we best ensure that learning is implemented?

Common themes included building on existing examples of good practice and trusted vehicles to avoid/minimise duplication. A combination of web based e-learning, remote and face to face learning were all advocated as effective channels for the dissemination of learning. Situational multi-disciplinary team training including simulation of emergency scenarios, as incorporated by the PROMPT⁷ programme, was widely recognised as an effective gold standard.

Another key theme amongst responses included the need for each trust to have a designated contact point/champion for maternity safety⁸. There were also comments attempting to identify where this function would most appropriately sit within the organisation i.e. within each maternity unit, within the clinical risk team etc.

Specific suggestions for ensuring effective implementation of learning included the following:

- Continued professional training – mandatory training packages updated annually on the basis of common themes;
- Agreed local, regional and national training pathways;
- Annual system-wide events;
- Mandatory workshops/study days;
- Identifying learning champions within Trusts/Units/Clinical risk teams;
- PROMPT: Evidence based multi-professional training programme utilised successfully at Bristol Southmead hospital. Uses a variety of practice-based tools, workshops and drills including emergency simulation;
- NRLS patient safety alerts;
- CAS (Central Alerting System) patient safety alerts;
- National learning and alert service used by NPSA;
- Confidential enquiries along the lines of the MBRRACE model;
- Monthly newsletter covering common issues identified;
- Absorption of national guidance into local protocols/SOPs⁹/action plans;
- Engaging the support of experts in adult learning techniques;

⁷ Practical Obstetric Multi-Professional Training developed at North Bristol NHS Trust

⁸ This initiative is already underway. Every trust committed to appoint one when they received funding from the Maternity Safety Training Fund earlier this year.

⁹ Standard Operating Procedures

- Use of new technologies.

In addition to conducting training and facilitating learning, many respondents emphasised that ensuring learning is embedded is equally vital. This included regular monitoring, inspection, audit and review through local, regional and national vehicles such as trust governance boards, LMS and the CQC. It was noted that the CQC already supports trusts by reviewing their safety improvement plans as part of their inspection programme¹⁰.

Mandated training was a frequent theme with respondents also highlighting the need for resources to provide necessary backfill and dedicated time to participate in training within working hours. Linking learning to mandatory professional re-validation was also a key theme, with some suggesting that continued registration be dependent on completion of mandatory training, with demonstration of knowledge mandated as part of the annual appraisal process. Some noted a role for professional regulators and the Royal Colleges to ensure relevant training has been completed amongst their membership and competence acquired/maintained.

Others suggested that financial incentives be shaped to ensure learning is absorbed and embedded within units and trusts. Examples mentioned included the NHS Resolution 'Sign up to safety' campaign which offered trusts the opportunity to bid for dedicated funding to develop and implement local safety improvement plans, and a suggestion that trusts' CNST premia may be linked to relative performance and risk.

One respondent queried whether the RRR scheme could provide independent support to expert audit to ensure learning implementation. This could include provision of audit toolkits including benchmarking performance against outcome data and evidence of training attendance and learning implementation.

7. Do you think there are additional potential barriers to learning that are not addressed by the current design of the policy?

Predominant issues raised within responses included the following:

- Investigation quality: The current poor quality of some investigations inhibits the learning process;
- Resources: Availability of financial resources to obtain backfill cover whilst staff participate in training. Some respondents noted that a long term funding commitment to this would be required for the initiative to succeed;
- Lack of protected time for staff to attend training or undertake practice based learning meaning that they are forced to complete training in their own time. Protected time should be built into contracts and job plans;
- Frequent rotation of staff/problems with retention meaning institutional memory/training is lost;
- Established professional hierarchies which may make it difficult for staff to challenge the practice and decisions of colleagues;
- Training of different professions in isolation. Need for a whole system approach encompassing multi-disciplinary training opportunities that bring together different

¹⁰ Which reviews five domains of safety and quality

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professions involved in the care pathway including midwives, obstetricians, neonatologists, paediatricians and paramedics. One respondent also noted the need to engage GP's in the process and the challenge this has presented;

- Competition: Overload of initiatives competing for space, both within the Quality Improvement/Patient Safety space and more broadly – limited bandwidth and resources both individually and as an organisation/unit to absorb;
- Training vs Learning: Difference between attendance at training and learning/knowledge (see discussion under Q6 above);
- Lack of regular support/supervision, particular problems noted for midwives following the removal of Local Supervising Authorities (LSA), and for doctors once they have completed their training¹¹
- Culture: An organisational and/or professional culture of blame/fear which prevents both constructive challenge and an open learning environment.

Whilst many respondents advocated the need for adequate time and resource to be dedicated to learning, some also highlighted the concern that without additional resource being introduced into the system, any time taken to engage will draw away from already over-stretched clinical teams.

8. What improved support could be provided to practitioners following these tragic events?

87% of respondents answered this question. Respondents noted the importance of dissolving the existing 'blame culture' and shifting towards 'honesty and openness' when handling these events. The importance of peer to peer support and discussions within and between professions was cited as vital, especially with other professionals who have been through a similar experience. The need for support from someone removed from the incident (who may have direct experience of another event) was also identified.

Learning opportunities was another frequent theme and many highlighted the need for access to training sessions as necessary to bring the practitioner back to confident safe practice. Respondents also noted the requirement to hold thorough de-briefs for both individuals and the team involved as soon as practicable after the event.

Suggestions for providing support within trusts included engagement of an effective and tailored Human Resources function, including a dedicated lead on clinician support. An effective supervision process with access to immediate emotional support from a dedicated support person with appropriate counselling was also highlighted.

The following list of existing clinician support services was provided:

- Royal Medical Benevolent Fund (RMBF)
- British Medical Association (BMA) Counselling and Doctor Advisor Service or 'Doctors for Doctors'

¹¹ One respondent noted that junior doctors have access to support within their Deanery whilst on their training scheme, however there is little support for consultants once qualified.

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- Association of Anaesthetists of Great Britain and Ireland
- British Doctors and Dentists Group
- British International Doctors' Association (BIDA)
- Doctors' Support Network
- NHS Practitioner Health Programme
- Royal Medical Foundation
- The Samaritans
- Sick Doctors Trust
- Facebook forum: Butterfly
- Facebook forum: Tea and Empathy
- Medical Royal Colleges
- General Medical Council (GMC) Resources to help doctors with health concerns

Time off for those involved to allow time for reflection was also suggested as another form of support.

9a- Do you agree that families should be provided with an early upfront payment, likely to be in the average range £50-100k, when avoidability can be established?

91% of respondents answered this question and of those who responded, 91% answered yes. This is a compound question bringing together elements relating to the provision of an early upfront payment, the average range of payment, and the linking of payment to the establishment of avoidability. In responding yes or no, respondents may have agreed or disagreed with one or all of the elements referenced. Many respondents provided more qualitative detail on the nature of their responses.

Despite overwhelming agreement that an early upfront payment would be useful in the early stages, a number of respondents commented that the sum proposed would not be enough to meet families' needs with comments including 'too little, too late' and 'too low and too slow'. The main reason provided was that the sum would not be adequate to cover home purchase/adaptation costs and the purchasing of essential equipment:

"The RRR scheme as currently proposed fails to make adequate lump sum/cash provision for the essential set up phase" (Legal professional)

"In most cases the three things that are required by age 4 (and often by age 2) are: level floor accommodation with suitable bathing facilities and space for equipment; a reliable car which is big enough for a buggy/ wheelchair; access to physiotherapy and speech and language therapy. If you are living in rented accommodation then you need to be able to purchase a suitable property and an award of £50k to £100k will not be adequate". (Legal professional)

"Suitable housing and adaptations are likely to be at least 3-4x the amount suggested. For example, in the area where I live a 3 bed house is in the region of £200k. A 3 bed bungalow is around £400k plus adaptations would be £30-50k. Therefore having a

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severely affected child would require housing costs of at least £250k more than having a healthy mobile child". (Family member)

Some noted that the size of the early payment should be closer to 500k, however many respondents suggested it would be better to set the amount in accordance with actual needs as opposed to a fixed arbitrary sum.

Points relating to the linking of the payment to the establishment of avoidability are picked up in question 9b below.

9b- If yes, do you agree that the first significant payment should be when avoidability can be established, which is around 4 years old?

91% of respondents answered this question and of those that responded, 73% answered yes. This is a compound question addressing whether provision of the first significant payment should be made when avoidability can be established, and the assertion that this would be at around 4 years old. In responding yes or no to this question, respondents may have agreed or disagreed with one or all elements referenced.

An area of contention was the necessity of establishing avoidability before providing payments. The majority of people who commented on this issue believed it to be essential for avoidability to be established before any payment can be made. However, some respondents highlighted that early interim payments should be made prior to the establishment of avoidability to mitigate financial hardship amongst affected families. A very small amount of people suggested a complete no fault style scheme along the lines of the New Zealand model.

Amongst the 100 qualitative responses provided, 30 stated that the first significant payment should be made as soon as avoidability is established, with 27 of those 30 stating that this could be done before the age of 4. The majority of these responses stated family hardship and meeting specialist care needs as the main reason for earlier payment, followed by the assertion that avoidability can often be established much earlier.

Respondents make the distinction between establishing avoidable harm and determining long term prognosis, noting that where scheme payments are staggered in line with periodic assessments, it is not necessary to establish long term prognosis before commencing payments under the scheme. To provide two illustrative examples, a neonatologist stated that in some cases avoidability can be established between 1-2 years of age, and one legal respondent noted that 'in most cases, whilst a child's prognosis may not be clear, avoidability can be established before the child reaches the age of four'.

Some respondents noted that the period between 0-4 is often the time of greatest stress and greatest risk of family breakdown occurring; to wait four years for assistance could cause unnecessary financial and emotional stress and hardship to parents.

Another respondent highlighted the importance of securing fast access to support, emphasising the potential to save long term health costs by 'providing early funding to access therapies and equipment which could help improve the child's condition – in the same way that early rehabilitation is accepted to be of value in reducing long term injury in personal injury claims' (legal).

Though not referenced in the consultation questions, some responded to the proposal that RRR compensation would be modelled at approximately 90% of a comparable litigation award:

"The compensation awarded in litigated cases are based on need" and "We do not think it is fair or reasonable that the injured baby/their family should have to forgo any of the

compensation that would be applicable if it were a court case in order to help pay for the scheme.” (Third sector organisation)

10i- Do you think that periodical payments should be made "in-kind" through a personal budgets type approach, administered by a case manager?¹²

89% of respondents answered this question which provided multiple choice options. Of those that responded, 61% agreed with the above statement; 23% favoured cash payments and 17% selected neither option. Affected family members were broadly in favour of cash over in-kind payments with only 36% of affected family members supporting this statement.

This is a compound question bringing together elements relating to the provision of periodical payments ‘in-kind’, a personal budgets type approach, and administration by a case manager. Many respondents utilised the comments section to provide more qualitative detail on the nature of their responses.

Common themes included that a personal budgets type approach is a good way to meet the changing care needs of a disabled child; however there were requests for a more detailed explanation of how an “in-kind” personal budget type approach would work. For example, what level of autonomy would be given to families to choose care providers for their child and would they be free to choose between state or private care providers? Some respondents noted that NHS services are not adequately equipped to provide the necessary quality of care required by claimants and provided examples including unacceptable waiting times, frequent cancellations and poor standards of care in comparison to private services. Others noted that statutory services are already underfunded and cannot adequately meet the needs of an additional cohort of neurologically injured children. Others noted that some families may not wish to access state care following their previous experience of avoidable harm within the NHS.

A common theme relating to the alternative option of cash payments was that this is preferable as it provides parents with autonomy and choice in determining how they manage their child’s compensation.

Many respondents suggested that a periodic payment comprising cash and in kind payments would be the best way to allow for regular reviews of a child’s needs and also balance families’ need for flexibility. As expressed by two different respondents;

“The scheme should allow state and private services to compete to offer the best service at the best price and it should then be up to parents to choose.” (Legal professional)

“I do think a proportion of the award should be in cash - however I do know of some individuals who have lost, as adults, value from awards made to them as children which were unwisely invested. A personal budget could protect against this perhaps - but it reduces autonomy. I think a mixed award is a good compromise.” (Midwife)

Another respondent made the point that ‘some specialised support that could be covered by ‘in-kind’ payments, should already be offered to parents free of charge as a result of their child’s condition, and so it will be important that payments are not used to subsidise services that

¹² Under an “in-kind” personal budget type approach families would have access to a range of services, and would be able to work with their case manager to choose the services that best suit their need and budget (note that this is different from, and more generous than, the personal budgets administered by a Local Authority to access state funded care).

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families are statutorily entitled to' (third sector organisation). The need to clearly differentiate between any personal budget awarded under RRR and a Local Authority personal budget was also highlighted.

In addition, comments were made about the use of a case manager to administer either cash or "in kind" payments. Some noted a case manager would be beneficial, providing support and assistance as well as easing the burden of financial management for the family. Others noted that a case manager would add an additional layer of bureaucracy making it harder for families to access the services they need. Concerns were also raised that families would lose the autonomy to make decisions about how best to utilise compensation for their specific needs.

A number of respondents stipulated the need for more information on the selection, expertise and training of case managers. It was noted that the skills requirements of the case manager role as set out are unrealistically broad, combining care co-ordination with financial management. Respondents queried where appropriate individuals with the necessary skills mix would be sourced from; what system of oversight would be put in place to oversee case managers; and whether case managers would be required to hold professional indemnity insurance, in the same way as a Court of Protection Deputy, to safeguard the interests of the child? Some respondents did not see how the proposed scheme would improve on the current system under litigation, whereby families are able to employ their own case manager and a Court of Protection Deputy is appointed to safe-guard the interests of the child.

Concerns were highlighted that the consultation gave no indication of how the child's best interests will be determined under the scheme, and some respondents also felt it would be necessary for the case manager to be independent of the NHS, or from NHS Resolution, for families to place their trust in the scheme. Respondents also noted the importance of ensuring that families have access to independent legal and financial advice at each stage of the process to ensure their best interests are met.

One legal professional noted that what families require is independence, certainty and financial security and that the scheme as described will not fulfil these needs instead offering 'uncertainty, inconsistency and poor quality of state provision'.

11i. Do you agree with the shift towards more staged (periodical) payments PPO¹³?

87% of respondents answered this question and of those who responded, 91 % answered 'yes'. A common theme in respondents' qualitative comments was that PPO would only be viewed positively if payments were individualised and reviewed regularly in order to meet the changing needs of the claimant:

"There should not be a blanket move towards smaller lump sums and more periodical payments. What is right for one claimant will not necessarily be right for another. There needs to be access to legal advice, experts and independent financial advisors to decide, on a case by case basis what is the right mix between lump sum and periodical payment for the individual claimant" (Legal professional)

Many respondents also highlighted that they would only be in agreement with PPO if substantial lump sum payments could be made up front towards housing and equipment costs. One respondent noted that a lump sum should still be required to cover past losses, general damages, loss of earnings and accommodation claims.

¹³ Periodical Payment Orders

Some respondents noted that periodic payments would be too slow in adapting to the changing costs of claimants' care and the differing needs of claimants must be considered, with PPO not suiting the needs of all.

'A blanket reduction in lump sum awards in favour of periodical payments will be wholly inappropriate where a person needs to adapt their existing home, or needs to move to a more suitable home. If more money is moved into periodical payments and away from the lump sum, people simply won't have the resources to do what is necessary to meet their child's needs.' (Legal professional)

It was also noted that greater use of PPO would help mitigate the recent change in the Personal Injury Discount Rate¹⁴ on total system costs.

12a-Do you agree that there should be an ongoing needs assessment of provisions for the injured child?

92% of respondents answered this question and of those who answered, 94% answered yes. There was a clear consensus that there should be ongoing needs assessment for the provision of children eligible for the RRR scheme to ensure the child's needs would be adequately met throughout the life-course, including after the parents may no longer be able to care for their child themselves. One respondent noted that most children with severe disability have an annual review in any case and that any assessment under RRR could be tied into this.

The following quotes reflect a range of answers provided by the minority of respondents (11) who provided qualitative comments against the inclusion of ongoing needs assessment within the scheme:

"An injured victim's entitlement to compensation for avoidable brain damage should be absolute. As soon as their condition and prognosis and probable needs can be determined, a full and final settlement (albeit paid partly by way of index-linked periodical cash payments) should be made over to them, once and for all." (Legal professional)

"The thought of there being ongoing needs assessment reviews at various intervals up to the age of 18 years is not a palatable one we would imagine for many families. There would be constant anxiety about forthcoming reviews, what the outcome would be, how to prepare for them and how to challenge them." (Family member with personal experience of obstetric negligence)

"(The) NHS do not have the skills to do these assessments across the country (and families) need flexibility to go to (a) private or expert centre." (Family member with personal experience of obstetric negligence)

Others noted that reviews should not be too frequent as this would create significant stress for families. In particular, there may be anxiety caused by uncertainty around whether payments would be increased, decreased or kept the same, which could affect families' ability to plan, retain long term care staff for their children etc.

12b- If yes, at which ages should these reviews be - ages 5, 12, 18?

¹⁴ The Personal Injury Discount Rate is applied to the lump sum element of any award.

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75% of respondents answered this question and of those who responded 74% answered yes. The main criticism provided was that each child is different and providing arbitrary assessment ages would not be appropriate. Alternative suggestions made by respondents were that:

- The appropriate ages for review should be determined with regard to each child's individual circumstances;
- The ages for review should be flexible, with parents/clinical professionals having the ability to trigger a review in the case that circumstances change;
- Educational milestones or clinical markers would be a good way to determine the appropriate ages for review.

As noted by one respondent:

“Conditions may worsen at any time, and children develop at different rates and stages, therefore arbitrary ages for reviews will not be enough to capture all changes in need. However it may be appropriate to set ages for reviews if there hasn't been a family triggered review in the preceding period.” (Third sector organisation)

13i. Do you agree that NHSLA (or new division within NHSLA) should administer the scheme?

94% of respondents answered this question, and of those who answered, 76% agreed that the NHSLA (now NHS Resolution) (or a new division within NHSLA) should administer the scheme.

Broken down by respondent group, 89% of healthcare professionals who responded agreed, whilst 55% of non-healthcare professionals agreed with this approach.

Responses to this question varied widely. In favour, respondents noted the NHSLA has the necessary experience, skill set, and infrastructure to implement the scheme, indeed, some respondents noted the NHSLA were the only organisation with the necessary experience to administer RRR.

Others expressed that the NHSLA as currently constituted would not be appropriate to oversee the scheme which goes beyond their existing scope and expertise, and would require significant organisational change. It was noted in particular that the NHSLA would need to expand its expertise beyond litigation with an associated cultural shift, and that the resolution process would also need to be made more timely and efficient.

Some respondents highlighted the need for trust and credibility in whoever will administer the scheme and voiced concerns that a conflict of interest could exist between the NHSLA's interests and the interests of the child/family:

“We fail to see how the potential defendant in the civil claim can administer the scheme, this would lead to problems and potential conflict” (legal professional)

Some respondents suggested that an independent body should administer the scheme, with suggestions including the recently formed HSIB or a new independent ombudsman established specifically for the purpose of administering the scheme. Others suggested that the NHSLA should administer the scheme but that it should be complemented by input and advice from other partners. Respondents noted that under this scenario, effective governance mechanisms would need to be put in place to circumnavigate any real or perceived conflict of interest, including the maintenance of a 'Chinese wall' between the RRR scheme and the litigation arm of the organisation.

Appropriate precedents within the organisation were cited as the NHS Resolution mediation service and the NHS Resolution Faculty of Learning, established to learn from inquests, effectively deliver candour and support Trust boards.

14ai- Do you agree that the clinical eligibility into the scheme should be defined using the RCOG definition of avoidable brain injury?

90% of respondents answered this question and of those who responded, 84% agreed with defining clinical eligibility into the scheme using the RCOG definition of avoidable brain injury.

The main reason in favour was existing familiarity and clarity around this definition and a tested and effective method of identification and reporting; all of which would improve the likelihood of consistent use. It was also noted as having the advantage of *'keeping scheme numbers reasonably low in the first instance, in effect acting as a pilot'* (legal professional).

A key concern with the RCOG definition was that the criteria were too narrow and would exclude many severely disabled babies whose cases should be included within the scheme. Respondents noted that many cases don't fit this paradigm which could exclude those who are severely disabled as a result of neurological birth injury but are missed by the clinical eligibility criteria as they were not comatose, or cooling was not offered or available.

Other respondents felt the RCOG criteria to be too broad, resulting in unnecessary use of resources and stress for affected families. Respondents noted that cooling is much more widely used than when the RCOG definition was written and one paediatrician noted cooling is now being used in babies for whom there is no direct trial evidence to do so. It was also noted that many babies who are cooled go on to be healthy babies; and the inclusion of this definition would make a larger cohort of babies than may be necessary eligible for investigation. Similarly, some respondents noted that babies who suffer neonatal seizures often go on to be healthy babies and therefore need not always be included within the scope of the scheme.

Alternative recommendations were made for the inclusion of HIE 2¹⁵ as a clinical marker in addition to HIE 3, or alternatively the use of 'all cooled' babies; the use of the 'Toby' register criteria¹⁶; or the use of an outcome measure, as opposed to an acute presentation i.e. acute brain imaging abnormality consistent with possible HIE.

It was also highlighted that effective determination of eligibility is dependent on the accuracy of internal coding which may be subject to manipulation or error, and also the quality of records available.

14b- If not, what are your objections or any proposed alternatives?

11% of respondents answered this question. In the main, responses involved suggestions for extending the scope of the scheme beyond the eligibility criteria outlined by the RCOG definition of avoidable brain injury.

¹⁵ HIE stands for Hypoxic Ischemic Encephalopathy; a condition associated with a reduction in oxygen supply to the baby from a variety of causes during the birthing process. The clinical syndrome of HIE is graded according to its severity with grade III being the most severe.

¹⁶ The UK TOBY Cooling Register is a UK research study conducted to assess the effectiveness of cooling as a treatment for infants who have suffered oxygen deprivation at birth. The eligibility criteria used in the TOBY study is included at Annex A.

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The most frequent suggestion was for all unexpected intrapartum stillbirths and early neonatal deaths to be included within the scheme. Respondents indicated that cases of stillbirth and early neonatal death often share many of the same contributory factors as cases of avoidable brain injury. However, in the case of stillbirths and early neonatal deaths it is clear that severe harm has occurred, whereas many babies meeting the RCOG definition of avoidable brain injury go on to be healthy babies. It was argued that the inclusion of stillbirths and early neonatal deaths would therefore enable greater learning into avoidable harm during birth and labour than a focus on Severe Brain Injury alone. Some respondents noted that without this inclusion it would be difficult to achieve the national Government ambition to halve the rates of stillbirths, neonatal deaths, maternal mortality and brain injuries that occur during or shortly after birth by 2030, with a 20% reduction by 2020.

“Determining eligibility by whether the baby survived is arbitrary: the lessons learnt from intrapartum stillbirths and neonatal deaths are equally valuable to those learnt from cases of severe brain injury. The inclusion of these babies in the scheme would have a limited effect on the overall cost as there would be no ongoing payments and any compensation offered by RRR would be low”. (Third sector organisation)

The following suggestions were also made for inclusion in the scheme:

- Women who have experienced complications such as pre-eclampsia or diabetes in the antenatal period;
- Babies who have experienced brain injury caused by antenatal care or care in the immediate post-natal period (up to 6 weeks);
- Premature babies (i.e. those born before 37 weeks);
- Multiple births;
- Severe birth trauma injuries e.g. fractured skull following forceps delivery or additional conditions such as hypoglycaemic brain injury or kernicterus;
- Babies born across other parts of the UK.

Respondents noted that after the initial launch of the scheme there may be pressure to extend eligibility to other conditions including neonatal sepsis, missed meningitis, GBS¹⁷ infection during birth and also adult neurologically damaged claimants in the future, and *‘the costs of resourcing such an extension should be considered from the outset’* (legal professional).

Other points made by respondents included:

- There should be an option for families/consultants to appeal the eligibility of individual babies whom they believe should be included, despite them not meeting the parameters of the scheme.
- Further clarity is required on if and how families can refer a case into the scheme should evidence come to light further down the line. There needs to be provision for this and the consultation is not clear on this point.
- Would families be able to enter the scheme having already gone down the litigation route but failed?

¹⁷ Group B streptococcus

- The time limit for conditions to be recognised should be extended beyond 7 days as criteria may not necessarily be apparent within this period.
- There is no need to include mortality cases within the RRR scheme as such cases will be investigated through the Perinatal Mortality Review Tool.
- A pilot version of the scheme should be conducted to trial the proposed markers and allow clinicians to provide feedback and input.

15i- Do you agree with the principle of administering the scheme using an avoidable harm test?

88% of respondents answered this question and of those that responded, 91% agreed with the principle of administering the scheme using an avoidable harm test.

Those who disagreed with this principle commented that the assessment of avoidability involves a determination of whether care met an agreed standard and hence sits uneasily with the principle of no blame redress; that the scheme should be made available to all babies who are seriously compromised at birth, regardless of the cause of their illness and whether or not it was avoidable; and that the state should provide good care to all seriously injured babies independent of causation.

One respondent commented that some consideration should be made for the lifestyle factors of the mother and the scheme allow for the acceptance of some, but not all avoidability.

The Bolitho principle¹⁸ was presented as an alternative administrative test, weighing the risks and benefits of a particular course of action to determine whether the patient was exposed to an unreasonable risk in the circumstances. Another respondent stated that the standard should be *'the standard which the patient has a right to receive'*.

Regarding the application of the test, a number of responses requested a more detailed description of what constitutes avoidable harm. A number of respondents stated that the persons expected to apply the avoidable harm test would need to be legal professionals, have legal training or access to appropriate legal advice.

16i- Do you prefer the proposed 'Experienced Specialist' test (Option A) or the 'Reasonable Care' test (Option B)?

85% of respondents answered this question and of those who answered, 43% expressed a preference for the 'Experienced Specialist' test and 57% for the 'Reasonable Care' test¹⁹.

The key themes cited in favour of the 'Reasonable Care' test were:

¹⁸ A legal test that modified the 1957 Bolam test used by the English courts to determine medical negligence. The Bolam test states that an action is not a breach of duty if it conforms with a reasonable body of professional opinion. The Bolitho test adds that the reasonable body of professional opinion must be capable of logical justification.

¹⁹ These figures include a number of respondents who disagreed with the principle of administering the scheme using an avoidable harm test in response to Q15i.

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- The test should maintain similarity to the current litigation test to ensure there is not a two tier system. It was noted that the current legal test²⁰ takes account of what might be expected of a reasonable clinician practising in the same or similar circumstances;
- It would be unwise to use a lower eligibility threshold to the current litigation test as this would lead to an increase in eligible cases and unsustainable cost pressures;
- This test reflects the standard that could be reasonably expected within a publically funded service, taking available resourcing into consideration. Unless the NHS is funded to provide a standard of care equivalent to the experienced specialist standard in all circumstances then the only appropriate test is the Reasonable Care Test;
- It would be better to continue with the Reasonable Care test as experts are already familiar with this terminology;
- It would not be reasonable to expect all care to be at the standard of an expert when healthcare settings are made up of staff with diverse levels of experience: ‘Clinicians need the opportunity to gain experience and our hospitals cannot just be staffed by specialists, so this would be a way of balancing that compromise’(Legal professional).
- Using a higher standard than ‘Reasonable Care’ will contribute to problems with staff morale, recruitment and retention: ‘Staff will consider they are being criticised for providing care which is objectionably reasonable’ (legal professional);
- Concern that the Experienced Specialist Test could effect a change in the general tortious burden (not just in maternity cases) over time.

The key themes cited in relation to the ‘Experienced Specialist’ test were:

- It is the best test to use if the intention is to drive up learning to achieve the highest standards of care: “‘Reasonable’ care isn’t enough. Clinicians should be held to the highest standard”;
- As the Experienced Specialist test has a lower burden of proof it will provide a larger pool of cases from which to learn;
- The Experienced Specialist test is more likely to facilitate an open learning culture and contribute to future harm reduction: “The RCT is effectively a blame laden liability test as currently used for litigation”;
- As the eligibility threshold is lower and the scheme potentially open to a wider cohort of cases, the scheme will provide a more attractive alternative to litigation;
- Some clinicians may not be happy with a scheme that finds ‘fault’ on the basis of a higher test than their actual level of experience;
- If the Reasonable Care test is used families may use RRR as a test bed for a subsequent litigation claim.

²⁰ The Bolam Test (which states that states that an action is not a breach of duty if it conforms with a reasonable body of professional opinion)

- Respondents noted that neither test addresses how causation will be addressed In relation to either test.
- Respondents also noted that irrespective of the test used the scheme is likely to stimulate the number of claims received (whether through RRR or litigation routes) and dramatically increase costs, especially if RRR is used as a ‘test run’ for a legal claim (legal professional).

17i. Should the scheme be piloted?

96% of respondents answered this question and of those who answered 82% agreed that the scheme should be piloted.

Key themes cited in favour of conducting a pilot were the opportunity this provided to test levels and processes of learning and harm reduction. It was noted that a pilot would ensure the design of the RRR scheme is efficient and effective and any issues, including unintended consequences, are addressed in advance of any national roll-out.

Some noted the importance of testing any additional workload that would be generated to the system by RRR, particularly with regards to front-line staff time. In addition, respondents noted that the pilot should be reviewed by a panel of independent experts, as well as patients.

Reasons expressed for not conducting a pilot included concerns that due to the relatively small size of the sample cohort, results would not be statistically significant, would take many years to manifest and could not be expected to demonstrate anticipated levels of harm reduction. In addition, some respondents felt a geographical pilot would be unethical, creating a ‘post-code lottery’ and inequality between families. One issue raised was what would happen to any cases included in a pilot if the scheme were subsequently withdrawn. It was noted that this could cause significant stress to families and should be avoided. Ensuring stability and continuity for families should this arise was of prime importance.

Respondents also noted that the fact the scheme is based on international evidence reduces the need for a domestic pilot. Others suggested the scheme should be piloted on the basis of historical cases.

One alternative suggestion was to commence immediate roll-out of the scheme with a commitment to monitor, review and modify over time. Some respondents noted that any pilot should be short and regional, and some trusts noted their willingness to participate in any pilot that may be conducted.

Additional evidence:

In addition to the structured questionnaire above, we also asked respondents to submit any additional evidence on a range of different operational and theoretical areas as set out below. We received a number of additional submissions which we are in the process of considering in further detail.

- Evidence A - Initiatives to reduce harm during labour and delivery.
- Evidence B - Initiatives to increase openness and transparency
- Evidence C - Scheme design to meet family’s needs
- Evidence D – Increase in claims from an avoidable compensation threshold
- Evidence E – The structure and timing of the administrative part of RRR

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- Evidence F – Growth in the number of clinical negligence claims received and settled
- Evidence H – Information on impact on the clinical negligence market
- Evidence I – Impacts on equalities, health inequalities and other considerations for families.
- Evidence J – Any other evidence?

A number of respondents shared the academic paper “Results from the National Perinatal Patient Safety Program in Sweden: the challenge of evaluation; by Millde Luthander et al²¹. The Swedish Safe Delivery Care programme introduced to Sweden in 2007 provides an important international comparison and source of evidence for RRR, however this evaluation was published too late to be considered prior to the consultation. The paper highlights the need for caution when evaluating large scale quality improvement interventions, such as the Swedish scheme, as different measures can suggest differing levels of success. They suggest that there is still disagreement within the field as to which outcome measures best reflect the quality of perinatal care, meaning that it is often important to use more than one outcome measure for evaluation. Some respondents also noted that the introduction of the Swedish scheme coincided with the increased use of cooling in Sweden which may also have contributed to the reduction in severe birth injury claims witnessed there in recent years and that the Swedish model is not comparable to the English system, having a smaller population, and greater levels of social security provision, meaning that capped levels of damages may be more workable there than here. Further consideration of the implications of the Swedish scheme and the findings of the Millde Luthander et al paper is needed.

In addition we also received two proposals setting out potential alternative operating and governance models for the delivery of RRR. The first is from academics at the Centre for Socio-Legal Studies at the University of Oxford and a former Chief Legal Ombudsman, proposing the establishment of a new independent ombudsman to oversee investigations and determinations of eligibility for compensation and levels and composition of compensation packages. The second is from The Royal College of Obstetricians and Gynaecologists proposing an extension of the existing Each Baby Counts scheme to support the operation of RRR, working with other system partners under a proposed Maternity Improvement Alliance. We are in the process of considering these alternative proposals with the authors and other partners.

Next steps:

We are in the process of considering consultation feedback and working with partners to develop a final workable policy proposal for implementing RRR. This forms part of this government’s commitment to reduce incidents of avoidable intrapartum harm and also to address the rising costs of clinical negligence.

This next stage of policy development includes continued engagement with partners and additional modelling to understand the impact of recent changes such as the change to the Personal Injury Discount Rate and alternative policy parameters as suggested through responses to the consultation. Particular areas for further consideration include:

- The final scope of the scheme
- Composition of investigation panels/leads

²¹ Millde Luthander C, Kallen K, Nystrom ME, Hogberg U, Hakansson S, Pukk K et al.

Results from the National Perinatal Patient Safety Program in Sweden: the challenge of evaluation; Acta Obstetrica et Gynecologica Scandinavica, 20 March 2016

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- Where the scheme/different elements of scheme should be located/housed
- The most appropriate Avoidable Harm test to use
- How payments should be structured under the scheme including:
 - Size and timing of any early/interim payments
 - Timing of commencement of regular payments under the scheme
 - Balance between lump sum and PPO
 - Balance between cash/in kind
- Structure and timing of ongoing assessments

Further consideration is also required of the:

- Best way to collate and disseminate information collated by the scheme
- Best way to implement training and learning
- Best way to support clinical staff

It is our aim to undertake additional engagement at pace throughout the remainder of this year and publish a final policy proposal in Spring 2018.

Annex A: Toby Criteria:

Eligibility for TOBY requires three sets of criteria to be satisfied (A, B and C).

A. Infants >36 weeks gestation admitted to the NICU with at least one of the following:

- Apgar score of <5 at 10 minutes after birth.
- Continued need for resuscitation, including endotracheal or mask ventilation, at 10 minutes after birth.
- Acidosis within 60 minutes of birth (defined as any occurrence of umbilical cord, arterial or capillary pH <7.00)
- Base deficit >16mmol/L in any blood sample (arterial, venous or capillary) within 60 minutes of birth. Infants that meet these criteria will be assessed for whether they meet the criteria B:

B. Moderate to severe encephalopathy, consisting of altered state of consciousness (lethargy, stupor or coma) AND at least one of the following:

- hypotonia
- abnormal reflexes including oculomotor or pupillary abnormalities
- an absent or weak suck
- clinical seizures, as recorded by study personnel.

Infants that meet criteria A & B will be assessed by a EEG (read by trained personnel).

C. At least 30 minutes duration of amplitude integrated EEG recording that shows abnormal background a EEG activity or seizures. There must be one of the following:

- normal background with some seizure activity
- moderately abnormal activity
- suppressed activity
- continuous seizure activity

Exclusion Criteria

- Infants expected to be >6 hours of age at the time of randomisation
- Major congenital abnormalities, such as diaphragmatic hernia requiring ventilation, or congenital abnormalities suggestive of chromosomal anomaly or other syndromes that include brain dysgenesis.