Department of Health

# A Rapid Resolution and Redress Scheme for Severe Avoidable Birth Injury: a Consultation

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# A Rapid Resolution and Redress Scheme for Severe Avoidable Birth Injury: a Consultation

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# Executive Summary

This document outlines the Government's proposal to introduce a Rapid Resolution and Redress (RRR) scheme - a voluntary administrative compensation scheme for families affected by severe avoidable birth injury.

## Why are we proposing this change?

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.[1] 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.[2] The RRR scheme will gather evidence and provide clinicians with additional support for learning, so that individual tragedies become lessons that save many more families from 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 current expenditure on maternity claims is nearly £500m per year[3]. There is also perceived inequity in the healthcare provision between those whose injury is due to clinical negligence and those that are not.

The National Maternity Review (Better Births, 2016) independently chaired by Baroness Cumberlege, recommended that the Department of Health should consider a RRR scheme for severe avoidable birth injuries. The aim is to tackle the three issues noted above: improving

[1] NHSLA data

[2] "Better Births" – National Maternity Review 2016, available at: https://www.england.nhs.uk/wp-content/uploads/2016/02/national-maternity-review-report.pdf

[3] NHSLA data

safety; improving the experience for families when things go wrong, and making more effective use of NHS resources so that more funds can be invested in frontline care.

## Proposals for change

The RRR scheme proposes a system of consistent, robust, and independent investigations for all instances where there may be severe avoidable birth injury; and for eligible babies and their families, the option to join an alternative system of compensation that offers support and regular payments without the need to bring a claim through the courts. This would be a voluntary scheme which would not affect an individual's right to litigate. The scheme would apply to harm associated with treatment under NHS maternity services in England only.

## This consultation

We are launching this public, 12 week consultation in order to gather a wide range of views which will enable us to design a policy which supports the needs of families; effectively reduces the number of harmful incidents; and is operationally deliverable.

This consultation will consider several options around the proposed scheme design, including;

- how the scheme is administered;
- the eligibility threshold for compensation; and
- how learning would best be disseminated and actioned to reduce future harm.

These options and other details will be described in the following chapters for your response. We also intend to use this consultation as a call for further data and evidence, to help us to further enhance the evidence base and inform future policy decisions.

We have listened to the concerns of families, clinicians, lawyers and others about the current system, and have considered and developed the proposal outlined in Better Births. We have launched this consultation to ensure that the proposal benefits from input from a wide range of views and experiences. Thank you for your time in engaging with this consultation, and we look forward to receiving your response.

# 1. About this Consultation

1.1. This consultation outlines the proposal to introduce a Rapid Resolution and Redress scheme (RRR) - a voluntary administrative compensation scheme for families affected by severe avoidable birth injury.

1.2. This new scheme would have the main aims of;

- 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.

1.3. For clarity, the policy design has been described in two parts; Stage One and Stage Two.

1.4. Stage One focusses on improving investigations into severe avoidable birth injuries and ensuring learning is shared and implemented to reduce future harm.

1.5. Stage Two is concerned with ensuring families are provided with ongoing support and compensation, without the need to bring a claim through the courts.

1.6. The relationship between Stages One and Two is crucial for the success of the scheme, as findings from Sweden[4] suggest that the non-adversarial delivery of compensation in Stage Two is critical is to creating an effective learning culture in Stage One.

## Invitation to respond

1.7. This consultation is being led by the Department of Health. You are invited to read this consultation and send in your views. Views on this consultation are particularly invited from:

- Families and individuals who have been affected by a serious birth injury, in particular injury resulting in cerebral palsy/brain damage;
- Clinicians who have experience of these serious events;
- Charities, patient groups and legal organisations that have experience of these incidents and the litigation process;
- National Research and Audit groups responsible for investigating these incidents currently.

1.8. Responses are not restricted to these groups. We welcome the views of any person or organisation with an interest in this policy, directly or indirectly.

1.9. This consultation will be distributed widely so that as many people and groups as possible will have the opportunity to provide their comments and feedback. Once we have considered the responses to the consultation, we will publish a response and final policy decision.

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[4] "Better Births" – National Maternity Review 2016, Annex D. Available at: https://www.england.nhs.uk/wp-content/uploads/2016/02/national-maternity-review-report.pdf

## Details of Consultation

1.10. This consultation seeks views on how the RRR scheme would best operate, so that we can design a policy that supports the needs of families, effectively reduces the frequency of harmful incidents and is operationally deliverable.

1.11. This consultation will consider several options around the proposed scheme design, including;

- how the scheme should be administered;
- where the eligibility threshold should be set; and
- how learning would best be disseminated and actioned.

1.12. These options and other details will be described in the following chapters for your response. We also intend to use this consultation as a call for further evidence and data, to help us to further enhance the evidence base and final policy decisions. We are interested in information concerning (but not limited to):

- initiatives to reduce harmful events during labour, both in the UK and internationally;
- initiatives to increase openness and transparency, looking both within healthcare settings and more broadly;
- how to design a compensation scheme which will best meet the needs of families;
- equalities, health inequalities and families considerations; and
- any other useful evidence.

1.13. Comments on the proposal can be submitted:

- online via Citizen Space (preferred);
- by post to RRR Policy Team, Acute Care & Quality Directorate; Department of Health; Room 239, Richmond House, 79 Whitehall, SW1A 2NS;
- by email to RRR-Consultation@dh.gsi.gov.uk

The consultation will close on **Friday 26th May 2017.**

## Impact Assessment

1.14. This consultation is accompanied by a consultation stage Impact Assessment (IA). The IA sets out the full body of evidence and analysis for the policy proposal; a full list of options which have been considered; and detailed analytical modelling for each of these. As further explained in the IA, a number of the options initially considered for the proposed RRR scheme have not been carried forward into this consultation after initial analysis deemed them unfeasible. Therefore only two of the IA's policy options have been proposed in this consultation for your consideration and response. These are set out in further detail below and in the IA.

1.15. Following the consultation, any final policy proposal will be subject to further analysis and a subsequent final Impact Assessment.

## Confidentiality

1.16. The Department will manage the information you provide in response to this consultation in accordance with the Department of Health's Personal Information Charter[5].

1.17. Information the Department receives, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

1.18. If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply, including obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information you have provided as confidential. If the Department receives a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

1.19. The Department will process your personal data in accordance with the DPA, and in most circumstances, this will mean that your personal data will not be disclosed to third parties.

## Devolved Administrations

1.20. The proposed scheme would be voluntary, and would only apply to injuries associated with NHS services in England. As such, these proposals do not apply to the Devolved Administrations.

1.21. People will be covered by the scheme if they experience injury associated with maternity care they received in England, regardless of where they live in the UK.

## Assessment of Equalities, Health Inequalities & Families

1.22. The Public Sector Equality Duty (PSED) places a duty on public bodies and others carrying out public functions. It aims to ensure that public bodies consider the impact of policy on all individuals that have one or more of the protected characteristics covered by the Duty. The PSED is set out in section 149 of the Equality Act 2010, and it applies across Great Britain to public bodies listed in Schedule 19 to the Act (and to other organisations when they are carrying out public functions).

1.23. The Family Test[6] is not a statutory duty but requires a number of questions to be considered when developing policy.

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[5] Personal Information Charter: https://www.gov.uk/government/organisations/department-of-health/about/personal-information-charter

[6] Family Test, Guidance for Government Departments 2014: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/368894/family-test-guidance.pdf

1.24. The expected impact of the RRR scheme on the various equalities set out above, including the Family Test, is detailed in the 'Equalities and the Public Sector Equalities Duty' section of the accompanying consultation stage Impact Assessment.

1.25. We welcome any additional evidence on the equalities impacts which will form part of the final consideration of the policy.

## Next Steps

1.26. Following this consultation, the Government intends to:

- analyse and consider the responses;
- hold further discussions with key interested parties; and
- publish a public consultation response document.

The principles of the final policy design will reflect key areas covered in this consultation. The specifics details of policy design (such as eligibility, and level of compensation awarded) will take into consideration responses to this consultation, alongside wider contextual factors, to form part of a final business case for cross-Government consideration.

# 2. The Case for Change

## Overview

2.1. In England each day over a million people are safely treated by the NHS. Having a baby is the most common reason for admission to hospital in England[7] and, in the vast majority of cases, the care that mothers and babies receive is excellent. However, in the small number of cases where things go wrong it is important that the system is set up to provide prompt support to families and to ensure that lessons are learned.

2.2. Serious incidents that arise from substandard care during birth (labour and delivery) are profoundly devastating events. Events such as these affect all parties involved and can be overwhelming for families as the resulting condition, potentially lifelong disabilities such as cerebral palsy or other forms of brain damage (collectively termed neurological injury), can require comprehensive and lifelong care for the affected individual. Avoidable injuries of this type are usually the result of oxygen deprivation during labour and delivery, perhaps due to a delay in identifying the need for urgent clinical intervention. The NHS Litigation Authority (NHSLA), which manages all clinical negligence claims for the NHS and uses claims data to drive forward safety improvements across the health system, settles around 100 multi-million pound maternity cases a year. This roughly equates to two multi-million pound settlements per week for children born with severe neurological injuries as a result of medical error.

2.3. Currently when a negligent incident occurs that causes injury at birth, the only means by which families can secure compensation is through the adversarial and often lengthy litigation process. This process takes time because the Court has to wait until the injured child's prognosis is clear in order to accurately decide the level of appropriate compensation, in the form of a full and final settlement or award. This adds uncertainty and stress for the families involved and creates the dual problems of delaying possible learning from incidents, and escalating the costs of litigation when claims are brought. The average length of time from an incident to a final settlement on birth injury claims is 11.5 years[8]. For those who have similar care needs but were not negligently harmed, state services are available but this is sometimes markedly less than what can be procured following a typical court award.

2.4. The annual cost of clinical negligence in the NHS in England has risen from £1.2bn in 2014/15 to £1.5bn in 2015/16.[9] The average value of medical litigation awards is increasing by around 9% per year - well above inflation.[10]

2.5. RRR is intended to provide an alternative means of resolution, support and compensation for families that suffer an avoidable birth injury. This is designed to improve the experience of families and clinicians, reduce future harm, and provide an important first step in managing the rising costs of litigation.

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[7] Committee of Public Accounts, 2014. Maternity services in England - Fortieth Report of Session 2013–14, House of Commons. Available at: http://www.publications.parliament.uk/pa/cm201314/cmselect/cmpubacc/776/776.pdf

[8] NHSLA data

[9] NHS Litigation Authority: Annual Report and Accounts 2015/16

[10] NHSLA analysis

# 3. Policy Objectives

3.1. The Rapid Resolution and Redress scheme (RRR) aims to introduce a system of consistent, robust, and independent investigations for all instances where there may be severe avoidable birth injury, along with access to ongoing support and compensation for eligible babies through an administrative scheme, with the main aims of:

- 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.

DH is committed to reducing harm, improving safety and managing the rising costs of NHS litigation as a whole. The RRR scheme is focused on a very small subset of babies which have suffered a severe avoidable birth injury. This is part of a wider DH programme of work to improve safety and improve the litigation process.

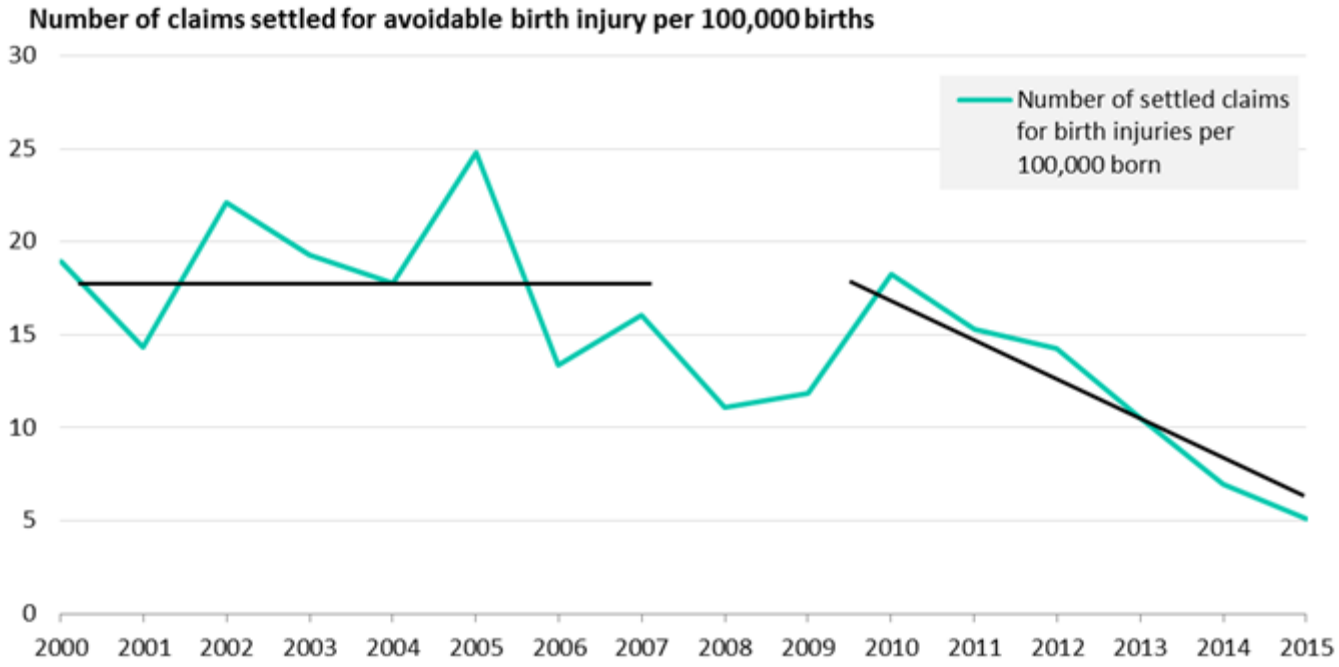
## Objective One: Reducing the number of severe avoidable birth injuries by encouraging a learning culture

3.2. The National Maternity Review led independently by Baroness Cumberlege (Better Births, February 2016), recommended that the Department of Health (DH) should consider introducing a RRR scheme for birth injury and death caused to babies during labour and delivery, and cited evidence from Sweden to support this model.[11]

3.3. In 2007, Sweden implemented an initiative called ‘The Safe Delivery Care Project' which appears to show evidence of a reduction of claims for severe neurological birth injury (Figure 1). The National Maternity Review uses the reduction in the total number of compensation claims in Sweden as a proxy indicating that there has been a reduction in the number of harmful incidents. As claims data for past incidents is collected in future years, there may be a slight increase in these claims in future due to late reporting. However, analysis from Swedish colleagues suggests that given the gap between incident and claim is purported to be short (3-4 years), the data is a reasonable indication of reduction in incidents per birth.

[11] Better Births. Improving outcomes of maternity services in England. A Five Year Forward View for maternity care (2016) NHS England.

**Figure 1: Data from Sweden showing the frequency per 100,000 born of settled claims involving serious birth injuries per year 2000-2015.**




3.4. Data from the NHSLA shows that the number of successful negligence claims for severe neurological birth injury in England has remained relatively static over the last 10 years, averaging around 129 families per year. While caution should be exercised over any direct comparison between England and Sweden[12], the data does give some indication that England has not experienced an equivalent reduction in the level of claims.

3.5. In November 2015, the Government announced a new national ambition for maternity services to reduce the rates of stillbirths, neonatal deaths, maternal mortality and brain injuries that occur during or shortly after birth by 50% by 2030, with a 20% reduction by 2020. RRR will support delivery of this ambition by incorporating some of the elements of policy design seen in Sweden (and in other examples) to improve learning and reduce future harm for specific groups of babies affected by severe avoidable birth injury.[13]

## Objective Two: Improving the experience of families and clinicians when harm has occurred

3.6. Currently the only route available to families who experience severe birth injury as a result of medical error is to pursue compensation through litigation. When a claim is brought against the NHS with respect to substandard care, the cases are managed by the NHSLA.

[12] Please refer to para 274 of the IA published alongside this consultation for a detailed explanation about why a direct comparison cannot be made.

[13] More information on the evidence base including Sweden is provided in the accompanying IA.

3.7. When birth injury cases are litigated, the process is often expensive and lengthy. This is because for clinical reasons, often the nature of the injury and the needs of the child cannot be established until school-age. This delay can be exacerbated further by the adversarial nature of litigation. Families instruct lawyers to consider their case (which may commence several years after the event) and often numerous expert reports are required to assess care needs. The limited availability of liability experts often delays the parties from being able to answer key questions, such as how harm was caused. Where liability is established, families are provided with interim compensation payments to help provide them with financial support until the child's full injury and lifetime needs can be assessed and a final settlement can be agreed.

3.8. Feedback from families, clinicians and other parties tells us the litigation process can be stressful and gruelling for families, who are also adapting to life providing constant and often complex care to their injured child. There is no consistent process for supporting a family whose baby is born with severe neurological injuries, and feedback also tells us that investigations into these incidents are not implemented consistently across the NHS. The Royal College of Obstetricians and Gynaecologists (RCOG) 'Each Baby Counts' report found that investigations are currently inconsistent and that parents are neither routinely involved in, nor given sufficient information on the investigatory process.[14]

3.9. The experience can also be hugely stressful for the clinicians involved, who may not be well informed about the processes of investigation and subsequent litigation. The label of 'negligence' may impart the suggestion of blame on individual practitioner(s), which may inhibit total candour or mask potential opportunities for shared learning and improvements at system level. .

3.10. RRR aims to improve the experience of families by providing a rapid, independent investigation to identify the root cause of an incident. This will be accompanied by a more open and transparent dialogue between clinicians and the family, including an early apology. Eligible families will have the option of joining an administrative scheme to access ongoing support and compensation. Alongside this the scheme aims to improve the experience of clinicians by focussing on 'avoidable' harm, rather than negligence and individual fault-finding. This will work alongside professional regulation (and is therefore not intended to diminish individual professional accountability), but will reinforce a cultural shift towards learning rather than blaming and identifying opportunities for system level improvement. This complements other recent policy developments such as the Duty of Candour[15].

## Objective Three: Making more effective use of NHS resources

3.11. The NHSLA has total liabilities (provisions) of £56bn, making it the second largest cross government liability. Annual costs (cash) have increased substantially – the annual cost of clinical negligence in the NHS in England has risen from £1.2bn in 2014/15 to £1.5bn

[14] Royal College of Obstetricians and Gynaecologists. Each Baby Counts: key messages from 2015. London: RCOG, 2016.

[15] A legal duty on hospital, community and. mental health trusts to inform and apologise to patients if there have been mistakes in their care that have led to significant harm. For more information on duty of candour, please refer to NHSLA: Introduction to Duty of Candour at http://www.nhsla.com/OtherServices/Documents/NHS%20LA%20-%20Duty%20of%20Candour%202014%20-%20Slides.pdf

in 2015/16.[16]. Data tells us that maternity claims tend to be of higher value due to the need to provide life-long care, and contribute disproportionately to litigation expenditure compared to the volume of claims lodged. In 15/16 obstetric claims made up around 42% by value of all newly reported clinical negligence claims (the largest single speciality item), but only 10% by number of newly reported claims. This represents less than 0.1% of all births in England during an equivalent time period.

3.12. The NHSLA settles around 100 multi-million pound maternity cases a year which roughly equates to two multi-million pound settlements per week for children born with severe neurological injuries as a result of medical error. Over the past 10 years the size of average awards has risen by around 9% per annum, well above general inflation and significantly larger than other inflationary indices, such as the general cost of providing care.

3.13. The average settlement for a severe neurological birth injury case equates to a value of £6.25m, including costs paid out over the injured person's lifetime. Therefore a scheme designed to reduce the number of infants harmed in this way in future years also has important potential to deliver savings. Savings may also be achieved through a more efficient and streamlined system that could negate the costs associated with the lengthy litigation process (such as legal fees), which could then be reinvested back into frontline care.

3.14. For explanatory purposes, we have described and modelled the proposed RRR scheme in a two-stage design, as depicted in Figure 1 below.

3.15. Stages One and Two are symbiotic in creating a culture of openness and it is important that they are considered together as part of one system. Findings from Sweden[17] highlighting that a non-adversarial system for redress is key to unlocking a learning culture and moving away from a defensive culture.

[16] NHS Litigation Authority: Annual Report and Accounts 2015/16

[17] "Better Births" – National Maternity Review 2016, Annex D. Available at: https://www.england.nhs.uk/wp-content/uploads/2016/02/national-maternity-review-report.pdf

# 4. Policy Development

4.1. We have described and modelled the proposed RRR scheme in a two-stage design, as depicted in Figure 1 below.

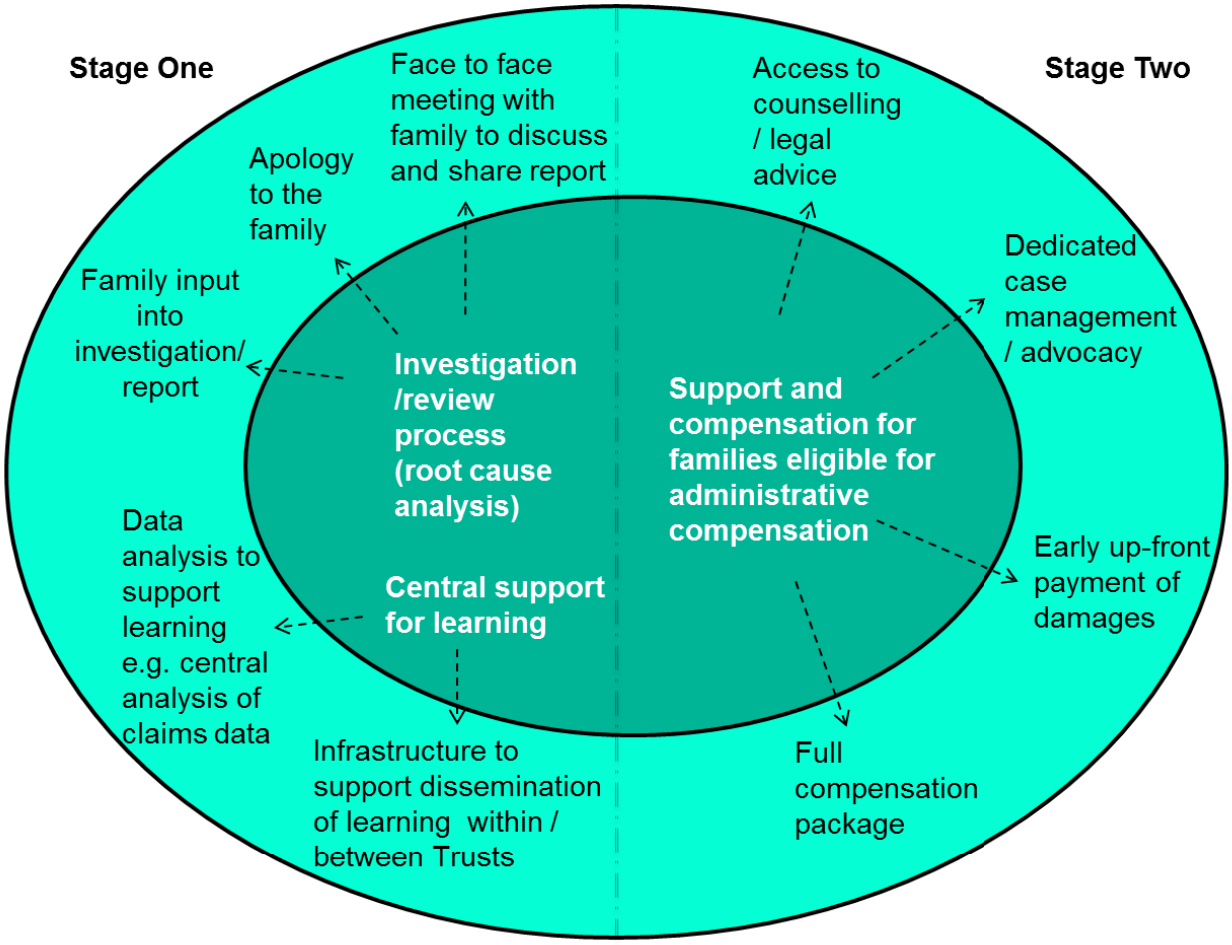



**Figure 1: A summary depiction of the different elements of the RRR scheme with Stage One and Stage Two detailed.**

## Stage One

4.2. Stage One introduces standardised, independent investigations of potentially avoidable instances of neurological birth injury. This will be supported by analysis of maternity and claims data across the country (similar to the Swedish Safe Delivery Care initiative), in order to better understand the common causes of avoidable harm and share learning to drive future harm reduction.

4.3. Note that immediately after birth, it may not be possible to determine with certainty the nature and extent of harm, which is usually necessary in order to establish causation and support an assessment of avoidability. We therefore propose that clinical markers

(set out below in 'Eligibility for Stage One') be used to determine whether or not a particular birth incident would be investigated.

4.4. While these types of incidents are often investigated within trusts, the procedure is not currently consistently applied across England. The need for standardisation has recently been highlighted by the RCOG who noted "There is a clear desire to bring together all of these disparate group, bodies, tools and methodologies into a standardised national approach which allows clear causes to be identified and lessons shared"[18]. Standardised investigations through Stage One of RRR will provide a framework for understanding the underlying reasons as to why the harm occurred, and focus on system-level failures rather than attributing blame to an individual.

4.5. A key success criterion (which we have heard already from stakeholders and families) is likely to be independence. We welcome views on what level investigations would need to be conducted at in order to support an impartial root cause analysis; for example whether this could be required through a neighbouring trust (perhaps organised through the proposed Maternity Clinical Networks[19] as recommended in Better Births); or with independent oversight (see options outlined in question below).

4.6. The investigative panel would involve a mix of different people with the appropriate skills and training in incident investigation. One option is to involve a panel consisting of at least one obstetrician and one midwife. The panel would conduct a thorough root cause analysis, and would be responsible for producing a report summarising the findings of the investigation.

| **Question One: Investigation Design.** | Yes | No |
|---|---|---|
| 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? | | |
| If yes, how independent would the investigating team need to be in order for families to have confidence in the findings? Would investigations need to be conducted;<br>- by clinicians in the trust, that were not involved in the incident being investigated nor have had direct management of those involved. | | |
| - outside the trust involved, for example through the proposed regional Maternity Clinical Networks (proposed by Better Births)? | | |
| - with oversight from the Royal Colleges or other independent bodies? | | |
| Any further comment: | | |

[18] Royal College of Obstetricians and Gynaecologists. Each Baby Counts: key messages from 2015. London: RCOG, 2016.

[19] Recommended by Better Births, these networks are proposed to operate on a regional level and provide a space for commissioners, providers and professionals should come together to share learning and drive improvement in services

4.7. It is important that investigations are conducted in a timely manner. This will ensure that families can receive the clarity they need on what happened, and that any learning from the incident can be shared as soon as possible to reduce the likelihood of similar events occurring in future. Following discussion with clinical colleagues, this intention needs to be balanced against the time required to organise an independent investigative team who may have existing clinical commitments. On this basis we recommend that the full Stage One investigation is launched within 90 days.

4.8. Complementary action will be initiated during the intervening period (i.e. before 90 days). Trusts across the country often have varying internal processes for investigating incidents. It is important to note that the measures proposed under RRR will work alongside these existing processes, such as the current requirement on trusts to notify an event as a 'Serious Incident' under the Serious Incident Framework, which involves notification of an incident with 48 hours.[20] It is important that the RRR investigative process complements these existing processes and we are seeking views on how this is best achieved (Q.3 below).

| **Question Two: Investigation Design.** | Yes | No |
|---|---|---|
| We are aiming to launch an investigation into the incident with 90 days. Do you agree with this approach, or have comment on the feasibility? | | |
| Any further comment: | | |

4.9. As noted above, in addition it is important to note that the proposed investigative process would not impact on existing professional and regulatory processes, to ensure accountability in cases of professional misconduct. We welcome responses from clinicians and regulators in considering how these systems can best operate together.

| **Question Three: Investigation Design.** |
|---|
| How can we ensure alignment with, and avoid duplication of, other investigative processes, such as the Serious Incident framework and the role of Regulators? |
| |

4.10. The investigative process will provide opportunities for family involvement – firstly in providing evidence (if they wish) as key witnesses, and secondly in discussing the outcomes of the report produced by the investigation in a face to face meeting. Each

[20] NHS England, Serious Incident Framework: Supporting learning to prevent recurrence. NHS England, March 2015

case will inform system-wide learning. The reports will also assess whether there are early clinical markers of avoidable harm, which will inform decisions by an independent panel on eligibility for Stage Two of the scheme.

4.11. Importantly, Stage One also includes an early apology to families. This will take the form of an expression of regret for any harm that has occurred and commitment to thoroughly investigate the sequence of events to identify what went wrong and establish whether harm was avoidable, and to demonstrate how learning has been put into practice to avoid similar incidents in future.

| **Question Four: Investigation Design.** | Yes | No |
|---|---|---|
| Do you agree that the scheme should include an early apology to families, in the form of an early expression of regret? | | |
| 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? | | |
| Any further comment: | | |

4.12. A core part of Stage One is the local implementation of learning arising from the investigations, with the ultimate aim of reducing harm. This learning would then be disseminated across wider networks, for example potentially utilising the existing Maternity Clinical Networks on a regional basis, as recommended by Better Births. Also, on a national level, implementation of a centralised system for learning is proposed, which would involve analysing incident and claims data to identify areas for safety improvement. In order to disseminate learning as set out above, we are keen to explore any opportunities for this work to enhance and align with existing systems, such as the National Reporting and Learning System database[21] and other quality improvement initiatives.

| **Question Five: Dissemination of Learning.** | Yes | No |
|---|---|---|
| Do you agree that the scheme design should ensure learning is disseminated locally, regionally and nationally, building upon existing systems where possible? | | |
| Do you agree to the use of a central learning database to collate findings from investigations, which will then feedback nationally to trusts? | | |
| Any further comment / ideas for how this could best work?: | | |

[21] An NHS national, central database of patient safety incident reports.

4.13. By ensuring that eligible incidents are thoroughly investigated, that learning is disseminated, and by providing an alternative to the potentially lengthy and adversarial litigation process, it is intended that learning will be implemented faster.

| Question Six: Accountability/Review of Learning |
| --- |
| How could we best ensure that learning is implemented? |
| |

| Question Seven: Dissemination of learning. |
| --- |
| Do you think there are additional potential barriers to learning that are not addressed by the current design of the policy? If so, do you have suggestions about how these can be addressed? |
| |

4.14. Clinicians can be affected to a great degree by these incidents. It is important that clinicians receive the appropriate levels of emotional and professional support.

| Question Eight: Support for clinicians. |
| --- |
| What improved support could be provided to practitioners following these tragic events? |
| |

# Stage Two

4.15. Stage Two aims to provide an improved service to families, and reduce the current need for litigation as the default for fair compensation and appropriate care. This will include;

- Early access to counselling and support in accessing state services (for both the child and the wider family), which will be facilitated by a dedicated case manager. If required, access to legal advice will be available to help families understand the options available to them;
- Once eligibility is established a compensation package to provide for the current and future needs of the injured individual, including regular assessments of need.

4.16. The compensation package is likely to involve three elements. The suitability and extent of each of the three elements would be determined on a case by case basis and may vary significantly between injured individuals to reflect differing levels of need:

- An early up-front payment;
- Periodical payments; and
- A lump sum award.

4.17. The early payment, in the range of £50-100k, would be issued at around age 4. This is in line with the stage in childhood development when it is usually possible to establish the source and long-term nature of the injury, which is necessary for a final assessment of causation and avoidability of any harm. The early payment would support families with any up-front costs required to care for their child, such as adaptions to accommodation.

4.18. Note that before this time families of babies who are suspected to have been avoidably harmed would receive access to counselling, legal advice, and a case manager to direct them to the most appropriate state services to suit their needs. There would also be the potential for interim payments where avoidability is established earlier (similar to the interim payments awarded under litigation).

4.19. Following the early lump-sum payment, families would progress through the compensation scheme to receive a further lump sum award and periodical payments, calculated in line with need. The lump sum and any periodical payments would be provided on average a year earlier than they would via the court route.

4.20. The periodical payments are equivalent to the Periodical Payment Order (PPO) mechanism currently used in court awards, whereby claimants receive regular payments throughout the duration of their lifetime, normally to cover care needs. Under RRR, periodical payments and associated care provision would undergo a sensitive reassessment when appropriate to ensure they meet ongoing need. If an individual's care needs increase, the reassessment would likely increase the size of the periodical payment, and vice-versa. Suggested review points would be in line with key developmental milestones at around ages 5, 12 and 18 (to coincide with transition to adult services) - see Question 12 below.

4.21. Periodical payments under Stage Two of RRR could be made ‘in kind’ through a personal budget-type approach, administered by a case manager. Under this 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 social care - it would be much closer in value to compensation typically awarded through the court - see paragraph 4.24). Alternatively, periodical payments could be distributed as financial compensation (cash).

4.22. Regarding the lump sum payment, in line with current practice, whereby funds are held by the courts and families apply to a 'deputy' to access them, families would be able to access their cash funds through a dedicated case manager who would act on behalf of the family.

4.23. Under this scheme it is proposed that, compared to current court awards, a greater proportion of overall compensation (around 50%) will be made available through periodical payments. The shift towards staged payments is to ensure a greater responsiveness to need throughout a person's life.

4.24. For the purposes of modelling, the average total value of compensation (early up-front payment, periodical payments and lump sum award) is modelled in the central scenario

at around 90% of the average current court award (adjusting for inflation in care costs)[22].To reach this figure we took a bottom-up approach by examining recent litigation awards and current care costs, and exploring which elements of care and support are available through state-funded services and which require additional funding. On the basis of this work, an average of around 90% of the current court award was deemed to be a proportionate and reasonable offer under RRR. Note however that this policy does not propose a blanket figure for all cases; instead the compensation offered under RRR in each case would be calculated based on the needs of each individual child. The average level of compensation included in the final policy design will reflect responses to this consultation, wider contextual factors and cross-Government consideration of the final business case.

| Question Nine: Early Upfront Payments | Yes | No |
|---|---|---|
| **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?** | | |
| **If yes, do you agree that the first significant payment should be made when avoidability can be established, which is on average when the child is around 4 years old?<br>(As described in paragraph 4.18, earlier support such as a case worker will be available at an earlier stage)** | | |
| **Any further comments:** | | |

| Question Ten: Approach to accessing and paying for care | Yes | No |
|---|---|---|
| **Do you think that periodical payments should be made "in-kind" through a personal budgets type approach, administered by a case manager? (see para 4.2.1)** | | |
| **If not, do you think that they should be made as cash payments?** | | |
| **Any further comments:** | | |

| Question Eleven: Balance between PPOs and Lump Sum Payments | Yes | No |
|---|---|---|
| **Do you agree with the shift towards more staged (periodical) payments PPO?** | | |

[22] The IA presents sensitivity analysis of a range of options for average compensation in the range 80-100% of the average litigation award.

| |
|---|
| **Any further comments:** |

| **Question Twelve: Needs Assessment** | **Yes** | **No** |
|---|---|---|
| **Do you agree that there should be an ongoing needs assessment of provisions for the injured child?** | | |
| | | |
| **If yes, at which ages should these reviews be:** | | |
| • ages 5, 12, 18? | | |
| **Any other comments on age intervals?** | | |
| **Should families be able to trigger a needs assessment for their child, when services can be reviewed and care potentially adjusted (if found necessary)?** | | |
| **Any further comments:** | | |

# Administration of Stage Two

4.25. For the initial feasibility assessment, it was proposed that RRR would be administered by the NHSLA. Other initiatives are ongoing to develop the role of NHSLA in supporting learning and resolution, as an alternative to litigation (currently fewer than 2% of cases handled by the NHSLA end up in court[23]). Administering RRR would complement these initiatives.

4.26. Part of NHSLA's role in administering the scheme would to ensure that for each case there is a panel of independent experts, who would determine whether or not a particular incident met the threshold for Stage Two. If a particular incident was deemed to meet the relevant threshold, the family would be eligible for compensation under RRR, although they may choose to forego this and pursue compensation through litigation instead.

4.27. The Stage Two panel would have a different make-up to the panel of experts who conducted the investigation under Stage One, and may include clinical experts and access to legal support if required.

4.28. The panel would make their decision using evidence from the independent, root-cause analysis investigation conducted as part of in Stage One shortly after the incident occurred. There may be incidents that are put forward to Stage Two assessment that have not been through Stage One. These individuals would be assessed for their eligibility into Stage Two of the scheme based on the available evidence.

[23] NHS Litigation Authority, 2016, 'How we Handle Claims', available at http://www.nhsla.com/Claims/Pages/Handling.aspx on 25 November 2016.

4.29. When a panel would be able to decide on an infant's eligibility into a scheme would vary, as in some cases of severe neurological injury it can take several years for the extent of the condition to become clear. In other cases it is evident quite soon after birth that harm has been caused to the baby and for avoidability to be established.

| Question Thirteen: Scheme Administration | Yes | No |
|---|---|---|
| Do you agree that NHSLA (or new division within NHSLA) should administer the scheme? | | |
| Any further comment: | | |

## Overview of Eligibility

4.30. Different eligibility criteria are proposed for Stage One and Stage Two, as described below. While most individuals eligible for Stage Two would have also been eligible for Stage One, this may not always be the case - there may be families that apply for compensation under Stage Two several years after the birth injury occurred. Likewise, not all cases that are eligible for an investigation under Stage One will be eligible for compensation under Stage Two (for example where a full recovery is made). Eligibility for the scheme has therefore been considered as two discrete steps.

4.31. While the proposed criteria for Stage One and Stage Two are set out above, it is useful to note some types of incident are not within the current proposed scope of RRR. This includes:

- Stillbirths
- Neonatal deaths
- Maternal injuries and maternal deaths
- Harm associated with pre-natal and antenatal care
- Multiple births

For incidents that fall into the above categories, families would still be able to seek compensation through the courts.

4.32. RRR would be closely monitored during implementation to ensure it is delivering on its objectives, such as harm reduction. On the basis of its success, options for expanding the scheme to cover other types of avoidable harm would be considered. This approach provides an opportunity to test the voluntary scheme with a small number of incidents, and to refine it as appropriate before extending its scope. In the meantime the types of incident set out above will be included in wider efforts to improve maternal safety, including the through the Maternity Transformation Programme and delivery of the National Maternity Ambition to halve the rates of stillbirths, neonatal and maternal deaths and brain injuries that occur during or soon after birth by 2030. This includes

measures such as the Perinatal Mortality Review Tool[24] which will enable standardised recording and investigation of stillbirths and neonatal deaths, and will therefore complement RRR by gathering learning from these incidents.

# Eligibility for Stage One

4.33. In determining eligibility for Stage One investigation we have considered the need to strike the right balance between investigating all relevant cases, keeping in mind the scheme's focus on avoidable birth injuries, whilst being mindful of the burden on frontline staff.

4.34. For the current scheme design, Stage One eligibility has been defined using the Each Baby Counts criteria (see below). These markers have been developed by the Royal College of Obstetricians and Gynaecologists (RCOG), and aim to identify unexpectedly unwell babies within seven days after birth[25]

### RCOG Each Baby Counts (EBC) definition

RCOG have carried out extensive research into what may be considered a marker of a severe brain injury at birth.

The criteria developed are the following: Any baby, born at term (37 completed weeks or more) following labour, who in the first seven days of life present with:

- Hypoxic-Ischemic Encephalopathy grade 3 (an indicator of asphyxia related neonatal neurological abnormality)*

OR

- Any baby which has decreased central tone AND is comatose AND has seizures (of any kind)**

OR

- Any baby which receives active therapeutic cooling treatment***

We propose to use these criteria as the threshold to trigger an investigation under RRR.

[24] A proposed web-based tool to implement standardised perinatal mortality reviews across NHS maternity and neonatal units in England, Scotland and Wales. For more information see here: http://www.hqip.org.uk/tenders/hqip-hca-2000-perinatal-mortality-review-tool/

[25] Royal College of Obstetricians and Gynaecologists. Each Baby Counts: key messages from 2015. London: RCOG, 2016. Available at: https://www.rcog.org.uk/globalassets/documents/guidelines/research--audit/rcog-each-baby-counts-report.pdf

* Hypoxic Ischemic Encephalopathy (HIE) is 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.

** Decreased central tone is when the central muscles appear to be less firm than usual and the baby is floppy. Royal College of Obstetricians and Gynaecologists. Each Baby Counts: key messages from 2015. London: RCOG, 2016. Available at: https://www.rcog.org.uk/globalassets/documents/guidelines/research--audit/rcog-each-baby-counts-report.pdf

*** Active therapeutic cooling involves reducing a baby's body temperature to 33.5C and maintaining it at this level for up to 72 hours before a gradual re-warming process is started.

4.35. Eligibility is limited to pregnancies where a complication has not arisen before labour. Our current model assumes that only injury incurred during labour/delivery would be included (i.e. injury associated with pre-natal antenatal care would currently be out of scope).

| Question Fourteen: Clinical Eligibility | | Yes | No |
|---|---|---|---|
| **Do you agree that the clinical eligibility into the scheme should be defined using the RCOG definition of avoidable brain injury?** | | | |
| **If not, what are your objections and any proposed alternative?** | | | |

# Eligibility for Stage Two

4.36. A panel of independent experts would be responsible for determining whether or not a particular incident met the threshold for Stage Two, which offers compensation to eligible families. If a particular incident was deemed to meet the relevant threshold, the family would be eligible for compensation under RRR, although they may choose to forego this and pursue compensation through litigation instead.

4.37. The Stage Two panel would have a different make-up from the panel of experts who conducted the investigation under Stage One, and would involve access to legal support, if required. For each case the panel would look to assess the care received, the link between this care and the avoidable harm, and an initial assessment of the prognosis of the child.

4.38. The panel would make their decision in part by drawing from evidence from the independent, root-cause analysis investigation conducted as part of Stage One shortly after the incident occurred. There may be incidents that are put forward to Stage Two assessment that have not been through Stage One. These cases would be assessed for their eligibility into Stage Two of the scheme based on the available evidence, and may involve a later investigation.

4.39. When a panel would be able to decide on an infant's eligibility into a scheme would vary, as in some cases of severe neurological injury it can take several years to determine with sufficient certainty whether the harm was avoidable. In other cases it is evident quite soon after birth that harm has been caused to the baby.

4.40. There are several different ways in which medical injury compensation schemes are administered internationally, and many of these schemes have different criteria for establishing eligibility for compensation. These criteria are often based around the 'avoidability' of the harm. Schemes often apply slightly different tests, which affects the number of incidents that are eligible for compensation.

4.41. We have explored two options for a compensation threshold - options A and B set out below. While the text boxes explain each threshold in more detail, Option A is sometimes summarised as considering what 'could have been done differently', whereas Option B is sometimes summarised as considering what 'should have been done

differently'. The eligibility threshold included in the final policy design will reflect responses to this consultation, wider contextual factors and cross-Government consideration of the final business case.

**4.42. The two options are:**

### A. Experienced Specialist

The scheme would be open to a wider pool of claimants. Under this test, a given case would be eligible for compensation if harm could have been avoided under optimal clinical practice within the given circumstances, assessed against the standard of a leading clinical expert. This applies a higher standard for care than the current negligence threshold, and is similar to the test used in the Swedish scheme.

Estimated at 162 cases per annum

### B. Reasonable Care

Under this proposal, eligibility into the scheme would be assessed by whether the care provided by the involved clinicians was akin to that of what would be considered reasonable practice. This is an equivalent threshold to the test currently used in clinical negligence claims (which uses the standard of the reasonable practitioner). Using this threshold, the scheme would act as an alternative offer to the litigation route for cases that would be likely to have a successful claim with NHSLA under the current system.

The difference from current negligence claims is that there would be more of a focus on system-level failure (rather than individual blame/fault) with an investigation designed to identify what the system should have reasonably done differently and learn from this. Taking a system-level view considers the roles of all clinicians involved, their interactions and any additional circumstances that may have led to an incident, rather than focussing on identifying a single clinician at fault.
(Note: This system-level approach applies to Option A as well, and does not replace professional regulation - see para 3.10)

Estimated at 122 cases per annum (estimated from recent successful NHSLA claims data plus small increase in pool size to reflect administrative context).

| Question Fifteen: Administrative Eligibility | Yes | No |
|---|---|---|
| Do you agree with the principle of administering the scheme using an avoidable harm test? | | |
| Further comment | | |

| Question Sixteen: Avoidable Harm | ECT | RCT |
|---|---|---|
| Do you prefer the proposed 'Experienced Specialist' test (EST) or the 'Reasonable Care' test (RCT)? | | |
| Why/why not? | | |

4.43. RRR aims to provide the family with appropriate and consistent long-term support for the benefit of the child. However, if a family chooses to pursue a legal claim after an RRR package has been put in place, services under the scheme would likely be withdrawn (likely on a phased basis) to make sure resources are available for other eligible claimants. The intention is to strike a reasonable balance between the cost to the taxpayer and the needs of the family.

4.44. It is important to note that this scheme is a voluntary alternative to the tort route, and does not remove a family's ability to go to court if they were unsatisfied with the decision of the eligibility panel, or any other reason. This would therefore provide a route of appeal if a family is unhappy with the panel's decision. However, any compensation already received by the family under RRR would be off-set against the final court award to prevent double recoverability.

## Piloting the Scheme

4.45. A further option for implementing the RRR policy (with any of the considered Stage Two eligibility thresholds) is to begin with a pilot, likely to be on a regional basis, that covers a subset of the eligible cases in England. An example of running a pilot using the 'Experienced Specialist' test is considered in the IA (Option 4). The structure and size of any pilot would be informed by responses to this consultation.

4.46. A pilot would only help in testing operational delivery and is unlikely to measure long-term impact in terms of uptake and harm reduction (as described in the IA, Option 4).

4.47. An advantage of a pilot, however, is that it allows the scheme to be pursued on smaller scale, potentially mitigating operational risk and increasing the likelihood of a successful transition to full roll-out. A pilot may also mitigate some financial risk of a nationwide roll-out. However, a pilot would involve a smaller sample of incidents from which learning can be drawn, which may risk a delay in achieving harm reduction.

4.48. The pilot would probably operate most effectively at regional level. As set out in the IA - published alongside this consultation - any pilot would need to have a sufficient sample size if it is to act a statistically credible indicator of the effectiveness of the scheme. At trust level, there are too few incidents a year. At regional level there is a larger sample

size that could be used in the pilot. Such a pilot could be aligned with the existing Maternity Clinical Networks which operate on a regional level (as described in Better Births). Any cases not included in the pilot would be able to proceed through litigation to receive compensation through existing arrangements

4.49. If the pilot indicated that the scheme was not achieving its objectives, the pilot could be discontinued. If this were so, it should be done with minimal impact upon families that have already participated (including ensuring continuity of support which has already been awarded).

| Question Seventeen: Piloting the scheme | Yes | No |
|---|---|---|
| **Should the scheme be piloted?** | | |
| **Please provide rationale:** | | |

# 5. Evidence

5.1. While the accompanying Impact Assessment draws on a wide range of sources to support the policy, the Government is keen to receive views on whether there is any further evidence that you think is relevant to the scheme, to further build its evidence base. We are particularly keen to receive evidence regarding:

a) Initiatives to reduce harmful events during labour, both in the UK and internationally. In particular:
   - where harm reduction has been achieved through early investigations, root cause analysis and additional learning;
   - whether the eligibility for compensation has been shown to influence harm reduction;

b) Initiatives to increase openness and transparency in the system, both within healthcare settings and more broadly;

c) How to design a compensation scheme that will meet the needs of families, including information on the level of compensation relative to a litigation award required to meet the needs of families;

d) The proportionate increase in successful compensation claims expected from both the 'Experienced Specialist' test and the 'Reasonable Care' test (see the section on 'Eligibility for Stage Two' above) compared with the number of successfully litigated cases;

e) The structure and timing of the administration involved in supporting the implementation of RRR, such as the make-up of eligibility panels;

f) The expected growth in the number of clinical negligence claims received and settled;

g) Mechanisms and measures that could be used in order to effectively evaluate the scheme;

h) Relevant information of clinical negligence legal market;

i) Impacts on equalities, health inequalities and other considerations for families (see Section One); and

j) Any other evidence that is of relevance to the policy design and assumptions

## Evidence A - Initiatives to reduce harm during labour and delivery

**Please provide any further data or evidence that you think would assist the Department in considering the proposal. Please identify your organisation in your response.**

**We are interested in receiving:**

- Any evidence (academic or anecdotal) from initiatives to reduce harmful events during labour and delivery, both in the UK and internationally, in particular:
  - Where harm reduction has been achieved through early investigations, root cause analysis and additional learning; and

- Whether the eligibility for compensation has been shown to influence harm reduction and, if so, how and why.

**Please indicate whether your organisation would be willing to work with DH in providing more details on the impact for future IA analysis. This would be provided in confidence and anonymised in any future analysis.**

**Please provide evidence.**

## Evidence B - Initiatives to increase openness and transparency

**Please provide any further data or evidence that you think would assist the Department in considering the proposal. Please identify your organisation in your response.**

**We are interested in receiving:**

- Any evidence (academic or anecdotal) from initiatives to increase openness and transparency, looking both within healthcare settings and more broadly. In particular, evidence around how this has led to a reduction in harm.

**Please indicate whether your organisation would be willing to work with DH in providing more details on the impact for future IA analysis. This would be provided in confidence and anonymised in any future analysis.**

**Please provide evidence.**

## Evidence C - Scheme design to meet family's needs

**Please provide any further data or evidence that you think would assist the Department in considering the proposal. Please identify your organisation in your response.**

**We are interested in receiving:**

- Any information on how to design a compensation scheme to meet the needs of families; and
- We are also interested in receiving evidence on the level of compensation in order to do this relative to the current award provided through a successful litigation.

**Please indicate whether your organisation would be willing to work with DH in providing more details on the impact for future IA analysis. This would be provided in confidence and anonymised in any future analysis.**

**Please provide evidence.**

## Evidence D - Increase in claims from an avoidable compensation threshold

**Please provide any further data or evidence that you think would assist the Department in considering the proposal. Please identify your organisation in your response.**

**We are interested in receiving evidence around:**

- The proportionate increase in incidents expected from both the 'Experienced Specialist' test and the 'Reasonable Care' test (see the section on 'Eligibility for Stage Two' above) compared with the current likelihood of a successful litigation.

**Please indicate whether your organisation would be willing to work with DH in providing more details on the impact for future IA analysis. This would be provided in confidence and anonymised in any future analysis.**

**Please provide evidence.**

## Evidence E- The structure and timing of the administrative part of RRR

**Please provide any further data or evidence that you think would assist the Department in considering the proposal. Please identify your organisation in your response.**

**We are interested in receiving:**

- The structure and timing of the administration involved in supporting the implementation of RRR. This could include evidence around the numbers and professions of the individuals who conduct the investigation or make up the eligibility panel, or any of the other elements involved in delivering the policy.

**Please indicate whether your organisation would be willing to work with DH in providing more details on the impact for future IA analysis. This would be provided in confidence and anonymised in any future analysis.**

**Please provide evidence.**

## Evidence F - Growth in the number of clinical negligence claims received and settled

**Please provide any further data or evidence that you think would assist the Department in considering the proposal. Please identify your organisation in your response.**

**We are interested in receiving:**

- Any relevant information on the expected growth in the number of clinical

negligence claims received and settled.

**Please indicate whether your organisation would be willing to work with DH in providing more details on the impact for future IA analysis. This would be provided in confidence and anonymised in any future analysis.**

**Please provide evidence.**

## Evidence G - Measures for evaluating the scheme

**Please provide any further data or evidence that you think would assist the Department in considering the proposal. Please identify your organisation in your response.**

**We are interested in receiving:**

- Suggestions around mechanisms and measures for allowing the policy to be evaluated effectively.

**Please indicate whether your organisation would be willing to work with DH in providing more details on the impact for future IA analysis. This would be provided in confidence and anonymised in any future analysis.**

**Please provide evidence.**

## Evidence H - Information on impact on the clinical negligence market

**Please provide any further data or evidence that you think would assist the Department in considering the proposal. Please identify your organisation in your response.**

**We are interested in receiving:**

- Any relevant information about the clinical negligence legal market, such as any expected changes to the claims market, and the nature of recent claims

**Please indicate whether your organisation would be willing to work with DH in providing more details on the impact for future IA analysis. This would be provided in confidence and anonymised in any future analysis.**

**Please provide evidence.**

## Evidence I - Impacts on equalities, health inequalities and other considerations for families

**Please provide any further data or evidence that you think would assist the Department in considering the proposal. Please identify your organisation in your response.**

**We are interested in receiving:**

- Any information on the equalities, health inequalities and other considerations for families with respect to the proposed policy design.

**Please indicate whether your organisation would be willing to work with DH in providing more details on the impact for future IA analysis. This would be provided in confidence and anonymised in any future analysis.**

**Please provide evidence.**

## Evidence J - Any other evidence

**Please provide any further data or evidence that you think would assist the Department in considering the proposal.**

**Please indicate whether your organisation would be willing to work with DH in providing more details on the impact for future IA analysis. This would be provided in confidence and anonymised in any future analysis.**

**Please provide evidence.**

# 6. Responding to this Consultation

**How to get involved in the consultation**

6.1. The consultation will run for 12 weeks, from 2 March 2017 to midnight on 26 May 2017. We welcome responses from any interested person, organisation or business.

6.2. Respondents are encouraged to provide their views online but responses can be made in any of the following ways:

**Completing the online form on CitizenSpace at:**

**https://consultations.dh.gov.uk/rapid-resolution-and-redress/maternity-litigation**

**Emailing your responses to:**

RRR-Consultation@dh.gsi.gov.uk

**Posting your response to:**

Litigation Policy Team

Department of Health,

239 Richmond House,

79 Whitehall,

London,

SW1A 2NS.

The Department cannot respond specifically to individual consultation responses.

6.3. Respondents need not reply to all questions, and may prefer to focus only on the questions they have a particular interest in.

**Comments on the consultation process**

6.4. If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact:

**Address:**

Consultations Coordinator

Department of Health

2E26, Quarry House

Leeds

LS2 7UE

Email:

consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address

# 7. List of Consultation Questions

| Question One: Investigation Design. | Yes | No |
|---|---|---|
| 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? | | |
| If yes, how independent would the investigating team need to be in order for families to have confidence in the findings? Would investigations need to be conducted;<br>- by clinicians in the trust, that were not involved in the incident being investigated nor have had direct management of those involved. | | |
| - outside the trust involved, for example through the proposed regional Maternity Clinical Networks (proposed by Better Births)? | | |
| - with oversight from the Royal Colleges or other independent bodies? | | |
| Any further comment: | | |

| Question Two: Investigation Design. | Yes | No |
|---|---|---|
| We are aiming to launch an investigation into the incident with 90 days. Do you agree with this approach, or have comment on the feasibility? | | |
| Any further comment: | | |

| Question Three: Investigation Design. |
|---|
| How can we ensure alignment with, and avoid duplication of, other investigative processes, such as the Serious Incident framework and the role of Regulators? |
| |

| Question Four: Investigation Design. | Yes | No |
|---|---|---|
| Do you agree that the scheme should include an early apology to families, in the form of an early expression of regret? | | |
| 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? | | |

| | | |
|---|---|---|
| Any further comment: | | |

| Question Five: Dissemination of Learning. | Yes | No |
|---|---|---|
| Do you agree that the scheme design should ensure learning is disseminated locally, regionally and nationally, building upon existing systems where possible? | | |
| Do you agree to the use of a central learning database to collate findings from investigations, which will then feedback nationally to trusts? | | |
| Any further comment / ideas for how this could best work?: | | |

| Question Six: Accountability/Review of Learning |
|---|
| How could we best ensure that learning is implemented? |
| |

| Question Seven: Dissemination of learning. |
|---|
| Do you think there are additional potential barriers to learning that are not addressed by the current design of the policy? If so, do you have suggestions about how these can be addressed? |
| |

| Question Eight: Support for clinicians. |
|---|
| What improved support could be provided to practitioners following these tragic events? |
| |

| Question Nine: Early Upfront Payments | **Yes** | **No** |
|---|---|---|
| **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?** | | |
| **If yes, do you agree that the first significant payment should be made when avoidability can be established, which is on average when the child is around 4 years old?<br>(As described in paragraph 4.18, earlier support such as a case worker will be available at an earlier** | | |

| | | |
|---|---|---|
| **stage)** | | |
| **Any further comments:** | | |

| **Question Ten: Approach to accessing and paying for care** | **Yes** | **No** |
|---|---|---|
| **Do you think that periodical payments should be made "in-kind" through a personal budgets type approach, administered by a case manager? (see para 4.2.1)** | | |
| **If not, do you think that they should be made as cash payments?** | | |
| **Any further comments:** | | |

| **Question Eleven: Balance between PPOs and Lump Sum Payments** | **Yes** | **No** |
|---|---|---|
| **Do you agree with the shift towards more staged (periodical) payments PPO?** | | |
| **Any further comments:** | | |

| **Question Twelve: Needs Assessment** | **Yes** | **No** |
|---|---|---|
| **Do you agree that there should be an ongoing needs assessment of provisions for the injured child?** | | |
| | | |
| **If yes, at which ages should these reviews be:** | | |
| • ages 5, 12, 18? | | |
| **Any other comments on age intervals?** | | |
| **Should families be able to trigger a needs assessment for their child, when services can be reviewed and care potentially adjusted (if found necessary)?** | | |
| **Any further comments:** | | |

| **Question Thirteen: Scheme Administration** | Yes | No |
|---|---|---|
| Do you agree that NHSLA (or new division within NHSLA) should administer the scheme? | | |
| Any further comment: | | |

| Question Fourteen: Clinical Eligibility | Yes | No |
|---|---|---|
| **Do you agree that the clinical eligibility into the scheme should be defined using the RCOG definition of avoidable brain injury?** | | |
| **If not, what are your objections and any proposed alternative?** | | |

| Question Fifteen: Administrative Eligibility | Yes | No |
|---|---|---|
| **Do you agree with the principle of administering the scheme using an avoidable harm test?** | | |
| **Further comment** | | |

| Question Sixteen: Avoidable Harm | ECT | RCT |
|---|---|---|
| **Do you prefer the proposed 'Experienced Specialist' test (EST) or the 'Reasonable Care' test (RCT)?** | | |
| **Why/why not?** | | |

| Question Seventeen: Piloting the scheme | Yes | No |
|---|---|---|
| **Should the scheme be piloted?** | | |
| **Please provide rationale:** | | |

# 8. Glossary

| Term | Definition |
|---|---|
| Cerebral palsy/brain damage | The collective types of birth injury that will be potentially compensated under such a scheme. |
| Claimant | The person who brings a claim, usually the patient in clinical negligence claims (NHSLA) |
| Clinical negligence | Where clinical actions or omissions are assessed by the courts as amounting to a breach of duty, and where those actions or omissions have led to harm in the patient concerned |
| Duty of Candour | The Duty of Candour is a legal duty on hospital, community and mental health trusts to inform and apologise to patients if there. have been mistakes in their care that have led to significant harm |
| Each Baby Counts | The Royal College of Obstetricians and Gynaecologists' maternity quality improvement programme |
| Hypoxic ischemic encephalopathy (HIE) | Abnormal neurological function caused by birth asphyxia. |
| Intrapartum | During labour and delivery |
| Maternity Clinical Networks | Recommended by Better Births, these networks are proposed to operate on a regional level and provide a space for commissioners, providers and professionals should come together for two purposes:<br>- To share information, best practice and learning, to benchmark against each other and drive improvement in the quality of services across the region, focussing on the outcomes of care.<br>- To ensure that specialist services are available to women and babies with more complex needs, and that they receive consistently high quality treatment in centres with the right facilities and expertise, as close to their homes as possible. |

| | |
|---|---|
| National Maternity Review ("Better Births") | A review, published in February 2016 and led by Baroness Cumberlege, to assess current maternity care provision and consider how services should be developed to meet the changing needs of women and babies |
| Neonatal death | Death within the first 28 days of life. |
| Notification (of a claim/s) | The process whereby NHSLA becomes aware of a potential claim. |
| Perinatal | The time immediately before and after birth |
| Periodical Payment Order (PPO) | The payment order associated with some successfully litigated cases that provide a legal guarantee of payments for an individual's lifetime. |
| Prenatal/antenatal | Before birth events |
| Pre-term | A birth occurring earlier than 37 weeks. |
| Royal College of Obstetricians and Gynaecologists (RCOG) | RCOG is a professional association based in the UK that works to improve health care for women by setting standards, training and educating doctors, and advocating for women's health worldwide |
| Safe Delivery Care Project (Säker Förlossningsvård) | A Swedish initiative to reduce birth defects in children, primarily cerebral damage caused by avoidable lack of oxygen during delivery. |
| Serious Incident Framework | The Serious Incident Framework sets out guidance to ensure that in the NHS robust systems are in place for reporting, investigating and responding to serious incidents so that lessons are learned and appropriate action taken to prevent future harm |
| Settlement | The amount of damages agreed pursuant to a legally binding agreement between a Claimant and a Member in respect of a Claim (whether with or without admission of liability) or the amount of damages awarded in respect of a Claim pursuant to an order of a court or other tribunal, whether the payment of such damages will be made by a single payment or is a Periodical Payments regime and "settled" shall be construed accordingly |